

**DEFINING THE ROLE OF MATURE MINORS IN
THE MEDICAL RESEARCH CONSENT PROCESS**

by

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Submitted in partial fulfilment of the requirements
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À Dennis, pour ton aide, ton appuis et les milles et une autres choses que tu fais pour moi a tous les jours.

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ABSTRACT

In recent years, there has been an increase in the number of minors included in a broad range of medical research studies. To date, however, little attention appears to have been paid to how the role of minors in the consent process leading to participation in these studies should be defined.

This thesis reviews the legal and ethical instruments and principles that define the role of mature minors in the medical research consent process in Canada at present. The thesis goes on to recommend a framework that should be added to the *Tri-Council Policy Statement* whereby all minors undergo a capacity assessment using a validated instrument. According to this framework, the consent of those who are found to have decision-making capacity (i.e. are mature minors), unless precluded by law, shall be necessary and sufficient. There are few instances where the law prevents mature minors from consenting to their own participation.

LIST OF ABBREVIATIONS USED

CIHR	Canadian Institutes of Health Research
<i>ICH GCP</i>	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, <i>Good Clinical Practice: Consolidated Guideline</i>
<i>ICH CIMPPP</i>	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, <i>Clinical Investigation of Medicinal Products in the Pediatric Population</i>
NSERC	Natural Science and Engineering Research Council
SSHRC	Social Sciences and Humanities Research Council

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CHAPTER 1



INTRODUCTION

In the past, minors were largely excluded from medical research because they were presumed incompetent and thus too vulnerable.¹ It has also been said that studies involving minors are expensive and yield relatively low commercial returns, thereby discouraging the pharmaceutical industry from investing in this type of research.² These factors have led to the lack of pediatric indication for over 70% of drugs currently approved for adult use.³ Furthermore, as the benefits of some of these therapies were seen in adults, many physicians opted to treat their pediatric patients on an ‘off-label’⁴

¹ Minors are not the only group that has not been included in medical research in the past. As noted in Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010, online: <http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_web.pdf [*Tri-Council Policy Statement*], women have also historically been excluded from research. Reasons cited for the latter include the possibility of harming fetuses, newborns, and reproductive organs as well as difficulty controlling hormonal changes. As well, many researchers and research sponsors failed to recognize that men and women are affected by disease differently and respond to treatment differently. Finally, the exclusion of women has also been attributed to perceived liability concerns on the part of research sponsors. Concerns analogous to those raised in justifying the exclusion of women from research may have been at play in the case of minors. That said, these are seldom mentioned in the literature.

² Mark Greener, “Bitter Medicine: New Regulations Aim to Address the Dearth of Clinical Safety Trials For Drugs Used in Children” (2008) 9 EMBO Rep 505 at 506 [Greener].

³ Seema Shah *et al.*, “How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?” (2004) 291 JAMA 476 at 476 [Shah].

⁴ The labeling of medications relates to the indications and populations for which a medication has been approved by the relevant health authorities. In Canada, such approval is granted by Health Canada. In this thesis, ‘off-label’ use refers to the use of a drug for a purpose for an unapproved purpose. For example, ‘off-label’ use includes the use of prescription drugs only approved for adults on minors and adolescents.

basis.⁵ Such a practice obviously does little to restore the proper distribution of research harms and benefits among members of society. It also leads to a lack of information regarding the safety and efficacy of drugs and results in a reduction in the availability of drugs to the broader population.

Fortunately, society has come to recognize that the widespread exclusion of certain groups, including minors, from medical research is a clear violation of the principle of distributive justice. This cornerstone of research ethics in Canada requires that the benefits and burdens of research be fairly distributed among all members of society.⁶ It stipulates that individual groups “should neither be unjustly denied access to potential benefits, nor bear a disproportionate burden of the research.”⁷ The historical exclusion of certain groups contravenes the principle of distributive justice in two key ways. Firstly, being that they were the only ones receiving interventions whose safety and efficacy were unknown, men bore all the burdens of research yet they were not the only group to benefit from knowledge gains acquired through research. Secondly, although the excluded groups did derive some benefit from research carried out on men, considerably more benefits could have flowed to them had they been included. After all, the very reasons given for the exclusion of these groups are also reasons as to why they did not derive the maximum available benefit from research developments.

In response to this realization there appears to have been a move towards the greater inclusion of minors in research. The reasons for and effects of this shift towards

⁵ Jennifer Rosato, “The Ethics of Clinical Trials: A Child’s View” (2000) 28 J Law Med Ethics 362 at 362.

⁶ The importance of the just distribution of harms and benefits was recognized by the drafters of the *Tri-Council Policy Statement*, *supra* note 1, who included this notion among the guiding ethical principles of that framework.

⁷ *Supra* note 1.

inclusion are many. Minors may not have been afforded a greater role in medical research solely for their benefit. Rather, through legislative means, several governments have encouraged pharmaceutical companies to carry out research on minors. Notably, in the United States, the *Pediatric Research Equity Act of 2003*⁸ requires that any company submitting an application for approval from the United States Federal Drug Administration for new active ingredients, new indications, new dosage forms, new dosage regimens or new routes of administration provide safety and efficacy data from research conducted on minors. Waivers and deferrals can, however, be granted.⁹ In exchange for conducting such research, pharmaceutical companies are awarded patent extensions, which can be quite lucrative for the companies.¹⁰ In 2008, these efforts were at least partially responsible for the testing of 200 medicines in minors and adolescents in the United States.¹¹ In 2007, the European Union introduced similar legislation.¹² Although this type of legislation does not exist in Canada at present, it is possible that the American and European Union statutes play a role in determining what studies will be carried out within our borders. This is because many studies funded by pharmaceutical companies are carried out in institutions in several countries. Consequently, incentives beyond the best interests of minors may drive much of the pharmaceutical industry's research agenda in Canada.

Beyond the unfavourable reasons for and effects of including minors in research more frequently set out above, there are also some benefits to their inclusion. Arguably

⁸ Pub. L. No. 108-155, 117 Stat. 1936.

⁹ *Ibid.* For a description of how FDA approval is obtained, see Michael Baram, "Making Clinical Trials Safer for Human Subjects" (2001) 27 Am J Law Med 253 at 260.

¹⁰ *Supra* note 8 at 505B.

¹¹ B.G. Kapogiannis & D.R. Mattison, "Adolescents in Clinical Trials" (2008) 84 Clin Pharmacol Ther 655 at 655.

¹² See Greener, *supra* note 2 at 507 for a summary of these enactments.

the most notable benefit is that, when carried out with appropriate safeguards in place, the participation of minors in medical research can lead to improvements in the treatments routinely administered to them. More specifically, since minors are not merely small adults, it is important for the medical community to gain knowledge of how their bodies will respond to various therapies as well as what course a specific illness follows, to name only a few areas in which insight can be gleaned.

Despite the mixed motivation underlying the greater inclusion of minors in medical research, the trend has meant that minors now routinely participate in a broad range of research initiatives. This gamut includes everything from incidence studies to cancer treatment studies.¹³ Not only are minors and their parents now being offered the opportunity to enrol in the latter type of study, virtually all the treatment received by minors afflicted with cancer in Canada is determined by a research study protocol.¹⁴ Although the total number of Canadian minors participating in medical research at any given time has not been reported in the literature, it is clearly a significant number.

In recent years, minors have been included in research at an increasing rate without regard to their role in the process itself. This thesis attempts to partially remedy this procedural lacuna by critically examining the role of mature minors in the medical research consent process from both a legal and ethical standpoint. The framework that I set out as a result of this review has the potential to benefit many minors; both the mature

¹³ The breadth of areas of research in which minors are involved in can clearly be seen from the studies published in a single issue of *Pediatrics*, a medical journal published by the American Academy of Pediatrics. To this end, the February 2008 issue includes studies on infants, young children and adolescents on topics as diverse as arthritis, obesity, mental health issues, alcohol use, vascular disease, neonatal health, and cancer treatment.

¹⁴ Conrad V. Fernandez *et al.*, "Offering to Return Results to Research Participants: Attitudes and Needs of Principal Investigators in the Children's Oncology Group" (2003) 25 *J Pediatr Hematol Oncol* 704 at 705.

minors whose rights are better respected, and other minors who will subsequently benefit from the research findings.

I. DEFINING RESEARCH

The current trend towards greater inclusion of minors in medical research does not mean minors are being treated in an ethically and legally defensible manner. It just means more minors are involved in the research enterprise. Before turning to how the role of minors is presently defined and how it ought to be defined, it is necessary to pause briefly over how research is defined and why there is a need to draw a distinction between research and treatment. This section attempts to give readers some context for the detailed examination of when the law and ethics affords mature minors the right to consent to medical research found in Chapters 2 and 3 of this thesis, respectively.

A. What is research?

The law recognizes the ability of mature minors to consent to at least some medical treatment.¹⁵ To date, however, its ambit has not been extended into the realm of research by either courts or statutory enactments in Canada. It is, however, recognized by the authors of the *Tri-Council Policy Statement* that, subject to applicable laws, some minors may have decision-making capacity to consent to their own research participation. Specifically, the recently released second edition of the Policy Statement states “...children may also lack capacity to consent to participate in research...”¹⁶ The use of the word ‘may’ necessarily implies that some minors have capacity to consent.

¹⁵ The specific limitations placed upon the right of mature minors to consent to treatment are set out in Chapter 2, which provides a detailed review of relevant legal instruments.

¹⁶ *Tri-Council Policy Statement*, *supra* note 1 at 49.

At present, there is no universally accepted statutory definition of research (or of any analogous term).¹⁷ Some existing definitions are quite narrow, such as the definition of “clinical research” contained within the Federal *Food and Drugs Regulations*¹⁸ passed pursuant to the *Food and Drugs Act*¹⁹ which only applies to research being carried out as part of the drug approval process and consequently does not capture the large breadth of research that does not involve drugs nor does it govern those elements of research falling under provincial jurisdiction. In that instance a “clinical trial” is said to be “an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.”²⁰

Meanwhile, other statutes contain far broader definitions of research. An example of the latter can be found within the *Health Research Ethics Authority Act*²¹, a statute recently enacted by the Newfoundland and Labrador legislature which delineates the roles of research ethics boards. In so doing, it defines “health research involving human subjects” as “activities whose primary goal is to generate knowledge in relation to human health, health care and health care systems, and involving human beings as research

¹⁷ Analogous terms for the purposes of this thesis include “health research involving human subjects” and “clinical trial”.

¹⁸ C.R.C., c.870.

¹⁹ R.S.C. 1985, c. F-27.

²⁰ *Supra* note 18, C.05.001.

²¹ S.N.L. 2006, c. H-1.2.

subjects, health care information respecting human beings and human biological material.”²²

Beyond legal instruments, definitions of research can also be found in ethical instruments, such as in the *Tri-Council Policy Statement* where “research” is defined as involving “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.”²³ Despite being somewhat vague like the previously cited definitions of research, the lack of specificity contained therein also means that it captures the largest scope of activities, including all of that caught under the other definitions.²⁴ For that reason, the definition of research contained within the *Tri-Council Policy Statement* will apply throughout this thesis.

B. What is treatment?

Research and medical treatment are different but they can involve the same patient-research participant and be carried out by the same physician-researcher concurrently. When seen in that light, it is imperative for readers to remain aware of the distinction between these two concepts as they consider how the role of mature minors in the consent process for research should be defined.

To that end, unlike research, there are a number of provincial statutes that define treatment in the context of medical decision making by or for minors. Each of these statutes is considered in detail in Chapter 2. At this juncture, it is sufficient to point out that although provinces use different labels, be it “medical treatment”, “health care”, or “care”, there is considerable consistency between statutes as to the medical acts that are

²² *Ibid.*, s. 2.

²³ *Supra* note 1 at art. 2.1 and accompanying commentary.

²⁴ This does not mean that the *Tri-Council Policy Statement*, *supra* note 1, applies to all research captured under the legal instruments discussed above but rather that the definition of research itself is broader than the others. See Chapter 3 for a discussion on when the *Tri-Council Policy Statement* applies.

captured within the ambit of treatment.²⁵ This near-uniformity is readily apparent when one considers the definitions contained in consent to treatment statutes.²⁶ For example, New Brunswick's *Medical Consent of Minors Act*²⁷ defines "medical treatment" as including:

- (a) surgical and dental treatment,
- (b) any procedure undertaken for the purpose of diagnosis,
- (c) any procedure undertaken for the purpose of preventing any disease or ailment, and
- (d) any procedure that is ancillary to any treatment as it applies to that treatment.²⁸

Similarly, British Columbia's *Infants Act*²⁹ defines "health care" as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health related purpose, and includes a course of health care."³⁰

C. Innovative Therapy, Therapeutic Research and Nontherapeutic Research: Further Muddying of the Waters.

From the definitions of research and treatment set out above, it is hopefully clear to readers that distinguishing between the two concepts is not always straightforward. Before setting out my justification as to why it is nonetheless necessary to tease a part research and treatment, I raise three additional concepts – innovative therapy, therapeutic research and nontherapeutic research – which make the distinction appear even more difficult.

²⁵ Throughout this thesis, the term "treatment" will be used to refer to the provision of all health care services by a physician generally, unless speaking to a specific jurisdiction's legislation. In the latter instance, the terminology used in that province's statute will be employed.

²⁶ An in-depth review of the consent to treatment legislation enacted by a number of provinces is set out in Chapter 2.

²⁷ S.N.B. 1976, c. M-6.

²⁸ *Ibid.*, s. 1.

²⁹ R.S.B.C. 1996, c.223.

³⁰ *Ibid.*, s. 17(1).

Research can be particularly difficult to distinguish from a particular form of treatment known as innovative therapy. According to the Law Reform Commission of Canada, “innovative therapy” is “a treatment in the true sense of the word, an act performed for the direct and immediate benefit of the recipient, but not yet fully proved in scientific terms.”³¹ However, the lack of demonstrated scientific validity does not automatically bring an act under the research umbrella.³² Consequently, rather than looking to scientific data as a means of differentiating between innovative therapy and research, the implicit suggestion from the above is that one ought to look to the primary purpose or aim of that activity as well as whether the care is being delivered in accordance with a written protocol.³³ As evidenced by the National Council on Ethics in Human Research’s finding that many institutions have difficulty distinguishing between innovative therapy and research, these determinations are not easily done in practice.³⁴

The distinction between treatment and research is further blurred by the sub-classification of the latter by some authors into therapeutic and nontherapeutic research. Much like treatment, therapeutic research strives “to directly help or aid a patient who is suffering from a health condition”.³⁵ However, unlike treatment, this assistance is delivered through participation in a study designed to obtain generalizable knowledge

³¹ Law Reform Commission of Canada, *Working Paper 61: Biomedical Experimentation Involving Human Subjects* (Ottawa: Law Reform Commission of Canada, 1989) at 33.

³² National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979), online: <<http://ohsr.od.nih.gov/guidelines/belmont.html>>.

³³ Simon Verdun-Jones & David N. Weisstub, “Consent to Human Experimentation in Québec: The Application of the Civil Law Principle of Personal Inviolability to Protect Special Populations” (1995) 18 *Int’l J. Law & Psychiatry* 163 at 178-179; Kathleen Cranley Glass & Trudo Lemmens, “Research Involving Humans” in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds., *Canadian Health Law and Policy*, 2nd ed. (Markham: Butterworths, 2002) 459 at 461 [Glass & Lemmens].

³⁴ National Council on Ethics in Human Research, *Report on Site Visits: October 1998 to December 2001*, online: <http://www.ncehr-cnerh.org/pdf/publications/site_visits/Report_April_2002.pdf>.

³⁵ *Grimes v. Kennedy Krieger Institute, Inc.* 782 A.2d 807 (Md. 2001).

about that health condition. Nontherapeutic research, in turn, is much more akin to “research”, as defined above, in that participants in that class of research either do not have the condition being studied or they are not intended to benefit directly from the study in question. As is the case with research generally, the purpose of nontherapeutic research is to derive benefits for society rather than to aid individual participants.³⁶ In a sense then, “therapeutic research” covers much of the murky middle ground between treatment and research in their purest senses. However, the former includes elements that extend beyond standard care, such as additional tests, procedures, and hospitalizations.³⁷

The therapeutic/nontherapeutic research dichotomy is problematic and so that classification scheme has not been used in this thesis. It has garnered a great deal of criticism in recent decades.³⁸ Schwartz has aptly summarized the perceived problem with the sub-classification of research into therapeutic and nontherapeutic categories as follows:

The term “therapeutic research” fails to give due account to the differences between research and clinical care, in terms of both goals and methods. Although a clinical trial might be conducted with a reasonable expectation that those who receive the test article will be therapeutically benefited, the primary goal of the trial, like all other research, is the acquisition of generalizable scientific knowledge, following research procedures that may not accord with the goals of therapeutic care for individual participants. Moreover, in clinical care, treatment is determined by reference to the personal situation of the patient, whereas in research, treatment is determined by reference to the procedures specified in the research protocol.³⁹

³⁶ *Ibid.*

³⁷ Loretta M. Kopelman, “Pediatric Research Regulations Under Legal Scrutiny: *Grimes* Narrows Their Interpretation” (2002) 30 J.L. Med. & Ethics 38 at 41 [Kopelman].

³⁸ *Ibid.*

³⁹ Jack Schwartz, “The Kennedy Krieger Case: Judicial Anger and the Research Enterprise” (2002-2003) 6 J. Health Care L. & Pol’y 148 at 152 [Schwartz].

Despite this criticism, it is nonetheless worth noting that the Maryland Court of Appeals adopted this classification scheme in *Grimes v. Kennedy Krieger Institute, Inc.* in 2001, a case involving two minors under the age of five.⁴⁰ Specifically, the Court relied upon the distinction between therapeutic research and nontherapeutic research as a means of delineating the magnitude of risk permitted in pediatric research. After reviewing a number of authorities, including the *Declaration of Helsinki*⁴¹ and the *Nuremberg Code*⁴², the Court unequivocally stated that children, even with parental consent, could not participate in “nontherapeutic study that promises no medical benefit to the child whatever, so that any balance between risk and benefit is necessarily negative.”⁴³ Interestingly, this was framed as a holding by the Court, rather than as *obiter* despite the fact that it was wholly unnecessary for the Court to make such a

⁴⁰ The research giving rise to that case was aimed at determining the effectiveness of different lead paint abatement procedures by, among other things, collecting blood samples from children residing in specific homes on numerous occasions over a two-year period. Two sets of parents brought forward separate claims of negligence against the researchers for failing to inform them that lead remained a potential hazard in the home at the time informed consent was obtained as well as for failing to notify them of the high dust lead levels found in home during the study. At first instance, the researchers were successful on their summary judgment application on the basis that the researchers owed no duty to avoid the alleged injury. However, on appeal, the Baltimore City Circuit Court’s decision was reversed and the case was ordered to proceed to trial. Given the scathing criticism of the research practices contained within the Court of Appeal’s reasons, it is unsurprising that the case does not appear to have proceeded to trial.

⁴¹ World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Adopted at the 18th World Medical Assembly in Helsinki, Finland in June 1964. Amended at the 19th World Medical Assembly in Tokyo, Japan in October 1965; the 35th World Medical Association in Venice, Italy in October 1983; the 41st World Medical Assembly in Hong Kong in September 1989; the 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; the 53rd World Medical Assembly, Washington, U.S.A. in 2002; the 55th World Medical Assembly, Tokyo, Japan in 2004; and the 59th World Medical Assembly, Seoul, South Korea, in October 2008), online: <<http://www.wma.net/e/policy/b3.htm>> [*Declaration of Helsinki*].

⁴² U.S., *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, (Washington, D.C.: U.S. Government Printing Office, 1949) at vol. 2, 181-182, online: <<http://www.hhs.gov/ohrp/references/nurcode.htm>>.

⁴³ *Grimes*, *supra* note 35 at 862. Interestingly, in *Nielsen v. Regents of the University of California et al.*, No. 665-049 Cov. 8-9, a lawyer sitting on a university’s institutional review board⁴³ asked the court to make a similar declaration nearly thirty years earlier. No written reasons were ever released by the Court in that case.

pronouncement to review the summary judgment granted by the lower court. The research at issue was found to be nontherapeutic in nature.

Based on the breadth of sources referred to throughout its decision, it is doubtful that the Court was oblivious to the issues raised by Schwartz and other commentators. As such, the fact that the Court relied heavily on the therapeutic/nontherapeutic research distinction in the face of this criticism then clearly suggests that, at least in the eyes of the Maryland Court of Appeals, the classification of research as either therapeutic or nontherapeutic is less problematic than the “direct benefit” analysis proposed by critics of the former.⁴⁴ The basis for this preference is highly speculative but one possible reason might be that the term “therapeutic research” better recognizes the reality that some studies are truly a hybrid of treatment and research.

In the end, despite being heavily criticized and described as being “ill-considered”⁴⁵, the *Grimes v. Kennedy Krieger Institute, Inc.* decision remains a rare glimpse into how judges may choose to address the lack of clarity between treatment and research in the pediatric research context. Because of this, it has been, and will likely continue to be, studied beyond the Maryland state lines.⁴⁶

D. The Research and Treatment Dichotomy: Theoretically Tenuous but Practically Necessary.

There is nothing in the definition of research set out in the *Tri-Council Policy Statement* that requires that the primary aim be to generate generalizable knowledge. Similarly, there is also nothing in the definition of treatment (or other analogous term) in

⁴⁴ See e.g. *Grimes, ibid.*

⁴⁵ Schwartz, *supra* note 39 at 148.

⁴⁶ Loretta M. Kopelman, “Group Benefits and Protection of Pediatric Research Subjects: *Grimes v. Kennedy Krieger and the Lead Abatement Study*” (2002) 9 *Accountability in Research* 177 at 191 [Kopelman, “Group”].

any of the consent to treatment statutes that explicitly requires the primary or sole aim of the treatment to be improving the health of or providing optimal care for a particular patient. So, if the definitions themselves are not mutually exclusive, why is it necessary to clearly delineate research and treatment? Despite the inherent complexity in trying to distinguish between treatment and research, there are two important reasons why a distinction must nonetheless be made.⁴⁷

First and foremost, the applicable regulatory enactments and ethical statements as well as underlying legal and ethical principles depend on the context. Notably, the *Food and Drugs Regulations* and the *Tri-Council Policy Statement* only apply to research endeavours whereas consent to treatment legislation applies to all treatment and as I will argue in Chapter 2, to a limited range of research activities. One instance in which research and treatment may differ relates to the disclosure of risk. There is some debate amongst Canadian legal scholars as to whether the scope of risk that must be disclosed varies between the treatment and the research context.⁴⁸ The ability to define the proper role of mature minors in the medical research context does not depend on the resolution of that debate.⁴⁹ Awareness of this differential treatment however, will assist readers in understanding some of the possible motivations that may underlie arguments as to whether something constitutes research or treatment.

⁴⁷ These reasons are only discussed briefly in this thesis as a more exhaustive examination of them can be found elsewhere, such as in Glass & Lemmens, *supra* note 33 at 460.

⁴⁸ See Michael Hadskis, “The Regulation of Human Biomedical Research in Canada” in Jocelyn Downie, Timothy Caulfield, & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 3rd ed. (Markham: Butterworths, 2007) 257 at 286-289 [Hadskis], where it is argued that there is little authority for the proposition that a higher standard applies to the research context than that applied to treatment. See also Glass & Lemmens, *ibid* at 484-485, where it is suggested that the disclosure standard does in fact differ between research and treatment.

⁴⁹ For that reason, I have chosen not to pronounce myself, one way or the other, on this point.

Secondly, the role of physicians and researchers is different. As one author has argued the distinction between research and treatment acts as an “ethical warning flag” that signals when there may be a misunderstanding on the part of patients as to physician-researchers’ primary objective (i.e. acting solely for the benefit of the patient vs. acting to generate new knowledge).⁵⁰ The duties physicians and researchers owe to patients and/or research participants, as the case may be, as well as the standards against which their behaviour will be measured are also different. With different motivations, duties and standards guiding the actions of physicians and researchers (or physician-researcher if an individual wears both hats), it is necessary to ensure that the legal and ethical parameters that apply to each context are appropriate.

The most confusion arguably arises when the roles of physician and researcher completely merge, as is the case when a physician administering therapy is also the researcher responsible for carrying out the particular research study in question.⁵¹ This fusion benefits the young patient/research participant in that she will be more familiar with the individual and will not need to interact with another individual. However, the dual role can lead to some confusion for the minor in terms of what aspects are necessary to improve her own health and what is being done for the sake of advancing scientific knowledge. That being said, there is some suggestion in the literature that this confusion may be more of a theoretical problem. Notably, Marion Broome and her colleagues have shown that adolescents with either diabetes or cancer are able to distinguish between

⁵⁰ T. Lewens, “Distinguishing Treatment from Research: A Functional Approach” (2006) 32 J Medical Ethics 424 at 424-425.

⁵¹ Based on the institutional affiliations given for authors publishing the results of pediatric research studies, it would appear that virtually all medical research involving children is carried out in tertiary care facilities. That is, most research is done in children’s hospitals by individuals that are both clinicians and researchers. For an example of these affiliations, see the February 2008 issue of *Pediatrics*.

those activities that were part of their treatment regimen and their involvement in a research study.⁵²

From the above discussion, it is clear that there are valid reasons to distinguish between research and treatment but that doing so leads to a somewhat artificial distinction in certain instances. Nonetheless, the remainder of this thesis considers only the research context and thus assumes that a distinction can in fact be made. It is also worth noting at this juncture that the discussion to follow largely focuses on hospital-based medical research because most of the relevant literature has come out of that setting. The proposed means of ensuring that mature minors' decisions are given appropriate consideration has been developed as a tool to be incorporated into the *Tri-Council Policy Statement* but can also function as a stand-alone instrument.⁵³ Nonetheless, the framework proposed herein ought to be applied to research being carried out by physicians and allied health professionals, be it in hospitals or in private offices.

II. STRUCTURAL OVERVIEW

This thesis is divided into five chapters. Following this overview, the second chapter contains a detailed examination of the legal instruments that could potentially apply to the research context, from various spheres. Specifically, international instruments such as the United Nations' *Convention on the Rights of the Child*⁵⁴ are

⁵² Marion E. Broome, Deborah J. Richards & Joanne M. Hall, "Children in Research: The Experience of Ill Children and Adolescents" (2001) 7(1) *Journal of Family Nursing* 32 at 40-42.

⁵³ Since a detailed examination of the *Tri-Council Policy Statement*, *supra* note 1, has been included at Chapter 3, at this juncture it is only necessary to note that it applies to investigators conducting research at institutions receiving funding from the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, or the Social Sciences and Humanities Research Council of Canada. It also applies to other organizations, including Health Canada, the National Research Council, and the Community Research Ethics Board of Alberta.

⁵⁴ GA Res. 44/25, UN GAOR, 1989, online: Office of the High Commissioner for Human Rights <<http://www.unhchr.ch/html/menu3/b/k2crc.htm>>.

considered. There is then an in-depth review of the Supreme Court of Canada's decision in *A.C. v. Manitoba (Director of Child and Family Services)* where the Court had the occasion to discuss a minor's ability to make medical treatment decisions. Lastly provincial and territorial legislative instruments, being child protection legislation and consent to treatment legislation, as well as the *Civil Code of Quebec* are examined. The third chapter reviews the ethical instruments that apply to most research carried out in Canada, not the least of which is the *Tri-Council Policy Statement*. I also discuss key ethical principles that govern how research involving minors ought to be carried out. With knowledge of the law and ethics, the discussion shifts in Chapter 4 to proposing a way in which to define the role of individual minors in the medical research consent process throughout all common law jurisdictions in Canada. As readers will see, the framework proposed requires an individualized capacity assessment of each minor whose participation in research is sought using a validated instrument. Lastly, the thesis ends with Chapter 5, where general conclusions are set out as well as suggestions for next steps. The most significant such step involves mobilizing the research community, government stakeholders, lawyers, and bioethicists to develop an instrument that could be used to assess the capacity of minors. It is only after an instrument to assess the capacity of minors has been validated and its use becomes an established part of the consent process for research studies involving minors that I will have achieved my ultimate goal of ensuring that the rights of minors involved in research are respected and properly defined.

III. CONCLUSION

Before turning to the substance of this thesis, I feel it is useful to give readers insight into the lens through which I have approached this thesis. Today, I am a practicing lawyer and a parent. Before attending law school, I completed undergraduate studies in a health sciences discipline. I also spent over a year and a half working as a research associate at the Children's Hospital of Eastern Ontario. During that period of time, I was involved in medical research that was sponsored by various pharmaceutical companies as well other research that was made possible by grants from the Canadian Institutes of Health Research. I have actively participated in all phases of the research process – from study design to the preparation of the consent form to carrying out the study to preparing manuscripts. Given the many hats I have worn and continue to wear, I think I approach the issue of the role of mature minors in the medical research consent process from a unique perspective. Hopefully the thoughts, opinions, and insights that follow serve to generate debate and discussion.

CHAPTER 2

**

LEGAL INSTRUMENTS

I. INTRODUCTION

Before one can propose a change in how the rights of mature minors are addressed in the medical research context, a thorough understanding of how minors are treated under the law at present is required. Furthermore, where the aim is to provide lawyers, researchers, and health care institutions with a framework that can be applied on a national scale, the legal regimes in place within each Canadian jurisdiction must be canvassed. These ends are achieved in this chapter by beginning with the broadest legal and quasi-legal instruments that affect the rights of minors – those set out in international law. The legal requirements imposed by the Federal Government are then reviewed. This is followed by a detailed examination of the mature minor concept at common law and how it has been modified by child protection and consent to treatment statutes. Finally, the unique regime in place in Quebec is discussed.

II. INTERNATIONAL INSTRUMENTS

With medical research being carried out throughout the world, it is of little surprise that international bodies have drafted guidance documents as a means of ensuring a certain degree of consistency in the way research is carried out in different

countries. The two such documents that are the most relevant to the present examination of the role that ought to be afforded to mature minors in the informed consent process in the research context are the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use's *Good Clinical Practice: Consolidated Guideline*⁵⁵ and the *ICH Harmonised Tripartite Guideline: Clinical Investigation of Medicinal Products in the Pediatric Population (E11)*.⁵⁶ These documents do not address the more procedural elements of research, which are captured under national laws and policies, nor do they address the legal rights of children generally. The latter is left to the United Nations' *Convention on the Rights of the Child*, which is an international treaty that has been ratified by Canada. The *ICH GCP* and *ICH CIMPPP* focus on the general conditions necessary for ethical research while also flagging potential legal requirements. In doing so, they straddle the gap between law and ethics. Given the impossibility of characterizing these documents as either purely legal or ethical instruments (and thus allowing them to fit nicely into one of the broader categories of analysis of this thesis) a review of these documents has somewhat arbitrarily been left to Chapter 3 of this thesis. Before proceeding with a discussion of the *Convention on the Rights of the Child*, it is worth noting that by adopting the *ICH GCP*, Health Canada also indirectly mandates compliance with the *Declaration of Helsinki*, which is also discussed in the following chapter.

⁵⁵ International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Good Clinical Practice: Consolidated Guideline*, online: <http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/ich/efficac/e6_e.html> [*ICH GCP*].

⁵⁶ International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Clinical Investigation of Medicinal Products in the Pediatric Population*, online: <http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/e11_e.html> [*ICH CIMPPP*].

The United Nations' *Convention on the Rights of the Child* was ratified by Canada on December 13, 1991. As its title suggests, this legal instrument delineates all universally recognized rights of children, from the right to education to the right to freedom of speech and beyond. The United Nations monitors compliance with the *Convention on the Rights of the Child* by requiring signatories to submit reports periodically. Canada's most recent submission in this regard was on November 20, 2009.⁵⁷

Obviously, not all the rights set out in the *Convention on the Rights of the Child* are germane to the present discussion. That said, because it supersedes all other Canadian or international law that may apply in Canada unless such other laws "are more conducive to the realization of the rights of the child"⁵⁸, it is essential to briefly examine the Convention's recognition of the evolving capacity of children. Although the tenets of the *Convention on the Rights of the Child* apply to all individuals under the age of eighteen, it is nonetheless clear that respecting the rights of children necessitates different actions depending on the age and maturity of a child.⁵⁹ Notably, article 5 reads in part:

States Parties shall respect the responsibilities, rights and duties of parents or, where applicable, the members of the extended family or community as provided for by local custom, legal guardians or other persons legally responsible for the child, to provide, in a manner consistent with the evolving capacities of the child, appropriate direction and guidance in the exercise by the child of the rights recognized in the present Convention.⁶⁰

⁵⁷ See Canada, *Canada's Third and Fourth Reports on the Convention on the Rights of the Child* (20 November 2009), online <<http://www.pch.gc.ca/pgm/pdp-hrp/docs/pdf/canada3-4-crc-reports-nov2009-eng.pdf>>. Interestingly, under the heading "Articles 12 and 3(1): Right of the child to express views on matters affecting him/herself and the best interests of the child" where in Appendix 1, there is a brief discussion of the Manitoba Court of Appeal's decision in *Director of Child and Family Services v. A.C.*, 2007 MBCA 9, 276 D.L.R. (4th) 41.

⁵⁸ *Supra* note 54, art. 41.

⁵⁹ See *ibid.*, art. 1, where child is defined as including being those under the age of 18.

⁶⁰ *Ibid.*, art. 5.

For added clarity, article 12(1) states that:

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.⁶¹

A strict interpretation of Article 12(1) reveals that, although children must be allowed to express their views, these views are not necessarily determinative. Specifically, giving “due weight” to the views of children could mean as little as including these views as one of several considerations to be weighed when contemplating research participation. It could, however, also grant mature minors the right to autonomous decision-making with respect to their participation in medical research where local laws permit such action. Based on the review of the law set out in this chapter, the laws of each common law jurisdiction lend themselves to such an interpretation.

Adopting a position somewhere between considering a minor’s views part of a collection of factors and allowing a mature minor’s views to be determinative is obviously not a simple task. It is perhaps for this reason that, apart from Quebec, no provincial legislation has made any pronouncement on the role to be given to the views of minors in the research context. The Federal Government has also not passed any legislation concerning participation in research by minors.⁶² Although theoretically, this inaction by government actors has left the interpretation of the pivotal phrase “due weight”⁶³ to the courts, to the three Councils, and to other bodies requiring adherence to

⁶¹ *Ibid.*, art. 12(1).

⁶² The only federal legislation governing research more generally is the *Food and Drug Regulations*, *supra* note 18.

⁶³ *Convention on the Rights of the Child*, *supra* note 54, art. 12(1).

the *Tri-Council Policy Statement*, practically the decision is made by researchers and research ethics boards, at least until a legal challenge is raised. Obviously, leaving such key decisions to the discretion of individuals untrained in the law provides little reassurance to mature minors whose rights hang in the balance.

Despite the fact that it remains somewhat vague how the evolving capacity of minors needs to be recognized in the research setting to meet the standard contained within the *Convention on the Rights of the Child*, it is abundantly clear that the transition from childhood to adulthood is a legal reality.

III. NATIONAL INSTRUMENTS

The principles enshrined in the *Convention on the Rights of the Child* inform how some pediatric medical research is carried out throughout Canada. On a national level, there is then also the *Canadian Charter of Rights and Freedoms*⁶⁴ as well as a few initiatives developed by Health Canada. In order to avoid unnecessary repetition, the discussion on the *Charter* can be found under subsection B(v) below, as part of the discussion of the Supreme Court of Canada's ruling in *A.C. v. Manitoba (Director of Child and Family Services)*⁶⁵. Prior to discussing the other initiatives by Health Canada, it is worth noting that the measures discussed in this section, those from the previous section, and criminal laws are the only tools that apply in all Canadian jurisdictions.

⁶⁴ Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [Charter].

⁶⁵ 2009 SCC 30, [2009] 2 S.C.R. 181.

Beyond these instruments and so long as it respects the division of powers limits, each jurisdiction is free to enact its own laws regulating the pediatric research enterprise.⁶⁶

A. Health Canada's Initiatives

Beyond adopting the *ICH GCP* and *ICH CIMPPP*, Health Canada has also undertaken a couple of projects in an attempt to fulfill the emerging need for additional information on therapeutic and safety issues involving children. In 2005, it developed the Office of Paediatric Initiatives. This Office was intended to deal with issues affecting children throughout the health product life cycle, including pre-market approval and post-market surveillance and evaluation.⁶⁷ Unfortunately, as no further details on this rather vague mandate or on the current activities of the Office could be found the specific work it is doing is unknown. Secondly, Health Canada also established a Paediatric Expert Advisory Committee under the auspices of its Health Products and Food Branch in 2009. This Committee was intended to provide policy advice on health and safety issues involved in the regulation of health products and food. It is unknown precisely what this committee has achieved to date or what ties (if any) it has to the Office of Paediatric Initiatives. It is nonetheless interesting to note that no one with legal expertise was targeted by Health Canada for potential membership to the Committee.⁶⁸ Given the lack of information available on either the Office of Paediatric Initiatives or the Paediatric Expert Advisory Committee, it is doubtful that any clarity on the role to be afforded to

⁶⁶ Marie Hirtle, "The Governance of Research Involving Human Participants in Canada" (2003) 11 Health L. J. 137. See also Martha Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L. J. 95, for discussion on jurisdiction over 'health' generally.

⁶⁷ Canada, Health Canada, online: Office of Paediatric Initiatives <<http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/opi-bip/index-eng.php>>.

⁶⁸ Canada, Health Canada, *Frequently Asked Questions: Paediatric Expert Advisory Committee* (Ottawa: Health Canada, undated), online: <<http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/opi-bip/peac-cceip/faq-eng.php>>.

mature minors in the research context will flow from these mechanisms in the near future. After all, one would expect any significant developments in this sphere to have been disseminated to the public through the media or publicly available government documents.⁶⁹

B. The Mature Minor at the Supreme Court of Canada

On June 26, 2009, the Supreme Court of Canada handed down its decision in *A.C. v. Manitoba (Director of Child and Family Services)*. This is our highest court's first pronouncement on the applicability of the common law mature minor rule to the medical treatment context. Given that this decision shapes how the earlier jurisprudence should be interpreted as well as how trial-level and appellate courts will define the role of mature minors in future cases, a thorough review of *A.C. v. Manitoba (Director of Child and Family Services)* is warranted.⁷⁰ In the discussion below, I argue that the majority did not discuss the common law in any meaningful way, despite its claims that it did. As a result, I construct a description of the mature minor rule at common law that is consistent with previous jurisprudence and properly supported conclusions contained in the present case. Throughout the remainder of the discussion, readers will find that I am somewhat critical of the majority and minority's reasoning. This criticism has been levelled because I want to ensure that if any aspects of this decision are incorporated into the capacity assessment tool that needs to be developed (a point which is discussed further in Chapter 4), it is necessary that they be cast in the correct light.

⁶⁹ Efforts to obtain further information through numerous telephone and email requests have also failed.

⁷⁰ Should readers be interested in reading the facts filed by the parties and interveners in this case, they can be found at The David Asper Centre for Constitutional Rights, online: <http://www.aspercentre.ca/constitutional-cases/scc-facts/alpha-list-cases/a_c_-v-director-of-child-and-family-services.htm>.

(i) **Background**

The facts of the case are quite straightforward. It involved a minor, A.C., who was admitted to hospital when she was 14 years and 10 months old because of gastrointestinal bleeding caused by Crohn's disease. A few months prior to her hospital admission, she had signed an advance directive indicating she did not want to receive any blood transfusions. During her admission, her treating physician determined that she required a blood transfusion. A.C., a Jehovah's Witness, refused the blood transfusion. Her parents supported her decision. As a result of this refusal, three psychiatrists carried out a psychiatric assessment, in which it was determined that A.C. was competent. The Director of Child and Family Services then apprehended her as a child in need of protection under Manitoba's *Child and Family Services Act*⁷¹ and brought an application pursuant to sections 25(8) and 25(9) for an order authorizing treatment.⁷² Those provisions read:

25(8) Subject to subsection (9), upon completion of a hearing, the court may authorize a medical examination or any medical or dental treatment that the court considers to be in the best interests of the child.

25(9) The court shall not make an order under subsection (8) with respect to a child who is 16 years of age or older without the child's consent unless the court is satisfied that the child is unable

(a) to understand the information that is relevant to making a decision to consent or not consent to the medical examination or the medical or dental treatment; or

(b) to appreciate the reasonably foreseeable consequences of making a decision to consent or not consent to the medical examination or the medical or dental treatment.⁷³

⁷¹ C.C.S.M. c. C80.

⁷² *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 5-11.

⁷³ *Supra* note 71, ss. 25(8)-25(9).

Kaufman J., the judge hearing the application, proceeded on the assumption that A.C. had the requisite capacity. Despite this finding, he granted the order sought by the Director on the basis that the statutory scheme did not restrict the court's ability to order medical treatment that was in a minor's "best interests" even if that minor was competent where the minor was less than sixteen years of age. Potential breaches of the *Charter* were not considered.⁷⁴

A.C. and her parents appealed the order to the Manitoba Court of Appeal, challenging the legislative scheme on the basis that it contained an irrebuttable presumption of incapacity for minors less than sixteen years of age.⁷⁵ There, speaking on behalf of a unanimous court, Steel J.A. dismissed the appeal. In so doing, the Court held that under the *Child and Family Services Act*, the court was empowered to make treatment decisions for minors under the age of sixteen based on a "best interest" test, whether or not the minor demonstrated decision-making capacity. Stated differently, the Court explicitly held that the legislative scheme ousted the common law mature minor rule entirely with respect to minors under the age of sixteen.⁷⁶ The Court further held that the scheme did not violate section 7 of the *Charter* because it was not arbitrary, nor did it violate section 15(1). Finally, any violation of sections 2(a) could be justified under section 1.⁷⁷

A.C. and her parents further appealed to the Supreme Court of Canada. Ultimately, the Court upheld the constitutionality of the legislative scheme at issue. However, unlike the Manitoba Court of Appeal, the Supreme Court of Canada was

⁷⁴ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 12.

⁷⁵ *Ibid.* at para. 25.

⁷⁶ *Director of Child and Family Services v. A.C.*, *supra* note 57 at paras. 50, 57.

⁷⁷ *Ibid.* at paras. 62-107.

divided, with three separate sets of reasons being written; Abella J. wrote the majority reasons on behalf of a four justice majority, McLachlin C.J. wrote minority reasons on behalf of herself and Rothstein J., and Binnie J. wrote dissenting reasons. The analysis of the decision that follows is broken down by topic so as to better allow comparison of the different views held by the three groups of justices and how those views might be applied to the medical research context. Those topics are: (1) the characterization of the issue, (2) the capacity of minors at common law, (3) the rights of minors under the *Charter*, (4) the capacity assessment, (5) the application of the decision to A.C., (6) how the decision can be applied to the research context, and (7) the questions left unanswered by the Court.

(ii) **Characterization of the Issue**

A.C. v. Manitoba (Director of Child and Family Services) is about the constitutionality of sections 25(8) and 25(9) of the *Child and Family Services Act*. Specifically, according to the majority the issue before the Court was “whether the statutory scheme strikes a constitutional balance between what the law has consistently seen as an individual’s fundamental right to autonomous decision making in connection with his or her body and the law’s equally persistent attempts to protect vulnerable children from harm.”⁷⁸ Such tacit endorsement of the welfare principle⁷⁹ is also seen in the manner in which the majority carefully interprets “best interest” as requiring that a

⁷⁸ *Supra* note 65 at para. 30.

⁷⁹ As noted by Joan M. Gilmour, “Death, Dying and Decision-Making About End of Life Care” in Jocelyn Downie, Timothy Caulfield, & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 3rd ed. (Markham: LexisNexis Canada Inc., 2007) 437 at 441, citing Manitoba Law Reform Commission, *Minors’ Consent to Health Care* (Report No. 91) (Winnipeg: The Commission, 1995) at 5 [Manitoba Law Reform Commission], the welfare principle is the “argument that a minor can only consent to care that would be of benefit”. This concept is considered in greater detail in subsection (viii)(1) below.

minor's views become more important as maturity evolves but then refuses to go so far as to say that once capacity is attained, the minor's decision will be determinative.⁸⁰

In his dissenting opinion, Binnie J. defines the issue quite differently; the issue "is not *what* is to be decided about medical treatment but *who* is to make the decision" [emphasis in original]⁸¹. As noted in the dissenting reasons, the "*Charter* is not just about the freedom to make what most members of society would regard as the wise and correct choice"⁸². Implicit in Binnie J.'s characterization of the issue is the view that mature minors should be allowed to consent to and refuse any treatment, contrary to the majority and minority's shared view that mature minors should be afforded "freedom to exercise wishes that are in the minor's best interests"⁸³. In Binnie J.'s view, the only way this can be achieved is by allowing minors under the age threshold contained in a statute to rebut the presumption of incapacity and that, once rebutted, they be treated like competent adults. Binnie J.'s reading of sections 25(8) and 25(9) of the *Child and Family Services Act* does not allow for that interpretation.⁸⁴

The majority, minority and dissent disagree on the sources of information that must be canvassed in order to assess the constitutionality of the legislative scheme. Notably, the majority deemed it necessary to review the legislative scheme, the common law, international jurisprudence, and "relevant social scientific and legal literature"⁸⁵ while the minority rejects the relevance of the common law on the basis that the scheme

⁸⁰ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 21-22. See also the discussion below on factors to be considered in evaluating a minor's capacity.

⁸¹ *Ibid.* at para. 165.

⁸² *Ibid.* at para. 163.

⁸³ Ireh Iyioha & Yusuff A. O. Akorede, "You Give Me Welfare But Take My Freedom: Understanding the Mature Minor's Autonomy in the Face of the Court's *Parens Patriae* Jurisdiction" (2009-2010) 13 *Quinnipiac Health L. J.* 279 at 288.

⁸⁴ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 176, 209-210.

⁸⁵ *Ibid.* at para. 30.

“displaces” the common law mature minor rule and instead focuses its constitutional analysis on the statute itself.⁸⁶ The dissent, in turn, considers the common law before focusing much of its attention on the wording of the statute.⁸⁷

(iii) The Mature Minor Rule at Common Law

The common law mature minor rule recognizes the transition from childhood to adulthood and accords certain minors greater rights. It reflects the fact that the capacity to make medical treatment decisions does not suddenly materialize on the day an individual reaches the age of majority. The mature minor principle applies in all common law jurisdictions in Canada, unless it has been modified or overridden by legislative enactments or the court through its *parens patriae* jurisdiction.⁸⁸ To date there does not appear to be a reported decision from a Canadian court involving the research context. It must therefore be recognized that the mature minor rule has evolved in a rather narrow sphere.

Prior to the decision in *A.C. v. Manitoba (Director of Child and Family Services)*, the mature minor rule was described as the legal concept whereby those under the legislated age of majority can consent to medical treatment when they are found to have “sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not.”⁸⁹ The jurisprudence was also unclear as to whether the mature minor rule incorporated the

⁸⁶ *Ibid.* at para. 123.

⁸⁷ *Ibid.* at paras. 162-236.

⁸⁸ The court’s *parens patriae* jurisdiction as well as the welfare principle are discussed in detail in subsections (iii)(2) and (iii)(3) below.

⁸⁹ Joan M. Gilmour, “Children, Adolescents, and Health Care” in Jocelyn Downie, Timothy Caulfield, & Colleen M. Flood, eds., *Canadian Health Law and Policy*, 2nd ed. (Markham: Butterworths, 2002) 205 at 211 [Gilmour, “Children”].

welfare principle, which is the notion whereby minors can only consent to treatment that is perceived by others as being in their best interest.⁹⁰

The majority of the Supreme Court of Canada in *A.C. v. Manitoba (Director of Child and Family Services)* seems to think it has clarified this ambiguity in favour of importing a best interest requirement into the common law mature minor rule. Notably, Abella J. concludes that “...while courts have readily embraced the concept of granting adolescents a degree of autonomy that is reflective of their evolving maturity, they have generally not seen the “mature minor” doctrine as dictating guaranteed outcomes, particularly where the consequences for the young person are catastrophic.”⁹¹ It is also noted that “[w]here a child’s decisional capacity to refuse treatment has been upheld, on the other hand, it has been because the court has accepted that the mature child’s wishes have been consistent with his or her best interests.”⁹² These comments, however, miss the mark. The reason for this failing is that, under the heading “Common Law for Minors”, Abella J. claims to discuss the rule at common law but in fact reviews cases in which the applicable legislation requires the minor’s best interest to be considered in all two cases.

The discussion in this section of this chapter begins with a review of the jurisprudence referred to by the majority in its discussion of the common law mature minor rule. Focus then shifts to how the rule is characterized by the majority after the erroneous reasoning is teased out. The latter subsection includes support for my position that the welfare principle does not apply to circumstances arising under the common law. The last subsection of this section briefly describes the court’s *parens patriae*

⁹⁰ Manitoba Law Reform Commission, *supra* note 79.

⁹¹ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 69.

⁹² *Ibid.* at para. 62.

jurisdiction. Although the latter jurisdiction is not discussed in *A.C. v. Manitoba (Director of Child and Family Services)* it nonetheless forms part of the complete ‘picture’ of the common law landscape.

(1) *The Supreme Court of Canada’s Flawed Review of the Jurisprudence*

In the discussion of the common law as it applies to minors, the majority makes reference to ten earlier Canadian decisions involving the right of minors to refuse medical treatment. In doing so, however, Abella J. ignores the fact that the determination as to whether the minor’s refusal of treatment would be respected was only based on the common law mature minor rule in two of these cases. The determination in all eight other cases referred to by Abella J. was rooted in legislative provisions that mandated that the minor’s best interests be considered. In light of this criticism, it is appropriate to describe in some detail each of the cases relied upon by the majority.

The first case referred to by Abella J., that being *C.(J.S.) v. Wren*⁹³, is the only case not involving legislative interpretation. That case involved a girl aged 16 years and 8 months wanting to have a therapeutic abortion against her parents’ wishes. The girl obtained approval from both her physician and from the therapeutic abortion committee. Her parents then sought an injunction prohibiting the defendant physician from performing the abortion. Ultimately the Alberta Court of Appeal found that she had “sufficient intelligence and understanding to make up her own mind and did so.”⁹⁴ The decision makes no mention of best interests.

⁹³ (1986), 76 A.R. 118 (Q.B.), aff’d (1986), 76 A.R. 115 (C.A.).

⁹⁴ *Ibid.* at para. 16.

The second case referred to by Abella J. is *Van Mol (Guardian ad litem of) v. Ashmore*⁹⁵, involved legislative interpretation of the *Infants Act*⁹⁶, as it then read, which partly preserved the common law mature minor rule.⁹⁷ In that case, Melanie Van Mol required a third surgery to repair a congenital heart defect. The first two surgeries had been done when she was two and six years old while the third was to be done when she was sixteen years and three months old. As a result of complications that arose during the third surgery, she was left confined to a wheelchair. At no time was Melanie's capacity at issue. Rather, the debate revolved around what limits are imposed on her decision-making capacity as a mature minor and the role of her parents in making medical treatment decisions. In a split decision, a two-judge majority of the British Columbia Court of Appeal found that Melanie was a mature minor and as such, was the only person who could consent to the surgery. In discussing the implications of being a mature minor at common law, Lambert J.A. on behalf of the majority commented:

...once the required capacity to consent has been achieved by the young person reaching sufficient maturity, intelligence and capability of understanding, the discussions about the nature of the treatment, its gravity, the material risks and any special or unusual risks, and the decisions about undergoing treatment, and about the form of the treatment, must all take place with and be made by the young person whose bodily integrity is to be invaded and whose life and health will be affected by the outcome. At that stage, the parent or guardian will no longer have any overriding right to give or withhold consent. All rights in relation

⁹⁵ 1999 BCCA 6, 168 D.L.R. (4th) 637 [cited to D.L.R.].

⁹⁶ R.S.B.C. 1979, c. 196.

⁹⁷ Under section 16(4) of the *Infants Act*, *ibid.*, the consent of all minors sixteen years of age or older was given the same weight as the consent of persons over the age of majority, where either parental consent or a written opinion from a physician stating that the "treatment or procedure to be undertaken is in the best interest of the continued health and well being of the infant" was obtained. Despite these requirements which render the mature minor's decision non-binding, section 16(5) of the Act preserved the common law mature minor rule. As such, based on the latter provision, the Court was free to apply the test at common law, which clearly constrained the rights of mature minors to a lesser degree. After the British Columbia Court of Appeal rendered its decision, the relevant provisions of the *Infants Act* were revised in 1992 and again in 1996.

to giving or withholding consent will then be held entirely by the child. The role of the parent or guardian is as advisor or friend. There is no room for conflicting decisions between a young person who has achieved consenting capacity, on the one hand, and a parent or guardian on the other.⁹⁸

The majority then went on to find that the surgeon failed to disclose relevant risks to Melanie.⁹⁹

The third case referred to by Abella J. is *H.(T.) v. Children's Aid Society of Metropolitan Toronto*¹⁰⁰. As noted by Abella J., it involved a 13-year-old suffering from aplastic anaemia and her mother, both of whom refused to consent to treatment involving blood products. This refusal resulted in the minor being made a temporary ward of the state under the *Child and Family Services Act*¹⁰¹. This means that the minor's capacity was evaluated in the child protection context and not strictly based on the common law mature minor rule.

The fourth case referred to by Abella J is *D.(T.T.), Re*¹⁰², which involved an application brought by the Minister of Social Services pursuant to Saskatchewan's *Child and Family Services Act*¹⁰³ to determine if the earlier nine month supervisory order that had been granted to the Minister ought to be terminated or varied. That order had been issued when T.T.D. began receiving chemotherapy to treat osteosarcoma and his parents refused to consent to the treatment. After receiving two courses of chemotherapy, T.T.D., who was thirteen years old at the time, indicated to the pediatric oncologist

⁹⁸ *Van Mol (Guardian ad litem of) v. Ashmore*, *supra* note 95 at para. 75.

⁹⁹ *Ibid.* See the discussion under subsection IV(B)(i) for further comment on the relevant provisions of the *Infants Act*, *supra* note 29.

¹⁰⁰ (1996) 138 D.L.R. (4th) 144 (Ont. Ct. (Gen. Div.)).

¹⁰¹ R.S.O. 1990, c. C.11 [*Child and Family Services Act* (Ontario)].

¹⁰² (1999), 171 D.L.R. (4th) 761 (Sask. Q.B.). The majority refers to this decision as *Dueck (Re)* but all other references to this case I have found use the style of cause *D.(T.T.), Re* and so the latter has been used throughout this thesis.

¹⁰³ S.S. 1989-90, c. C-7.2 [*Child and Family Services Act* (Saskatchewan)].

treating him that he did not want any further chemotherapy and that he did not want to have surgery. This refusal of further treatment was found to be based, in part, on T.T.D.'s belief that he had been healed by God.¹⁰⁴ The court ultimately determined that T.T.D. was not a mature minor. The bases for this finding included a psychologist's conclusion that T.T.D. was "less mature than average thirteen year old children in Saskatchewan", as well as that his father set all the rules for the family and had provided T.T.D. with misleading information about the success of alternative treatment.¹⁰⁵ It was further ordered that all treatment be administered in the absence of his parents on the basis that such action was in the boy's best interests.¹⁰⁶

The fifth case referred to by Abella J. is *H.(B.) v. Alberta (Director of Child Welfare)*¹⁰⁷. In that case, the Director of Child Welfare sought an apprehension and medical treatment order under the *Child Welfare Act*¹⁰⁸. It is in that context that Jordan J. of the Provincial Court determined that Bethany Hughes was not a mature minor, irrespective of the opinions of her treating physicians. She went on to find, however, that even if Bethany had been found to be a mature minor, the *Child Welfare Act* treats all children under the age of eighteen the same; it overrides any rights mature minors held at common law. Jordan J. also firmly asserts that parents have not only a right but a "duty to make decisions affecting the child" so long as those decisions are made in the minor's best interests. After all, she states that "it would be a difficult day for parents and guardians if their sixteen year-olds had an unfettered right to make every decision

¹⁰⁴ *D.(T.T.), Re, supra* note 102.

¹⁰⁵ *Ibid.* at paras. 9-10.

¹⁰⁶ *Ibid.* at para. 16.

¹⁰⁷ 2002 ABPC 39, [2002] 11 W.W.R. 752 at para. 62, aff'd 2002 ABQB 371, 3 Alta. L.R. (4th) 16, aff'd 2002 ABCA 109, [2002] 7 W.W.R. 644 [*H.(B.) v. Alberta (Director of Child Welfare) No. 1* cited to W.W.R.].

¹⁰⁸ R.S.A. 2002, c. C-12.

affecting them...”¹⁰⁹ On appeal, the Alberta Court of Queen’s Bench accepted the alternative position put forth by Jordan J., that being that Bethany was a mature minor at common law but that this status was altered by statute. The Alberta Court of Appeal dismissed the appeal on the basis that Bethany was not a mature minor at the time the decision was to be made.¹¹⁰ Neither the Court of Queen’s Bench nor the Court of Appeal commented on Jordan J.’s characterization of the rights of parents.

The sixth case referred to by Abella J. is the Quebec Superior Court’s decision in *Hôpital Ste-Justine v. Giron*¹¹¹. There, Ste-Justine Hospital sought court authorization to administer blood transfusions against the fifteen-year-old minor’s wishes. Such authorization was required under the applicable articles of the *Civil Code of Quebec*¹¹². Emanating out of Quebec, this is clearly not a case applying the common law mature minor rule.

The seventh case referred to by Abella J. is *U.(C.)(Friend of) v. McGonigle*¹¹³, where an apprehension order was sought under Alberta’s *Child Welfare Act*¹¹⁴ after the sixteen and a half year old minor refused to consent to the administration of blood transfusions, should such transfusions become necessary during a surgery to control dysfunctional menstrual bleeding. C.U.’s decision was supported by her parents, all of whom were Jehovah’s Witnesses. The Provincial Court Judge granted the treatment order, a decision which was upheld by the Alberta Court of Queen’s Bench.¹¹⁵ As was the case with A.C., C.U. had already received blood transfusions by the time the case

¹⁰⁹ *H.(B.) v. Alberta (Director of Child Welfare) No. 1*, *supra* note 107 at para. 52.

¹¹⁰ *Ibid.* at paras. 11-13.

¹¹¹ 2002 CanLII 34269 (Qc. C.S.).

¹¹² S.Q. 1991, c. 64.

¹¹³ 2003 ABCA 66, 223 D.L.R. (4th) 662 (C.A.) [cited to D.L.R.].

¹¹⁴ S.A. 1984, c. C-8.1. This Act has since been repealed and replaced with the *Child Welfare Act*, *supra* note 108, which is discussed in greater detail under section IV(C) below.

¹¹⁵ *U.(C.)(Friend of) v. McGonigle*, *supra* note 113 at paras. 6-9.

reached the Court of Appeal but the case was heard so that it could serve as a precedent in subsequent cases. The latter court was clear that in child protection proceedings in Alberta “a mature minor’s wishes respecting medical treatment will not be dispositive of the issue, but rather will be one factor to be considered in determination of their best interests.”¹¹⁶ The Court of Appeal explicitly stated at paragraph 4:

...mature minor rule does not apply in child welfare proceedings in which a child refuses to consent to essential treatment recommended by a physician. While the court must consider the expressed wishes of a mature child, it is not bound to comply with those wishes. Instead, the best interests of the child govern.¹¹⁷

The eighth case referred to by Abella J. is *K. (L.D.), Re*¹¹⁸, an action in which a twelve year old refused to consent to chemotherapy that would require blood transfusions. She refused for religious reasons as well as because she did not want to experience the pain related to such treatment. In the face of this refusal, the Children’s Aid Society brought an application seeking an order that the child was in need of protection, as defined under the *Child Welfare Act*¹¹⁹. The application was dismissed by Main Prov. Ct. J. on the basis that “proper” medical treatment had not been refused. Specifically, the mega-vitamin treatment proposed by L.D.K. and her parents was “proper” because it allowed L.D.K. to try to overcome her illness with dignity.¹²⁰ Undoubtedly, the fact that the chemotherapy proposed by specialist physicians only had a thirty percent change of success and had many severe side effects played into the balancing by the court.

¹¹⁶ *Ibid.* at para. 39.

¹¹⁷ *Ibid.* at para. 4.

¹¹⁸ 1985 CarswellOnt 318, 48 R.F.L. (2d) 164, 23 C.R.R. 337.

¹¹⁹ R.S.O. 1980, c. 66. Note that this statute has been repealed. In its place, there is now the *Child and Family Services Act* (Ontario), *supra* note 101.

¹²⁰ *Supra* note 118 at para. 34.

The ninth case referred to by Abella J. is *Y. (A.), Re*¹²¹. There, the Director of Child Welfare sought an order finding the fifteen year old minor involved in the action to be a child in need of protection and an order authorizing blood transfusions. A.Y., a Jehovah's Witness, consented to intensive chemotherapy but refused to consent to blood transfusions that may become necessary. Contrary to what Abella J. indicated in her reasons at paragraph 63, his treating physician was not of the view that he "required blood transfusions". Rather, his physician's view was that blood transfusions were often required by individuals receiving intensive therapy but that there were other options. The physician himself was also unwilling to administer blood transfusions against A.Y.'s wishes. Ultimately Wells J. held that A.Y. was not in need of protection because blood transfusions were not "essential". A.Y. was also found to be a mature minor. However, the decision provides little detail as to what criteria were considered in making that determination. That being said, Wells J. does state that "it is proper under the Act, and in law generally, for me to take into consideration his wishes".¹²² He then goes on to look at what course of action is in A.Y.'s best interests. As was the case in the other decisions outlined above, the decision in this case was based on the provisions of the applicable child protection statute, not on the common law mature minor rule.

Lastly, in *Walker (Litigation Guardian of) v. Region 2 Hospital Corp*¹²³, Joshua, a fifteen year old Jehovah's witness, refused to consent to blood transfusions should such transfusions become a necessary component of his treatment for acute myeloid leukemia. The Court of Appeal was called upon to review the lower court's interpretation of the interaction between the common law mature minor rule and the provisions of the *Medical*

¹²¹ (1993), 111 Nfld. & P.E.I.R. 91.

¹²² *Ibid.* at para. 34.

¹²³ (1994), 150 N.B.R. (2d) 366, 116 D.L.R. (4th) 477 (C.A.) [cited to N.B.R.].

Consent of Minors Act. In his reasons on behalf of the majority, Hoyt, C.J.N.B. remarked:

At common law, when a minor is mature, no parental consent is required. As noted, New Brunswick has codified the common law to the extent that it is expressed in the **Medical Consent of Minors Act**.

...

In New Brunswick, the **Act** makes provision for permitting mature minors to make decisions about their medical treatment. By s.3(1)(b), the common law right to self-determination by a person under 16 years of age is modified so that, in addition to the informed consent of the mature minor, there must also be opinions from two medically qualified practitioners that the minor is capable of understanding the nature and consequences of the treatment and that such treatment is in the best interests of the minor and his continuing health and well-being. In the event there are changes proposed to the treatment, a further consent may be required.¹²⁴ [Emphasis in original]

In sum then, the majority's review of the jurisprudence consists of referring to only two cases that were decided on the basis of the common law mature minor rule. Neither one of these cases considered what action was in the minor's best interests. Six other cases involved child protection statutes which require that the minor's best interests be considered while another case involved consent to treatment legislation that had altered the rule at common law. Finally, the last case discussed by Abella J. was decided under the civil law of Quebec.

(2) *The Common Law Mature Minor Rule: Post-A.C. v. Manitoba (Director of Child and Family Services)*

The essence of what remains to be considered in terms of the common law mature minor rule can be boiled down to what a minor needs to prove to establish that she has

¹²⁴ *Ibid.* at 14-16.

capacity and what beyond capacity is required for her medical treatment decisions to be respected. Each of these two issues is considered in turn below, with the latter subdivided into an examination of the welfare principle and *parens patriae* jurisdiction.

(a) The Common Law Mature Minor Rule Generally

The mature minor rule allows minors to make their own medical treatment decisions where they have “sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not.”¹²⁵ As discussed further below, it has been suggested that the welfare principle also forms part of the rule. For reasons set out in the following subsection, I disagree. Formulated in this manner, the mature minor rule essentially requires a minor to demonstrate that she has ‘capacity’. So, what is capacity?

Prior to deciding *A.C. v. Manitoba (Director of Child and Family Services)*, the Supreme Court of Canada had had the occasion to define the term in 2003 in *Starson v. Swayze*¹²⁶. There, capacity was said to be:

Capacity involves two criteria. First, a person must be able to understand the information that is relevant to making a treatment decision. This requires the cognitive ability to process, retain and understand the relevant information. ...Second, a person must be able to appreciate the reasonably foreseeable consequences of the decision or lack of one. This requires the patient to be able to apply the relevant information to his or her circumstances, and to be able to weigh the foreseeable risks and benefits of a decision or lack thereof.¹²⁷

Admittedly, *Starson v. Swayze* did not involve a minor. The concept has, however, been recently described by LeBlanc J. in *P.H. v. Eastern Regional Integrated Health*

¹²⁵ Gilmour, “Children”, *supra* note 89.

¹²⁶ 2003 SCC 32, [2003] 1 S.C.R. 722 [cited to S.C.R.].

¹²⁷ *Ibid.* at para. 78.

*Authority*¹²⁸, a case involving a sixteen year old who refused mental health treatment that was heard and decided after the Supreme Court of Canada handed down its decision in *A.C. v. Manitoba (Director of Child and Family Services)*. There, it was stated:

With regard to the first component of the test of competency stated above, the cognitive ability to process and retain relevant information must be present in determining whether a person understands information relevant to making a treatment decision. The person need not understand technical descriptions of their illness or issues, nor does the person have to agree with the specific diagnosis made of that condition but must be capable of recognizing that he or she is affected by an illness or condition.

For the second component of the test – being able to appreciate the reasonably foreseeable consequences of the treatment decision or lack of one, the person must have the ability to appreciate the consequences of the decision to be made. The person does not have to actually appreciate these consequences.¹²⁹

Precisely how a minor goes about demonstrating that she has the requisite capacity is not discussed by the majority in *A.C. v. Manitoba (Director of Child and Family Services)* under the heading “Common Law for Minors”. This omission is likely due to the fact that A.C. was assumed to be competent. That being said, some insight into the factors to be considered can be gleaned from the criteria to be weighed when carrying out a maturity assessment to determine a minor’s best interests. Discussion of each of those criteria is set out in a subsequent section below.

It nonetheless seems appropriate at this juncture to comment briefly on why the maturity assessment, as described by Abella J., should not be carried out on each minor. The maturity assessment should not be conflated with a capacity assessment; only the latter applies to all minors, whatever the context (i.e. at common law or based on child

¹²⁸ 2010 NLTD 34.

¹²⁹ *Ibid.* at paras. 38-39.

protection or consent to treatment legislation). The assessment of a minor's maturity is used to determine a minor's best interests and so is an additional requirement. Stated differently, the 'result' of a maturity assessment is not intended to tell a physician (or a judge) whether the minor is competent. Rather, it is meant to shed some light on whether respecting a minor's medical treatment decision is in her best interest.

This distinction between the required capacity assessment and the maturity assessment is aptly seen in the decision of LeBlanc J. of the Trial Division of Newfoundland and Labrador's Supreme Court in *P.H. v. Eastern Regional Integrated Health Authority*. The issue in that case was whether sixteen year old S.J.L. was competent to make her own mental health treatment decisions. At the time of the hearing, S.J.L. was detained by court order at Waterford Hospital, a hospital for adult inpatient psychiatric care. Without detailing her psychiatric history, it is sufficient to note that she had a history of self-harming behaviour and was suspected to have Borderline Personality Disorder. For purposes of this discussion, it is significant to note that unlike *A.C. v. Manitoba (Director of Child and Family Services)*, this was not a child protection case.

In deciding the case, LeBlanc J. considered testimony and reports from four psychiatrists (two of whom were treating physicians and the other two prepared reports at the Court's request) and one treating psychologist. These experts reached different conclusions as to whether S.J.L. was legally competent. As well, S.J.L. filed an affidavit and met briefly with LeBlanc J. Lastly, P.H., S.J.L.'s mother testified at the hearing.¹³⁰

¹³⁰ S.J.L. was presumed competent under section of the *Advance Health Care Directives Act*, S.N.L. 1995, c. A-4.1.

LeBlanc J. found that it is necessary to first consider if S.J.L. is legally competent, based on the test from *Starson v. Swayze*.¹³¹ On the evidence, he held that the presumption of capacity with respect to S.J.L.’s ability to understand the information relevant to a treatment decision is not rebutted. This conclusion was consistent with the finding of legal competence by one of S.J.L.’s treating psychiatrist and went against the finding of incompetence by the two psychiatrists retained by the Court. However, LeBlanc J. then found that S.J.L. did not appreciate the consequences of her treatment decisions or lack thereof. The presumption that S.J.L. was competent had consequently been rebutted on the balance of probabilities.¹³²

LeBlanc J. then found that whether or not the presumption of capacity was rebutted, the court “in the exercise of its *parens patriae* jurisdiction should go further and consider the young person’s level of maturity in determining whether it will force treatment in the face of the right of autonomous decision-making given to such a person”¹³³. Despite the Supreme Court of Canada not stating whether best interests could be considered where minors are over the age of sixteen and where there is no best interest requirement under the applicable statute, LeBlanc J. held that a “sliding scale application

¹³¹ It is worth noting that despite claiming to carry out an examination of how adults and minors are treated at common law with respect to consent to medical treatment, Abella J.’s majority reasons in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, do not even mention the *Starson v. Swayze*, *supra* note 126, decision. Although this omission can be partially attributed to the fact that A.C.’s capacity was not at issue, in my view the test for capacity is still a necessary part of any discussion on the common law right to consent to treatment and consequently ought to have been included in Abella J.’s reasons (as it was by Binnie J. at para. 194).

¹³² *P.H. v. Eastern Regional Integrated Health Authority*, *supra* note 128 at paras. 83-91. Note that throughout the application of the test to S.J.L., LeBlanc J. is considering her ability to make medical treatment decisions generally, which goes against the notion that competence is time and situation specific. Based on LeBlanc J.’s order that counsel return with suggestions of treatment options so that His Lordship can determine what treatment is in S.J.L.’s best interest, it is clear that there had not even been a treatment plan proposed at the time of the capacity assessment.

¹³³ *Ibid.* at para. 52.

of the best interest standard”¹³⁴ is to be applied to all minors.¹³⁵ Although the decision is not explicit on this point, I would suggest that in using the phrase “all minors”, LeBlanc J. really means “all minors where the preservation of life is at stake”.¹³⁶ LeBlanc J. then went on to cite the list of factors that, according to Abella J., could be considered when assessing the maturity of an adolescent. There is no discussion included in LeBlanc J.’s reasons as to how any of these factors apply to S.J.L. Rather, LeBlanc J. essentially concluded that S.J.L. was not mature enough to make her own treatment decisions.¹³⁷

Ultimately then, the first reported decision after *A.C. v. Manitoba (Director of Child and Family Services)* sets out to expand the “very limited class of cases”¹³⁸ where a minor’s wishes must accord with her best interests to be upheld. It remains to be seen if this is merely a one-off flawed application of the Supreme Court of Canada’s reasons.

¹³⁴ *Ibid.* at para. 51.

¹³⁵ *Ibid.* at para. 45.

¹³⁶ Support for this position is derived from comments made by LeBlanc J., *ibid.* at paras. 45, 92. Specifically, LeBlanc J. stated:

[45] It is with all of this in mind that I must proceed to assess the evidence before me as to the competency of S.J.L. Before doing so, however, due to her age and level of maturity, I find it necessary to refer to what I consider is another aspect of the decision that I must make in this case, that being the application of the best interest standard. It is my opinion that the best interest standard should have application, where the treatment decision is related to the preserving of life of a person who is not legislatively recognized as an “adult”. I am of the opinion that the best interest standard must be applied in line with the level of maturity had by the individual involved as well as the independence of their judgment. My reason for concluding that this is a proper consideration is based upon the rationale used by the Supreme Court of Canada’s majority decision in **A.C. v. Manitoba (Director of Child and Family Services)**.

...

[92] A consideration of best interests here will have two aspects. First of all, as I indicated earlier in reference to the law, I am satisfied that even if I were to have found S.J.L. met the legal competency test set out in **Starson**, consideration of the best interests standard based on her level of maturity on a sliding scale as referred to earlier would still be necessary here. Clearly in this case a decision by S.J.L. to refuse to seek treatment for her mental condition would likely result in further increasingly serious self-harming acts. I am satisfied that death or serious bodily harm would result, either intentionally or accidentally. The evidence I have heard, including what S.J.L. has said, supports this. [Emphasis in original]

¹³⁷ *Ibid.* at paras. 92-94.

¹³⁸ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 86.

LeBlanc J.'s reasons in *P.H. v. Eastern Regional Integrated Health Authority* also provide no guidance as to how the maturity assessment proposed by Abella J. ought to be applied.

(b) The Welfare Principle

The welfare principle is the notion whereby minors can only consent to treatment that is perceived by others as being in their best interest.¹³⁹ It has been described by Joan M. Gilmour as follows:

While a mature minor can consent to medically recommended treatment, the extent to which he or she has the power to consent to a treatment that is not beneficial or therapeutic remains unclear. The argument that a minor can only consent to care that would be of benefit (or refuse that which is of little or no benefit) is sometimes referred to as “the welfare principle”. It suggests that a mature minor can only make those decisions about medical care that others would consider to be in his or her interests; as such, it challenges the extent of the commitment in law to mature minors’ interests in self-determination and autonomy. . . .

. . . [The welfare principle] reflects an uneasiness with autonomy as the overriding value that the law advances in this context, rather than protection of the minor’s life and health as one who is still vulnerable.¹⁴⁰

As noted above, the majority does not explicitly endorse or reject the inclusion of the welfare principle into the common law mature minor rule. Given this lack of clear pronouncement from the Supreme Court of Canada, a discussion of the mature minor rule would not be complete without considering whether such rule includes a best interest requirement or not. My view is that it does not include a best interest requirement. There are three principal reasons why I have adopted this position, all of which are consistent with the majority’s reasoning.

¹³⁹ Manitoba Law Reform Commission, *supra* note 79.

¹⁴⁰ Joan M. Gilmour, “Death and Dying”, in Mary Jane Dykeman et al., eds., *Canadian Health Law Practice Manual*, looseleaf (Toronto: Butterworths, 2008) 8.01 at ss. 8.52, 8.54.

Firstly, the Court unanimously holds that some but not all children are in need of protection. None of the Justices require that all minors, who are all captured under the definition of “child” set out in s.1(1) of the *Child and Family Services Act* be liable to have their medical treatment decisions overridden when their decision is seen as being against their best interests. The difference between the majority and minority on the one hand and the dissent on the other is precisely who those “some” children are. For the majority and minority, any minor under the age of sixteen who requires medical treatment to protect her life and where such treatment is in the minor’s best interest and is necessary to protect her life is in need of protection.¹⁴¹ This position is consistent with the protection is afforded under section 25(8) of the *Child and Family Services Act*. The dissent, in turn, only finds that minors who are not mature minors are in need of protection.¹⁴²

Secondly, the court and the appropriate provincial or territorial government department retain the ability to override the medical treatment decisions of a minor when her refusal will endanger her life or health without the need to subject all minors to a best interest requirement. That recourse is through child protection proceedings because when a minor refuses such treatment, child protection legislation generally applies. The only circumstance in which it would not apply is if the specific child protection statute did not require that the minor’s best interest be considered, as is the case for minors over the age of sixteen in Manitoba. Beyond being found to be constitutional by the majority and

¹⁴¹ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para 86.

¹⁴² *Ibid.* at paras 176, 209-210. As well, Binnie J. cites the British Columbia Court of Appeal’s decision in *Van Mol (Guardian ad Litem of) v. Ashmore*, *supra* note 95 at 75 for the proposition that at common law, once a minor has been found to have the requisite capacity to consent, “the decision about undergoing treatment, and about the form of treatment, must all take place with and be made by the young person whose bodily integrity is to be invaded and whose life and health will be affected by the outcome”.

minority, such an approach is also supported by the majority's view that medical treatment decisions are not all created equal. Specifically, support for the proposition that the welfare principle does not apply unless the minor's life or health is in danger can also be found in the majority's reasons. Notably, Abella J. states at paragraphs 85 and 86:

In the vast majority of situations where the medical treatment of a minor is at issue, his or her life or health will not be gravely endangered by the outcome of any particular treatment decision. That is why courts have determined that medical practitioners should generally be free to rely on the instructions of a young person who seems to demonstrate sufficient maturity to direct the course of his or her medical care.¹⁴³

Where a young person comes before the court under s. 25 of the *Child and Family Services Act*, on the other hand, it means that child protective services have concluded that medical treatment is necessary to protect his or her life or health, and either the child or the child's parents have refused to consent. In this very limited class of cases, it is the ineffability inherent in the concept of "maturity" that justifies the state's retaining an overarching power to determine whether allowing the child to exercise his or her autonomy in a given situation actually accords with his or her best interests. The degree of scrutiny will inevitably be most intense in cases where a treatment decision is likely to seriously endanger a child's life or health.¹⁴⁴

Thirdly, the assessment of maturity is subjective and imprecise. Abella J. herself acknowledges this difficulty:

I acknowledge that because we are dealing with the inherent imprecision of childhood and adolescent development, maturity is necessarily an imprecise standard. There is no judicial divining rod that leads to a "eureka" moment for its discovery; it depends on the court's assessment of the adolescent, his or her circumstances and ability to exercise independent judgment, and the nature and consequences of the decision at issue. But I am

¹⁴³ *A.C. v. Manitoba (Director of Child and Family Services)*, *ibid.* at para. 85. Note the use of "rely on the instructions of", thereby suggesting that mature minors have the right, at common law, to consent or refuse medical treatment.

¹⁴⁴ *Ibid.* at para. 86.

nonetheless strongly of the view that in order to respect an adolescent's evolving right to autonomous medical decision making, a thorough assessment of maturity, however difficult, is required in determining his or her best interests.¹⁴⁵

Given this difficulty, it seems rather nonsensical to impose a best interest requirement to protect minors who have not been shown to be in need of any protection.

For these three reasons, I see no good reason why the welfare principle should be incorporated into the common law mature minor rule. For similar reasons, I see no room for the welfare principle in the expansion of the common law mature minor rule to research involving minors. More specifically, much like not all minors eligible to make medical treatment decisions are in need of protection, not all minors whose participation in a research study is sought require protection. Research covers a broad spectrum of activities, some of which carry little risk while others involve greater risks. Although there are no statistics available, I would suspect that relative to the total number of studies conducted on minors, participation is only rarely required to protect the life of a minor. This is because prior to getting to that point, a minor would generally have had to exhaust all proven treatments. Furthermore, even where proven treatments had not been tried or found to be inferior, the researcher would have to think that participation in the study was an acceptable course of action before even proposing it to the minor.

As well, mature minors already have the right to decline research participation.¹⁴⁶

This means that even where the research activities are captured under the definition of "treatment", they cannot ethically be imposed on a minor. Admittedly, the resolve to

¹⁴⁵ *Ibid.* at para. 4. Note that the majority uses "maturity" as a measure of competence in some instances (as seen at para. 86) and, as seen in this paragraph, as a means of determining an individual's best interest elsewhere. Based on the criteria included in the majority's 'maturity assessment', it seems that the latter characterization is more consistent with the majority's overall reasoning.

¹⁴⁶ *Tri-Council Policy Statement, supra* note 1 at art. 3.10.

uphold this ethical standard has not yet been tested in the courts. It is consequently possible that a court would override a minor's refusal to participate where the activities at issue could be brought under ambit of the applicable child protection statute.

It is also worth noting that the justification for the welfare principle appears to be largely based on the need to protect minors from improvident decisions. In the case of research, I suggest that less rights-limiting protective measures are more appropriate than denying a mature minor her autonomy. Such measures include the duty of researchers and research ethics board to ensure ethically sound recruitment practices and, as discussed in greater detail in Chapter 4, ensuring that the means of communication used are appropriate. Many of these alternatives also apply in the treatment context, which further strengthens the argument for treating minors in these two spheres in a similar fashion.

Prior to concluding my discussion of the welfare principle, it is necessary to respond to the possible argument that the research context ought to be treated more akin to the child protection context than to the treatment context because the minor is exposing herself to risks for little or no benefit in at least some instances. My response to this is quite simple: exposure to some risk is not the same as putting one's life in jeopardy or exposing oneself to severe harm. As discussed in Chapter two, clinical trials are only conducted on minors once some safety data has already been accumulated, unless the condition cannot be studied in an older population. Furthermore, if participating in a particular research study does include the possibility of death, the mere fact that participation is proposed as an alternative means that, as noted above, the minor has exhausted proven treatment.

(c) The *Parens Patriae* Jurisdiction

In finding that when a mature minor is less than sixteen, her treatment decision is not determinative but rather only part of a “best interest” analysis, the majority and minority recognize the courts’ *parens patriae* jurisdiction, which vests the court with the “discretion is to do what is necessary for the protection of the person for whose benefit it is exercised”¹⁴⁷. Stated differently, by leaving the determination of the mature minor’s best interests to the judge hearing the case (rather than to the minor or her parents), the discretion to override the minor’s decision remains with the court. Conversely, had Binnie J.’s view that in order to be constitutional, mature minors had to be able to rebut the presumption of incapacity and be permitted to consent to and refuse all medical treatment, courts would have relinquished their *parens patriae* jurisdiction with respect to treatment decisions made by mature minors. In my view and as explained more fully below, the latter would have been more consistent with the *raison d’être* of the *parens patriae* jurisdiction – that being the protection of those who need protection.¹⁴⁸

Before carrying out a more probing examination into the *parens patriae* jurisdiction than that provided to us by either the majority or minority, it is necessary to comment a little further on how the majority and minority apply the *parens patriae* jurisdiction. Much like the welfare principle, the majority and minority focus little attention on how the jurisdiction has been applied by Canadian courts before they use it to justify, as the majority describes it, the “sliding scale of scrutiny”¹⁴⁹ with respect to the decision-making of minors under the age of sixteen. The majority does, however, note

¹⁴⁷ *E. (Mrs.) v. Eve*, [1986] 2 S.C.R. 388 at para. 77.

¹⁴⁸ *Ibid.* at para. 73. Although being unable to care for oneself encompasses more than an individual’s capacity, for purposes of the present discussion, my comments are directed at a lack of capacity.

¹⁴⁹ *Supra* note 65 at para. 22.

that in the United Kingdom as well as in Australia, courts have relied on the *parens patriae* jurisdiction to override medical treatment decision of a mature minor where such treatment is in the mature minor's best interest.¹⁵⁰

How did the Supreme Court of Canada define and apply the *parens patriae* jurisdiction in earlier cases? The Court first commented on it in the 1986 seminal case of *E. (Mrs.) v. Eve*, where it stated that the *parens patriae* jurisdiction is "founded on necessity, namely the need to act for the protection of those who cannot care for themselves".¹⁵¹ The constraints on the applicability of the jurisdiction were then made more explicit by the Ontario Court of Appeal in the subsequent case of *Fleming v. Reid*¹⁵², where Robins J.A. made the following remarks:

The *parens patriae* jurisdiction was intended to operate only where a person is unable to take care of himself or herself. It cannot be exercised by the state to overrule a treatment decision made by a competent patient, who, by definition, is able to direct the course of his or her medical care, regardless of the fact that the decision may be considered by objective standards, medically unsound or contrary to the patient's best interest.¹⁵³

Following this line of reasoning, the majority of the New Brunswick Court of Appeal in *Walker (Litigation Guardian of) v. Region 2 Hospital Corp.* held that the *parens patriae* jurisdiction of the court could not be used to override the refusal of blood transfusions by a fifteen year old boy suffering from acute myeloid leukemia. The main thrust of Chief Justice Hoyt's reasons was that the *parens patriae* jurisdiction of the court did not apply in the case of mature minors. Without ruling out unequivocally that the

¹⁵⁰ *Ibid.* at paras. 56, 68.

¹⁵¹ *Supra* note 147 at para. 73. Although being unable to care for oneself encompasses more than an individual's capacity, for purposes of the present discussion, my comments are directed at a lack of capacity.

¹⁵² (1991), 82 D.L.R. (4th) 298 (Ont. C.A.).

¹⁵³ *Ibid.* at 315-316.

parens patriae jurisdiction may have some application to those under the age of sixteen, the Chief Justice asserted that sections 2 and 4 of the *Medical Consent of Minors Act* in New Brunswick specifically excluded the application of the court's inherent jurisdiction to those between sixteen and nineteen years of age.¹⁵⁴ In his concurring reasons, Angers J.A. agreed with the majority that section 2 of the *Medical Consent of Minors Act* extinguished the supervisory role of both parents and the court for minors who were sixteen years of age or older.¹⁵⁵

However, in a separate set of reasons concurring in result, Ryan J.A. reasoned that since the *Medical Consent of Minors Act* only refers to "consent to treatment" it does not grant mature minors the right to refuse life-sustaining treatment. As well, he also expressed a willingness to impose limits on the respect to human dignity owed to mature minors. Specifically, despite labelling this respect as a principal of fundamental justice, it was his opinion that the State retained a right to intervene where the withholding of treatment will likely result in the "underage" patient's death.¹⁵⁶ This contention implies that the court can use its *parens patriae* jurisdiction where an individual under the age of majority, whether a mature minor or not, refuses life-sustaining treatment. Since the boy in the present case's refusal of blood transfusions was not likely to lead to his death, the *parens patriae* jurisdiction was not applicable on the facts of that particular case.

The British Columbia Court of Appeal, however, reached the opposite conclusion. In *Van Mol (Guardian ad Litem of) v. Ashmore*, Huddart J.A. in his concurring reasons commented that "in the case of a person under 19 years of age in British Columbia, the

¹⁵⁴ *Walker (Litigation Guardian of) v. Region 2 Hospital Corp*, *supra* note 123 at para. 27.

¹⁵⁵ *Ibid.* at para. 36.

¹⁵⁶ *Ibid.* at paras. 59-62.

ultimate resort is to the *parens patriae* jurisdiction of the Supreme Court.”¹⁵⁷ However, no reasons were given for this holding. As well, the majority judgment delivered by Lambert J.A. in that case does not so much as mention the *parens patriae* jurisdiction.

Despite the lack of justification provided by Huddart J.A. or the fact that the New Brunswick Court of Appeal’s decision was based on statutory language, the Court of Queen’s Bench in *H.(B.) v. Alberta (Director of Child Welfare)*¹⁵⁸ stated that opposite conclusions had been reached by the appellate courts of New Brunswick and British Columbia with regards to the applicability of the *parens patriae* jurisdiction. However, after noting these differing opinions, Kent J. declined the opportunity to add to the debate and did not express an opinion on the matter.¹⁵⁹

With the release of its decision in *A.C. v. Manitoba (Director of Child and Family Services)*, the Supreme Court of Canada has made it clear that the *parens patriae* jurisdiction can be used to restrict the right of a mature minor to refuse medical treatment in child protection matters. What is less certain is whether courts can use this jurisdiction to override a mature minor’s decision outside the child protection context.

Contrary to the conclusion reached by LeBlanc J. in *P.H. v. Eastern Regional Integrated Health Authority*, I argue that the *parens patriae* jurisdiction does not apply to medical treatment decisions or decisions regarding research participation made by mature minors. My reasons for adopting this position are similar to those outlined above as to why the welfare principle does not form part of the common law mature minor rule. Those reasons will therefore not be repeated here. Additionally, it is necessary to note

¹⁵⁷ *Supra* note 95 at para. 143.

¹⁵⁸ 2002 ABQB 371, 3 Alta. L.R. (4th) 16, aff’d 2002 ABCA 109, [2002] 7 W.W.R. 644. [*H.(B.) v. Alberta (Director of Child Welfare) No. 2* cited to Alta. L.R.].

¹⁵⁹ *Ibid.* at paras. 30-33.

that finding that the welfare principle does not apply at common law but then preserving the *parens patriae* jurisdiction would amount to allowing a best interest requirement that I have disallowed through the front door to come in through the back door.

(iv) **The Maturity Assessment**

Despite opting not to rule on A.C.'s capacity to refuse blood transfusions, the majority does provide a list of considerations that could be included in the "careful and sophisticated analysis of the young person's ability to exercise mature, independent judgment"¹⁶⁰ that should be carried out. Notably, possible considerations include:

- What is the nature, purpose and utility of the recommended medical treatment? What are the risks and benefits?
- Does the adolescent demonstrate the intellectual capacity and sophistication to understand the information relevant to making the decision and to appreciate the potential consequences?
- Is there reason to believe that the adolescent's views are stable and a true reflection of his or her core values and beliefs?
- What is the potential impact of the adolescent's lifestyle, family relationships and broader social affiliations on his or her ability to exercise independent judgment?
- Are there any existing emotional or psychiatric vulnerabilities?
- Does the adolescent's illness or condition have an impact on his or her decision-making ability?
- Is there any relevant information from adults who know the adolescent, like teachers or doctors?¹⁶¹

Before discussing each of these "considerations" individually, it is necessary to provide some context. Firstly, these "considerations" appear under the heading "*Interpreting Best Interests*". Secondly, they come after the majority's comments regarding the need to consider a minor's best interests in the "very limited class of

¹⁶⁰ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 87.

¹⁶¹ *Ibid.* at para. 96.

cases”¹⁶² involving child protection proceedings. Taken together, these contextual points suggest that the maturity assessment only needs to be carried out in child protection matters and in situations where the applicable legislation only authorizes minors to consent to treatment that is in their best interests. It may be that in other instances where there are serious consequences at play, a minor’s refusal of treatment (or research participation where such participation is captured under the relevant child protection statute) may trigger the application of child protection provisions. For reasons set out earlier in this chapter, it is entirely consistent with the majority’s reasons in *A.C. v. Manitoba (Director of Child and Family Services)* not to import the assessment of maturity into the research realm. Thirdly, despite my position that the maturity assessment does not apply to research, it is nonetheless relevant to examine each of the “considerations” included in the maturity assessment because they could serve to inform the development of the capacity assessment tool that is required under the framework set out in Chapter 4. With those general comments in mind, it is now possible to turn to an examination of each of the “considerations”.

The first factor, described by Abella J. is “the nature, purpose and utility of the recommended medical treatment”¹⁶³. It is unsurprising that the nature of the decision to be made plays a role in evaluating the capacity of a minor to consent to or to refuse medical treatment. After all, more significant treatment decisions undoubtedly require understanding of a more complex medical intervention as well as graver consequences. Similarly, more complex research protocols would demand a greater appreciation of precisely what participation entails, including acknowledgement of the associated risks

¹⁶² *Ibid.* at para. 86.

¹⁶³ *Ibid.*

and benefits. As well, more complex protocols would be harder to understand. As well, although it may be appropriate to consider utility in the medical treatment context, it becomes more problematic in the research realm where some but not all activities have little utility to research participants. Stated differently, the utility criterion would generally weigh against respecting a minor's wishes in the research realm without allowing for the consideration of society's need for research involving minors.¹⁶⁴

The second consideration, being the demonstration of “the intellectual capacity and sophistication to understand the information relevant to making the decision and to appreciate the potential consequences” is merely an articulation of the common law mature minor rule.¹⁶⁵ Specifically, elsewhere it has been defined as the legal concept whereby those under the legislated age of majority can consent to medical treatment when they are found to have “sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not.”¹⁶⁶ This principle applies in all common law jurisdictions in Canada, unless it has been modified or overridden by legislative enactments. At first blush, it seems somewhat circular to include an articulation of the common law mature minor rule as a factor to be considered when determining if a minor has capacity (i.e. amounts to saying look at whether a minor has capacity when assessing capacity). However, it is possible that Abella J. included this consideration to clarify that understanding the

¹⁶⁴ The role of minors in the research enterprise is discussed in greater detail in Chapter 1.

¹⁶⁵ As I argue above, the common law mature minor rule does not include the welfare principle. Prior to the release of the decision in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, it was somewhat unclear if the welfare principle formed part of the common law mature minor rule. The majority of the Supreme Court of Canada, despite having the opportunity to clearly state that the welfare principle formed part of the mature minor rule, did not do so.

¹⁶⁶ Gilmour, “Children”, *supra* note 89.

proposed course of action and the consequences of consenting and refusing such action is but one factor in the determination.

The third factor, the stability of views and whether a decision reflects a minor's true values. This entails looking at the degree of resolve they have (and how long they have had it) with respect to their position. The inquiry therefore indirectly requires a consideration of the minor's age and maturity, both of which had been previously considered by courts. With respect to age, courts have appeared willing to evaluate the capacity of children to consent to medical treatment once they reach twelve years of age, hence the reason why much emphasis in this thesis is on adolescence rather than childhood more generally. Even where the treatment to be given is relatively common and poses no more than minimal risk, the courts seem unwilling to extend the mature minor status to younger children.¹⁶⁷ The emphasis on age may be due to the fact that it is readily ascertainable, it does not require a subjective inquiry into the minor's mind, and is not context-specific. It is also used in several child protection statutes to define the role of minors in the decision-making process.¹⁶⁸ Unlike age, maturity is much harder to assess. In the treatment context, the requisite age and maturity to demonstrate sufficient understanding of what purpose the treatment will serve and what it entails is variable. There is no reason to believe that this would be any different in the research setting. That being said, in the case of research, minors would, beyond understanding the research activities themselves, also have to show an understanding of which aspects of their care

¹⁶⁷ See e.g. *Chmiliar v. Chimiliar*, 2001 ABQB 525, [2001] 11 W.W.R. 386 [*Chmiliar* cited to W.W.R.], where a father brought an application for an order that his two children be vaccinated against their mother's wishes, the judge hearing the case immediately deemed the 10 year old boy not to be a mature minor without pursuing any sort of inquiry into his capacity. The boy's 13 year old sister, however, was found to be a mature minor whose capacity to consent had been removed by the undue influence of her mother.

¹⁶⁸ See discussion below under subsection IV(C) for a synopsis of the relevant portions of the child protection statute for each province and territory.

are being delivered for research purposes and which they would receive whether or not they participated in the particular study.

The fourth factor labelled as “...the adolescent’s lifestyle, family relationships and broader social affiliations”¹⁶⁹ by Abella J. is in part equivalent to what courts have historically labelled the child’s dependence on her parents or guardian. In that regard it is worth noting that although living apart and being financially independent from one’s parents is not required under this criterion, emancipation is likely to weigh heavily in favour of granting mature minor status to a minor.¹⁷⁰ But, the absence of emancipation will not necessarily lead to the denial of a minor’s rights. Rather, despite the fact that no other possible ways of demonstrating independence have been explicitly noted in the jurisprudence, it would nonetheless seem that a minor’s ability to drive a motor vehicle, to work part-time, and to assume various responsibilities around the home would be worth raising in future cases. After all, as early as 1910, courts have treated children as mature minors where they showed themselves to be “capable of taking care” of themselves and “capable of doing a man’s work.”¹⁷¹

The reference to “the potential impact of...broader social affiliations” included within Abella J.’s fourth consideration clearly captures religious practices. This is the first suggestion by any court that membership in a religious group and the effect of such membership on one’s views need to be considered. One author has gone further, arguing that inclusion of this factor suggests that the majority questions the ability of a minor

¹⁶⁹ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 96.

¹⁷⁰ Jeffery Wilson, *Wilson on Children and the Law* (Toronto: Butterworths, 1994) at para 5.21.

¹⁷¹ *Booth v. Toronto General Hospital* (1910), 17 O.W.R. 118 (S.C. Jud. (H.C.J.)). Although the mature minor rule had not been articulated at that time, the court nonetheless allowed an individual under the age of majority to pursue an action in negligence against a physician.

raised by religious parents to ever be found to have the capacity for autonomous decision-making.¹⁷²

The fifth and sixth considerations outlined by Abella J. relate to the effect the illness to be treated or any other unrelated condition may have on the minor's ability to make autonomous decisions. Although this was never explicitly included by other courts in their capacity assessments, I would suggest that it was part of the broader examination into the minor's understanding of the proposed treatment.

The last factor explicitly endorses the view that information from others is relevant to the capacity assessment. Depending on how this is interpreted by the courts, this factor may be the most troublesome. If it is taken to mean that physicians are to consider any information regarding capacity from others that is presented to them, I have no problem with this factor. However, if it should be interpreted as permitting physicians to seek out information from others, I see this factor as highly problematic because essentially means according different privacy rights to an individual whose capacity is not yet ascertained from one who has already been found to be competent. Competent individuals are entitled to expect that their privacy regarding their health status (and therefore any treatment they are offered) will be respected. I see no reason why individuals who have not yet been found to be competent or incompetent should be treated any differently. Once an individual is found to lack capacity, physicians are free to discuss health issues and possible courses of treatment with her authorized decision maker (usually parents in the case of a minor). I suspect that it is the former of the two

¹⁷² Christopher Bird, "A.C. v. Manitoba: Saving Pressing Questions for Later" *The Court* (10 July 2009), online: The Court (by Osgoode Hall Law School) <<http://www.thecourt.ca/2009/07/10/ac-v-manitoba-saving-pressing-questions-for-later/>>.

possible interpretations that will carry the day because it is doubtful that the court would be allowing privacy violations.

Despite taking the time to set out some of the elements that may be included in a maturity assessment, Abella J. provides no guidance on how each of these factors would apply to a particular case because she declined the opportunity to carry out an assessment of A.C.'s "ability to exercise mature, independent judgment"¹⁷³. We also have been given no guidance from our Highest Court as to how findings pertaining to each consideration would be weighed collectively.

(v) **Mature Minors, Medical Treatment and the Charter**

(1) Application of the Charter

The *Charter* applies to all government laws and actions. It also applies to all bodies whose authority is derived from those laws.¹⁷⁴ According to those criteria and how they have been explained by the Supreme Court of Canada in *McKinney v. University of Guelph*¹⁷⁵, I argue that once the framework proposed in Chapter 4 of this thesis is incorporated into the *Tri-Council Policy Statement* (as is proposed it should be), it will attract *Charter* scrutiny. There are two principal justifications for this conclusion.

Firstly, there are the ties between the Interagency Advisory Panel on Research Ethics (PRE) who authored the *Tri-Council Policy Statement* on the one hand and the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council on the other. PRE is a body of experts that was established by the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and

¹⁷³ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 87.

¹⁷⁴ *Supra* note 64, s. 32.

¹⁷⁵ [1990] 3 S.C.R. 229.

Engineering Research Council. After it was prepared by PRE, each of the latter three entities adopted the *Tri-Council Policy Statement* as a means of discharging their legislative mandates.¹⁷⁶ Specifically, the Introduction of the *Tri-Council Policy Statement* describes those mandates as:

The people of Canada, through Acts of Parliament,¹ have created and funded the Agencies to promote and assist research within their respective legislative mandates. In discharging their mandates, the Agencies wish to promote research that is conducted according to the highest ethical standards. The Agencies have therefore adopted this Policy as a benchmark for the ethical conduct of research involving humans. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the application sections of the articles.¹⁷⁷

Secondly, the three national research agencies (i.e. the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council) act on behalf of the Federal Government. Specifically, the Canadian Institutes of Health Research is an agent for Her Majesty and acts as an adviser to the Government. All employees as well as the Presidents of the Canadian Institutes of Health Research are members of the federal public service.¹⁷⁸ The Social Sciences and Humanities Research Council and the Natural Science and Engineering Research Council report to the Minister of Science, Industry and Technology. They are agents for and must exercise all of their powers in the name of Her Majesty. Both Councils must report annually to Parliament.¹⁷⁹ Briefly stated, the three

¹⁷⁶ Interagency Advisory Panel on Research Ethics, online: < <http://pre.ethics.gc.ca/eng/panel-group/about-apropos/reference/>>. More detailed information on PRE's mandate and terms of reference are available on its website.

¹⁷⁷ *Tri-Council Policy Statement*, *supra* note 1 at 5.

¹⁷⁸ *Canadian Institutes of Health Research Act*, S.C. 2000, c. 6, ss. 3(2), 5(e), 8, 12, 25.

¹⁷⁹ *Social Sciences and Humanities Research Council*, R.S.C. 1985, c. S-12, ss. 4(1)(b), 15(1), 20; *Natural Sciences and Engineering Research Council Act*, R.S.C. 1985, c. N-21, ss. 14(1), 18(1); *Order Designating the Minister of Industry, Science and Technology as Minister for Purposes of the Social*

research councils are controlled by Government, thereby making the *Tri-Council Policy Statement* Government policy.

In light of my conclusion that the *Charter* applies to the *Tri-Council Policy Statement* and my recommendation in Chapter 4 of this thesis that the framework proposed be incorporated into a revised version of the *Tri-Council Policy Statement*, it is necessary to examine how legislation affecting mature minors has been evaluated in light of the *Charter*. This is accomplished in the discussion of the Supreme Court of Canada's decision in *A.C. v. Manitoba (Director of Child and Family Services)* with respect to sections 1, 2(a), 7, and 15(1) of the *Charter* set out below. Before proceeding to that discussion, it is necessary to note that because the rights enshrined in the *Charter* are continually evolving as well as the fact that a complex body of jurisprudence has already been developed, an exhaustive review of the *Charter* and the jurisprudence on how it should be interpreted will be left for another time.

(2) Section 2(a): Religious freedom

Section 2(a) of the *Charter* guarantees the right to “freedom of conscience and religion”.¹⁸⁰ As has been noted by at least one other author, all three sets of reasons provide no more than a cursory examination of the alleged violation of A.C.'s section 2(a) right.¹⁸¹ The brevity of the discussion on this point can undoubtedly be partially attributed to the fact that the Director of Child and Family Services conceded that the

Sciences and Humanities Research Council Act and as Appropriate Minister with Respect to the Social Sciences and Humanities Research Council for Purposes of the Financial Administration Act, SI/94-18; Order Designating the Minister of Industry, Science and Technology as Minister for Purposes of the Natural Sciences and Engineering Research Council Act and as Appropriate Minister with Respect to the Natural Sciences and Engineering Research Council for Purposes of the Financial Administration Act, SI/93-234.

¹⁸⁰ *Supra* note 64 at s. 2(a).

¹⁸¹ Shawn H.E. Harmon, “Body Blow: Mature Minors and the Supreme Court of Canada’s Decision in *A.C. v. Manitoba*” (2010) 4 McGill Journal of Law and Health 83 at 93.

legislative scheme violated section 2(a) of the *Charter*.¹⁸² Despite not even noting this concession in its reasons, the majority's comments on this point are very brief and only essentially amount to saying that according a minor's views greater weight as her maturity increases strikes an appropriate balance between religious rights and the need to protect minors.¹⁸³

Both the dissent and the minority accept the Director of Child and Family Services' concession of a section 2(a) violation. The minority, however, finds that A.C.'s claims need really only be addressed under section 7:

In this case, the s. 7 and s. 2(a) claims merge, upon close analysis. Either the *Charter* requires that an ostensibly "mature" child under 16 have an unfettered right to make all medical treatment decisions, or it does not, regardless of the individual child's motivation for refusing treatment. The fact that A.C.'s aversion to receiving a blood transfusion springs from religious conviction does not change the essential nature of the claim as one for absolute personal autonomy in medical decision making.¹⁸⁴

I question the appropriateness of the approach adopted by the minority. Conflating two *Charter* right violations into one diminishes the significance of each right, thereby making it easier for the state to justify the infringement. Specifically, both section 2(a) and 7 *Charter* rights can be "constrained by law to reflect other competing societal interests"¹⁸⁵. I submit that upholding a violation of an individual's right to freedom of religion and her right to liberty and security of the person under section 1 requires more compelling reasons than actions that violate only one of these two rights.

¹⁸² *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 (Factum of the Respondent at para. 21).

¹⁸³ *Ibid.* at paras. 112-113.

¹⁸⁴ *Ibid.* at para. 155.

¹⁸⁵ *Ibid.* at para. 137, citing *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519.

This is because the cumulative effect on an individual's constitutionally protected rights is greater where there are two violations.¹⁸⁶

(3) Section 7: Right to Liberty and Security of the Person

Section 7 of the *Charter* 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.”¹⁸⁷ In order to establish a section 7 violation, an individual must therefore first prove that a statutory scheme deprives her of her right to life, liberty or security. Thereafter, it must be proven that the deprivation is not in accordance with the principles of fundamental justice.

In this case, A.C. claimed that her section 7 right to liberty and security were violated because the statutory scheme arbitrarily denies competent minors under the age of sixteen their right to autonomous decision-making by allowing a court to order treatment against the wishes of such minors.

All seven of the justices hearing the case agreed that imposing medical treatment on an individual implicates the liberty and security interests captured under section 7 of the *Charter*.¹⁸⁸ This is rather unsurprising given the court's earlier pronouncement on this issue. Both Abella J. and Binnie J., cite *Ciarlariello v. Schacter*¹⁸⁹ in support of their view. In that case, Cory J. explained:

It should not be forgotten that every patient has a right to bodily integrity. This encompasses the right to determine what medical procedures will be accepted and the extent to which they will be accepted. Everyone has the right to decide what is to be done to one's own body. This includes the right to be free from medical treatment to which the individual does not consent. This concept

¹⁸⁶ Admittedly, I was unable to find a reported decision in which this notion was explicitly argued.

¹⁸⁷ *Supra* note 64 at s. 7.

¹⁸⁸ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 101, 136, 219.

¹⁸⁹ [1993] 2 S.C.R. 119.

of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient. If, during the course of a medical procedure a patient withdraws the consent to that procedure, then the doctors must halt the process. This duty to stop does no more than recognize every individual's basic right to make decisions concerning his or her own body.¹⁹⁰

There was also a general consensus that the principal of fundamental justice at play in the case was that laws cannot be arbitrary.¹⁹¹

Disagreement arises when the majority, minority and dissent apply the test for arbitrariness to sections 25(8) and 25(9) of the *Child and Family Services Act*. In particular, the majority and minority define the objective of the legislative scheme very differently from how it is construed by the dissent. According to the majority, the purpose of the Act is to protect children from harm. Specifically, unlike competent adults, “those who are vulnerable” are not “entitled to independently assess and determine their own best interests, regardless of whether others would agree when evaluating the choice from an objective standpoint”.¹⁹² Similarly, McLachlin C.J. on behalf of the minority states that the purpose of the legislative scheme “is to balance society's interest in ensuring that children receive necessary medical care on the one hand, with the protection of minors' autonomy interest to the extent this can be done, on the other”¹⁹³.

Allowing courts to force treatment upon minors under the age of sixteen where such treatment is in their “best interest” while granting those over sixteen years of age the

¹⁹⁰ *Ibid.* at 135.

¹⁹¹ As noted in *Chaoulli v. Quebec (Attorney General)*, 2005 SCC 35, [2005] 1 S.C.R. 791 at para. 131, “in order not to be arbitrary, the limit on life, liberty and security requires not only a theoretical connection between the limit and the legislative goal, but a real connection on the facts”.

¹⁹² *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 81. See also paras. 31, 104, 108 and 115.

¹⁹³ *Ibid.* at para. 141.

right to autonomous decision-making is then said to be a legitimate response to the legislative objective and therefore not arbitrary in the eyes of the majority and minority. Consequently, section 25(8) and 25(9) of the *Children and Family Services Act* are held not to violate section 7 of the *Charter*.¹⁹⁴ The majority does admit, however that if the “best interest” standard had been found to include a presumption of incapacity that was irrebutable (as Binnie J. finds), the impugned law would be arbitrary and therefore violate section 7.¹⁹⁵ Although not acknowledged by Abella J., the majority’s interpretation of “best interest” was first articulated by the Alberta Court of Appeal in *U.(C.)(Friend of) v. McGonigle* six years earlier.

Binnie J., however, holds that the objective of sections 25(8) and 25(9) is “to defend the “best interests” of children who cannot look after themselves and who are, therefore “in need of protection”.”¹⁹⁶ In his opinion, the state interest is grounded in a lack of capacity and so when capacity is established, there is no longer a valid state interest. The irrebutable presumption of incapacity that applies to all minors under the age of sixteen included within the legislative scheme leads to a deprivation of liberty and security of the person that is arbitrary and consequently not in accordance with the principles of fundamental justice.¹⁹⁷ As a result, according to Binnie J., sections 25(8) and 25(9) violate section 7 of the *Charter*.

In light of the above comments, it is clear that whether the statutory scheme would be found to violate section 7 of the *Charter* depended solely on whether mature minors under the age of sixteen are seen as being vulnerable or not. Binnie J. is, in my

¹⁹⁴ *Ibid.* at paras. 142-149.

¹⁹⁵ *Ibid.* at para. 107.

¹⁹⁶ *Ibid.* at para. 222.

¹⁹⁷ *Ibid.* at paras. 176, 179, 207, 223.

opinion, correct in being critical of the majority and minority's implicit assumption that all minors under the age of sixteen captured by the child protection statute are vulnerable and in need of protection. As he notes at paragraph 194, the majority and minority's holding that regardless of capacity, the views of a minor who is under the age of sixteen will not be determinative, cannot be reconciled with the Court's earlier commentary on balancing autonomy against the need for protection. Notably, in *Starson v. Swayze*, McLachlin C.J. herself remarked:

Like understanding, appreciation does not require agreement with a particular conclusion, professional or otherwise. A patient may look at the pros and cons of treatment and arrive at a different conclusion than the medical experts. Nor does it amount to a "best interests" standard. A patient who is capable has the right to *refuse* treatment, even if that treatment is, from a medical perspective, in his or her best interest. It is crucial to guard against interpreting disagreement with a particular diagnosis or proposed treatment plan as itself evidence of incapacity.¹⁹⁸

As well, although some minors are indisputably vulnerable and in need of the court's protection, the majority and minority provide no specific reason why mature minors under the age of sixteen are vulnerable and should therefore have their decisions subject to review by the courts. Even after carrying out an independent search of the social science literature on the decision-making ability of adolescents, Abella J. was unable to point to any such evidence.¹⁹⁹ As will be seen in the discussion on the need for protection in Chapter 4, it may be that Abella J. did not cite any such evidence because

¹⁹⁸ *Supra* note 126 at para. 19. It is particularly noteworthy that in that case, the Supreme Court of Canada does not limit its comments to those over the age of majority; it refers to "a patient".

¹⁹⁹ As reported in Cheryl L. Milne, "The Differential Treatment of Adolescents as a Principle of Fundamental Justice: An Analysis of *R. v. B.(D.)* and *C.(A.) v. Manitoba*" (2009) 47 S.C.L.R. (2d) 235 at 249 in footnote 56, only approximately 15% of the secondary sources cited by the majority were cited in the facts of any of the parties or intervenors. This point is also taken up by Binnie J. at para. 232 where he notes that the Attorney General of Manitoba chose not to lead any evidence on "the state interest in subjecting the medical treatment of minors under 16 to judicial control *irrespective* of capacity" [emphasis in original].

the literature supports the opposite conclusion; that being that there is no difference in decision-making capacity between older adolescents and young adults.

(4) Section 15: Right to Equality

Section 15(1) of the *Charter* guarantees that “every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.”²⁰⁰ The two-part test to determine if there is a section 15(1) violation was recently restated by the Supreme Court of Canada in *R. v. Kapp*²⁰¹ as: “(1) does the law create a distinction based on an enumerated or analogous ground? and (2) does the distinction create a disadvantage by perpetuating prejudice or stereotyping?”²⁰²

The majority held that there was no discrimination on the basis of age because the legislation allowed those under the age of sixteen to rebut the presumption that they lacked sufficient maturity to participate in medical treatment decisions. By defining the presumption at play as being rebuttable, the majority was then able to say the distinction drawn by the legislation was ultimately based on maturity not age.²⁰³ This is a highly dubious conclusion given that the Attorney General of Manitoba had itself conceded that the legislative scheme imposed differential treatment on the basis of age (it then denied that such treatment was discriminatory).²⁰⁴

The minority, however, agreed with A.C. and the Attorney General of Manitoba that the legislation made a distinction on the basis of age but then went on to find that the

²⁰⁰ *Supra* note 64 at s. 15(1).

²⁰¹ 2008 SCC 41, [2008] 2 S.C.R. 483 [cited to S.C.R.].

²⁰² *Ibid.* at para. 17.

²⁰³ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 110-111.

²⁰⁴ *Ibid.* (Factum of the Intervener Attorney General of Manitoba at para. 37).

distinction is ameliorative and therefore not discriminatory. It is said to be ameliorative because it (1) protects the interests of minors as a vulnerable group and (2) ensures that individual minors have input into treatment decisions.²⁰⁵ McLachlin C.J. on behalf of the minority also points to the fact that age is used in other contexts to distinguish between which minors will be accorded certain rights.²⁰⁶ The flaw with this reasoning is similar to that levelled by me against the majority and minority's reasoning with respect to section 7 above. Notably, it assumes vulnerability where there may not be any.²⁰⁷ It also affords some minors "input" when were it not for this distinction on the basis of age they would be the sole decision-maker.

The dissent declined the opportunity to carry out a section 15(1) analysis; instead choosing to consider A.C.'s argument on this point as part of her rebuttal to the government's section 1 justification. The reason given for this approach is that differential treatment on the basis of age is not A.C.'s pre-eminent concern with the legislative scheme. She is said to be more concerned with her rights under sections 2(a) and 7 of the *Charter*.²⁰⁸

(5) Section 1: Justifying Charter Violations

Any *Charter* violation must be justified by the state under section 1, which "guarantees the rights and freedoms set out in [the *Charter*] subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and

²⁰⁵ *Ibid.* at para. 152.

²⁰⁶ *Ibid.* at para. 145.

²⁰⁷ If the legislature's intent was to discern between those minors who are vulnerable and those who are not, it could have required an individualized capacity (or maturity) assessment for all "children", regardless of age. Instead, by including an age in the scheme, the legislature assumed that all minors under the age of sixteen captured by the act are vulnerable and need to be treated differently from those who are over sixteen years of age.

²⁰⁸ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at para. 231.

democratic society.”²⁰⁹ The test from *R. v. Oakes*²¹⁰ to be applied by the courts was succinctly described by Deschamps J. at para. 48 in *Egan v. Canada*²¹¹:

First, the objective of the legislation must be pressing and substantial. Second, the means chosen to attain this legislative end must be reasonable and demonstrably justifiable in a free and democratic society. In order to satisfy the second requirement, three criteria must be satisfied: (1) the rights violation must be rationally connected to the aim of the legislation; (2) the impugned provision must minimally impair the *Charter* guarantee; and (3) there must be a proportionality between the effect of the measure and its objective so that the attainment of the legislative goal is not outweighed by the abridgement of the right. In all s. 1 cases the burden of proof is with the government to show on a balance of probabilities that the violation is justifiable.²¹²

On the facts of *A.C. v. v. Manitoba (Director of Child and Family Services)*, the majority found that the legislative scheme at issue did not violate sections 2(a), 7, and 15 of the *Charter* and so did not carry out a section 1 analysis. The minority, having found a section 2(a) violation needed to consider if that violation could be saved under section 1. McLachlin C.J.’s reasons, however, merely state that the breach is justified under section 1 for the same reasons that the laws were not arbitrary under section 7.²¹³

The only thorough section 1 analysis is carried by Binnie J., who had earlier found violations of sections 2(a) and 7. He found that the first step of the *Oakes* test was met; the care and protection of children was a pressing and substantial objective. He then went on to find that the *Charter* violations could not be saved because there was no rational connection between the scheme and the objective. Specifically, denying minors under the age of sixteen the opportunity to rebut the presumption of incapacity was

²⁰⁹ *Supra* note 64, s. 1.

²¹⁰ [1986] 1 S.C.R. 103.

²¹¹ [1995] 2 S.C.R. 513.

²¹² *Ibid.* at para. 48.

²¹³ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at 156.

“arbitrary, unfair, or based on irrational considerations”²¹⁴. He also found that the use of an irrebutable presumption was not minimally impairing. In this respect, Binnie J. pointed to the fact that section 4(2) of the *The Health Care Directives Act*²¹⁵ allows minors under the age of sixteen to rebut the presumption of incapacity.²¹⁶

(vi) **Application of the Reasoning to A.C.**

By the time the Supreme Court of Canada heard the case, the issue insofar as A.C. was concerned was moot; blood transfusions had already been forced upon her. However, given the amount of time it takes for a case to reach our Highest Court and the urgency of situations where the state wants to apprehend children and force care upon them, it is unlikely that the Supreme Court of Canada would ever get to review a decision before irreversible action was taken. The Court nonetheless seized the opportunity to articulate how minors in the child protection contexts should be treated with respect to autonomous medical decision-making.

The majority and the minority both explicitly declined the opportunity to determine if A.C. herself was sufficiently competent to refuse blood transfusions, citing the lack of record from the lower courts on this point.²¹⁷ The minority also concludes that it was reasonable for the applications judge to assume capacity but notes that if possible, it would be preferable in future cases for the judge to outline the reasons he or she relies upon to determine the minor’s best interests.²¹⁸ The problem with this is that since time and circumstances do not always permit a judge to give reasons, I am left

²¹⁴ *R. v. Oakes*, *supra* note 210 at para. 70.

²¹⁵ C.C.S.M. c. H27.

²¹⁶ *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65 at paras. 209-211, 221-223, 232-237.

²¹⁷ *Ibid.* at paras. 119-120, 157-158.

²¹⁸ *Ibid.* at para. 159.

wondering how likely it is that time and circumstances would ever allow for “the careful and sophisticated analysis”²¹⁹ of the minor’s capacity proposed by the majority and minority. As well, how can the court know that the applications judge properly determined A.C.’s best interest if the only evidence before the Court was that A.C. had refused blood transfusions?

The Court was unanimous that A.C. should be awarded her costs, something that is generally awarded to the successful party.²²⁰ For the dissent, although not explicitly stated by Binnie J., this was likely simply the result of A.C. having been the successful litigant. The majority justified this decision on the basis that A.C. had successfully argued that the legislative scheme should be interpreted so as to allow “an adolescent under the age of 16 to demonstrate sufficient maturity to have a particular medical treatment decision respected”²²¹.

So, ultimately this decision means that if A.C. had been fourteen months older at the time she was admitted to the hospital, her refusal of the blood transfusions would likely have been upheld. Instead, she received blood transfusions she did not want and then spent the next three years fighting for greater recognition of the autonomy right of minors, for which she received money to cover part of her legal costs. Bluntly stated, such a result is unlikely to encourage other minors to take up the fight for their own rights in the future.

²¹⁹ *Ibid.* at para. 87.

²²⁰ *Ibid.* at paras. 121, 161, 239.

²²¹ *Ibid.* at para. 121.

(vii) **Application of the Reasoning to the Research Context**

When the governing law is the common law, there is nothing in the reasons of any of the justices to suggest that mature minors can only consent to research participation where such participation is in their best interests. That is, in those circumstances it would seem entirely reasonable to expect that if a minor can demonstrate that she has capacity and meets the other requirements for providing legally valid consent, her consent is both necessary and sufficient. As will be seen in the discussion that follows, however, when research activities are captured by either consent to treatment legislation or child protection legislation, there may be limits on a mature minor's right to autonomous decision-making. Specifically, in those contexts, a best interest requirement sometimes applies.

IV. PROVINCIAL AND TERRITORIAL INSTRUMENTS

The discussion in this chapter to date has set out the relevant international and national legal instruments that impact the participation of minors in medical research throughout Canada. The Supreme Court of Canada's decision in *A.C. v. Manitoba (Director of Child and Family Services)* and other relevant jurisprudence has also been explained. Together, these instruments and court decisions all set out general parameters on pediatric medical treatment and research, while also attempting to ensure some degree of consistency across jurisdictions. However, provincial jurisdiction over the "establishment, maintenance, and management of hospitals, asylums, charities and eleemosynary institutions"²²² and "property and civil rights"²²³ has meant that mature

²²² *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, s.92(7), reprinted in R.S.C. 1985, App. II, No. 5, s. 92(7).

minors residing in different provinces and territories are not necessarily accorded the same rights with respect to consenting to or refusing medical treatment. This inter-jurisdictional variability likely also extends to medical research. The discussion below explores how the common law mature minor concept has been varied through two forms of legislation: consent to treatment legislation and child protection legislation. Thereafter, the regime in place in Quebec is appraised.

A. Legislation Generally

Despite the need for a test that can be adapted to various settings and circumstances, through legislative enactments many provincial and territorial jurisdictions have opted to eliminate some of the discretion bestowed upon the courts while others have altered the parameters of the capacity assessment. The two general types of legislation – consent to treatment legislation and child protection legislation – used to these ends must be considered in order to understand the complex legal regime that regulates the rights of children.

Prior to reviewing each of these types of legislation, it is worth noting that provincial/territorial legislation is not a panacea for all the weaknesses of the common law mature minor rule. At the provincial/territorial level, legislation creates greater certainty, a value that is arguably even more important when those required to carry out the activities in question are not legal minds. But, however advantageous this certainty may be for some, it comes at a price for others. In the case of medical research involving mature minors, legislative enactments support the rights of some minors, arguably reject the existence of the rights of other minors, and remain entirely silent on the rights of yet

²²³ *Ibid.*, s. 92(13).

another group of minors. This is not a bad thing so long as legislators who choose to legislate in this sphere get the balance right. However, it becomes problematic when there is no legally and ethically defensible basis to deny an individual's rights. At the national level, provincial/territorial legislation can potentially, and as you see with child protection and consent to treatment legislation, does, lead to minors having different autonomy rights depending on their province of residence. I recognize that adults and children are sometimes treated differently under different provincial and territorial statutes.²²⁴ There are likely many reasons for this differential treatment, including a temporal component. Not all statutes were enacted in and around the same time nor is there political will to revise a given statute in every jurisdiction during the same limited period of time. In the case of the role of mature minors in the research process, we have essentially a blank slate. There is no legislation governing procedure, thereby affording us the best opportunity possible to treat like cases alike. Stated differently, there is nothing precluding the design of a framework to govern the role to be played by minors in the consent process that mandates the same procedural treatment for all minors despite the variation in legislative enactments across the country.²²⁵ With this backdrop in mind, it is now possible to examine the various statutes that have been enacted.

B. Consent to Treatment Legislation

Some provinces have legislated with respect to the right of minors to consent to treatment. Interestingly, the language used in each of these statutes differs somewhat,

²²⁴ Note that adults and minors are not always treated substantially differently. For example, all individuals aged 18 or 19 years of age in Canada have the right to vote.

²²⁵ Some may argue that there is nothing stopping legislatures from designing uniform frameworks in contexts where there is presently great variation. Although this is theoretically true, practically speaking I think it is far less likely to happen because opinions and positions have already been formulated in those other contexts.

thereby creating a continuum as to the statutory right of children to consent to medical treatment and research. At one end, there are those jurisdictions that have not legislated in this sphere whatsoever. These are Alberta, the Northwest Territories, and Nunavut. Moving away from this complete void of legislative intervention, there are the remaining provinces and territories, all of which have instituted a regime whereby the rights of minors to consent to treatment are recognized in varying degrees. The latter category includes British Columbia, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and Yukon. The statutory enactments in each common law jurisdiction are discussed below. Given the vastly different legal regime in Quebec, the specific statutory provisions contained within the *Civil Code of Québec* are set out in section D below. After reviewing the statutes by jurisdiction, the implications for research flowing from these statutes are discussed.

(i) British Columbia

Under the auspices of the *Infants Act*, a minor can consent to “health care” when a health care provider “(a) has explained to the infant and has been satisfied that the infant understands the nature and consequences and the reasonably foreseeable benefits and risks of the health care, and (b) has made reasonable efforts to determine and has concluded that the health care is in the infant's best interests.”²²⁶ Unlike New Brunswick’s *Medical Consent of Minors Act* and Ontario’s *Health Care Consent Act*²²⁷, the *Infants Act* does not limit the age at which a minor can give his consent. However, because of the “best interest” requirement the right of minors in British Columbia to

²²⁶ *Supra* note 29, s. 17(2)-(3).

²²⁷ S.O. 1996, c. 2, Sch. A.

autonomous decision-making with respect to “health care” under the *Infants Act* is likely more restricted than it would be at common law.²²⁸

Section 17 of the *Infants Act* defines “health care” as “anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health related purpose, and includes a course of health care”.²²⁹ The definition does not require that the primary justification for subjecting a minor to a particular intervention be to better the minor’s health; only that one reason for the intervention be for a “health related purpose”. The use of such a broad phrase clearly captures some research, but not all. Specifically, most research carried out on healthy subjects is not likely to be captured because by definition, healthy subjects do not require any action by physicians/researchers to improve or prevent the deterioration of their state of health. As well, research that is of no direct benefit to participants is unlikely to be captured because in that circumstance, nothing is done to the participant for a purpose related to her health. However, some individuals agree to participate in research because they hope that the investigational product will be of some benefit to them. Although the primary purpose of the research would be extend knowledge through a disciplined inquiry or systematic investigation²³⁰, the secondary purpose could be anything from hoping for an improvement in their health condition, hoping to stop a further deterioration of their health status, or hoping to learn more about their health impediment. Stated differently, individuals with such hopeful aspirations can

²²⁸ The phrase “likely more restricted” is used because the possibility that the Supreme Court of Canada added a “best interest” criterion to the common law mature minor rule in its decision in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, cannot be definitively ruled out at this time. For reasons set out in section III(A)(iii) above, I am of the opinion that the common law mature minor rule has not been altered in that way.

²²⁹ *Infants Act*, *supra* note 29, s. 17(1). Compare to section 1 of Yukon’s *Care Consent Act*, being Schedule B to *Decision Making, Support and Protection to Adults Act*, S.Y. 2003, c. 21, which defines health care in the same way and to section 1 of Manitoba’s *The Health Care Directives Act*, *supra* note 215, which defines “treatment” in the same way.

²³⁰ *Tri-Council Policy Statement*, *supra* note 1 at art 2.1.

be said to enrol in research for a health related purpose. The ability of minors to provide legally valid consent in those instances will therefore be governed by the *Infants Act*.

(ii) **Alberta**

There is no legislation regarding the ability of minors to consent to medical treatment currently in force in Alberta. Consequently, until they reach eighteen years of age, that being the age of majority in that province, the rights of minors in this regard are defined by the common law mature minor rule.²³¹

(iii) **Saskatchewan**

Saskatchewan does not have legislation that specifically addresses consent to treatment by minors. However, the province's *The Health Care Directives and Substitute Health Care Decision Makers Act*²³² does permit individuals who are sixteen years of age and older and have "capacity to make health care decisions" to make a health care directive. Under *The Health Care Directives and Substitute Health Care Decision Makers Act*, "health care decision" includes the affirmative and negative rights of consenting to and refusing treatment.²³³ Saskatchewan's Act also defines "capacity" in much the same way as the common law mature minor rule has been characterized in that it requires an understanding of the relevant information, an appreciation of the consequences of treatment and non-treatment, and an ability to communicate one's wishes.²³⁴

²³¹ *Age of Majority Act*, R.S.A. 2000, c. A-6, s. 1 [*Age of Majority Act (Alberta)*].

²³² S.S. 1997, c. H0.001.

²³³ *Ibid.*, s. 2(1)(d), 3.

²³⁴ *Ibid.*, s. 2(1)(b). Compare to Gilmour, "Children", *supra* note 89, who defines the mature minor rule as requiring "sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not."

As a whole, *The Health Care Directives and Substitute Health Care Decision Makers Act* does not affect the ability of minors to consent to medical treatment under the common law mature minor rule. It affords mature minors does not require a mature minor's best interests to be considered, grants mature minors the same right as that which I have argued earlier in this chapter they would possess at common law following the decision in *A.C. v. Manitoba (Director of Child and Family Services)* because it does not require the minor's best interests to be considered. It may in fact grant minors more expansive rights than those they hold at common law in that it explicitly bestows upon minors the right to refuse medical treatment.²³⁵

(iv) Manitoba

Under Manitoba's *The Health Care Directives Act*, minors who are sixteen years of age and older are presumed competent to make health care decisions while those less than sixteen are presumed incompetent. Both of these presumptions are rebuttable and apply to both consenting to treatment as well as refusing treatment.²³⁶ "Treatment" is in turn defined in *The Health Care Directives Act* in nearly the exact same manner as "health care" is defined under British Columbia's *Infants Act* and Yukon's *Care Consent Act* and how "treatment" is defined under Ontario's *Health Care Consent Act*. Specifically, under the Manitoba statute, "treatment" is said to be "anything that is done

²³⁵ The debate as to whether mature minors can refuse treatment has not been discussed in any great detail in this thesis because, in the case of research, the right to refuse is well-established. Readers should nonetheless be aware that there is some uncertainty as to whether a mature minor can refuse treatment. If the treatment is life-saving, child protection statutes are often triggered.

²³⁶ *Supra* note 215, ss. 1, 4(2).

for a therapeutic, preventative, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment.”²³⁷

(v) **Ontario**

Ontario’s *Health Care Consent Act* presumes all persons competent unless there are reasonable grounds to believe otherwise.²³⁸ It also explicitly requires that the treatment decisions of a capable person over the age of sixteen be respected.²³⁹ The Act defines “capacity” as being “able to understand the information that is relevant to making a decision about the treatment... and able to appreciate the reasonably foreseeable consequences of a decision or lack of decision.”²⁴⁰ Whether merely unintended consequences of a legislative enactment not directed solely at minors or not, Ontario’s *Health Care Consent Act* makes it easier for all minors to consent to their own medical treatment in that they do not need to establish their capacity.

The *Health Care Consent Act* defines “treatment” in a similar way to the definitions of “health care” in British Columbia’s *Infants Act* and Yukon’s *Care Consent Act* and of “treatment” in Manitoba’s *The Health Care Directives Act*.²⁴¹ The only

²³⁷ *Ibid.*, s. 1. Compare to *Infants Act*, *supra* note 29, s. 17(1), *Care Consent Act*, *supra* note 229, s. 1, and *Health Care Consent Act*, *supra* note 227, s. 2(1).

²³⁸ *Supra* note 227, ss. 4(2)-(3).

²³⁹ *Ibid.*, s. 1(c)(iii).

²⁴⁰ *Ibid.*, s. 4(1).

²⁴¹ *Ibid.*, s. 2(1) where “treatment” is defined as:

anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment, plan of treatment or community treatment plan, but does not include,

- (a) the assessment for the purpose of this Act of a person’s capacity with respect to a treatment, admission to a care facility or a personal assistance service, the assessment for the purpose of the *Substitute Decisions Act, 1992* of a person’s capacity to manage property or a person’s capacity for personal care, or the assessment of a person’s capacity for any other purpose,
- (b) the assessment or examination of a person to determine the general nature of the person’s condition,
- (c) the taking of a person’s health history,
- (d) the communication of an assessment or diagnosis,

noteworthy difference in this regard is that the Ontario statute specifically excludes anything that “poses little or no risk of harm” from the definition of treatment.²⁴² Even if it could be successfully argued that a minimal risk research study was “treatment” (which I think it cannot), all minimal risk research is explicitly excluded from the reaches of the Act. As well, the *Health Care Consent Act* does not affect the law on anything excluded from the definition of “treatment”.²⁴³ This means that research not captured under the Act (which I argue is those same categories not captured under British Columbia’s *Infants Act* set out above plus minimal risk research) could still be subject to the common law mature minor rule, if the latter was found to apply to the research context.

(vi) **New Brunswick**

Under New Brunswick’s *Medical Consent of Minors Act* all minors who are sixteen years or older are presumed competent. Those minors under sixteen can provide legally valid consent to treatment where she understands the nature and consequences of the proposed treatment and the treatment at issue is in the minor’s best interest.²⁴⁴ The Act defines “medical treatment” as including:

- (e) surgical and dental treatment,
- (f) any procedure undertaken for the purpose of diagnosis,
- (g) any procedure undertaken for the purpose of preventing any disease or ailment, and
- (h) any procedure that is ancillary to any treatment as it applies to that treatment.²⁴⁵

-
- (e) the admission of a person to a hospital or other facility,
 - (f) a personal assistance service,
 - (g) a treatment that in the circumstances poses little or no risk of harm to the person,
 - (h) anything prescribed by the regulations as not constituting treatment.

²⁴² *Ibid.*

²⁴³ *Ibid.*, s. 8(2).

²⁴⁴ *Supra* note 27, s. 3(1).

²⁴⁵ *Ibid.*, s. 1.

Looking more closely at each component of the definition, research would not be captured under (a) because research and treatment are distinct activities. Under (b), I argue that no research is again captured because in studies involving an experimental diagnostic test, the participant would nonetheless also have to undergo some other established test or procedure to allow researchers to determine if the experimental test was rendering the proper diagnosis.²⁴⁶ Given those circumstances, only the use of the established test is for “the purpose of diagnosis”. Unlike under (a) and (b), (c) captures some research activities, such as experimental vaccine studies.²⁴⁷ Considering the breadth of medical research activities, the fact that only those aimed at preventing a disease or ailment are captured under the *Medical Consent of Minors Act* means that any right to autonomous decision-making with respect to other research held by minors residing in New Brunswick is subject to the common law mature minor rule.

(vii) Nova Scotia

The *Hospitals Act*²⁴⁸ has essentially codified the common law mature minor rule. Specifically, under the Act all minors are presumed incompetent but must have their capacity assessed by the treating physician or “other suitable health professional determined by the hospital” before treatment is administered.²⁴⁹ Although the *Hospitals*

²⁴⁶ There needs to be some way of determining if the experimental test is accurate, whether that be by comparing results to those obtained using another diagnostic test or carrying out a procedure to otherwise confirm the diagnosis.

²⁴⁷ In experimental vaccine trials, researchers generally give a large number of health participants a vaccine and then periodically evaluate what proportion of those individuals who received the vaccine go on to develop the condition it was aimed to prevent. That result is then compared to the incident of the condition in the normal population or in a group who received a different vaccine, or both.

²⁴⁸ R.S.N.S. 1989, c. 208. As a result of the *Hospitals Approvals Regulations*, N.S. Reg. 212/2003, the *Hospitals Act* applies to the IWK Health Centre, the children’s hospital in Halifax. As such, although the *Hospitals Act* does not explicitly mention minors, it clearly applies to individuals under the age of majority.

²⁴⁹ *Hospitals Act*, *ibid.* at s. 2A(b), 54(1).

Act does not define “treatment”, it does explicitly state the criteria to be included when evaluating a patient’s capacity. Notably, the assessor is required to:

- consider whether the person understands and appreciates
- (a) the condition for which the specific treatment is proposed;
- (b) the nature and purpose of the specific treatment;
- (c) the risks and benefits involved in undergoing the specific treatment; and
- (d) the risks and benefits involved in not undergoing the specific treatment.²⁵⁰

After the assessment of capacity has been completed, the assessor is required to complete a “declaration of capacity”²⁵¹. It is only if this declaration indicates that an individual lacks capacity that consent can be sought from a third party, such as a parent.²⁵² It is also worth noting that under the *Hospitals Act*, if a minor’s capacity is not assessed prior to obtaining consent to treatment from her or her parent(s), she is presumed to have been competent. This means that if consent is obtained from a parent before a declaration of capacity indicating that the minor is incapable is completed, that minor would be able to bring an action for battery.

In addition to the *Hospitals Act*, on April 1, 2010 the *Personal Directives Act*²⁵³ came into force in Nova Scotia. Under the Act “a person with capacity may make a personal directive (a) setting out instructions or an expression of the maker’s values, beliefs and wishes about future personal care decisions to be made on his or her behalf...”²⁵⁴ Capacity is defined as “the ability to “understand information that is relevant to the making of a personal-care decision and the ability to appreciate the reasonably

²⁵⁰ *Ibid.* at s. 52(2A).

²⁵¹ *Ibid.* at s. 53(1).

²⁵² *Ibid.* at s. 54(2).

²⁵³ S.N.S. 2008, c. 8. This Act replaced the *Medical Consent Act*, R.S.N.S. 1989, c. 279, which applied only to those over the age of majority.

²⁵⁴ *Personal Directives Act, ibid.*, s. 3(1)(a).

foreseeable consequences of a decision or lack of a decision”²⁵⁵. The *Personal Directives Act* does not stipulate a minimum age at which capacity will be presumed nor does it preclude minors from making personal directives prior to reaching a certain age.

Based on the contents of the Act and the omissions noted above, the *Personal Directives Act* should be seen as a clear endorsement of the mature minor rule at common law. This view is further supported by the fact that, if a minor can specify how she would like future health care decisions to be handled, she must necessarily be able to make present day decisions.

(viii) Prince Edward Island

Prince Edward Island’s *Consent to Treatment and Health Care Directives Act*²⁵⁶ contains a rebuttable presumption whereby every person regardless of age is presumed capable of consenting to or refusing medical treatment.²⁵⁷ “Treatment” is defined, in part, as “a procedure or set of procedures that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment or group of associated treatments...”²⁵⁸ Consent to treatment or refusal to consent can be based “on any grounds, including moral or religious grounds, even if the refusal will result in death”²⁵⁹. This statute along with Yukon’s *Care Consent Act* offer mature minors the greatest opportunity to have their rights recognized and respected because it contains no age threshold and no best interest requirement.

²⁵⁵ *Ibid.*, s. 2(a).

²⁵⁶ R.S.P.E.I. 1988, c. C-17.2.

²⁵⁷ *Ibid.*, s. 3.

²⁵⁸ *Ibid.*, s. 1(p). Compare to *Infants Act*, *supra* note 29, s. 17(1), *Care Consent Act*, *supra* note 229, s. 1, *The Health Care Directives Act*, *supra* 215, s. 1, and *Health Care Consent Act*, *supra* note 227, s. 2(1), which all have similar definitions.

²⁵⁹ *Consent to Treatment and Health Care Directives Act*, *ibid.*, s. 4.

(ix) Newfoundland and Labrador

With the exception of the *Child, Youth and Family Services Act*,²⁶⁰ which is discussed under the child protection legislation section below, the only statute that speaks to the ability of minors to consent to medical treatment that is currently in force in Newfoundland is the *Advance Health Care Directives Act*.²⁶¹ It presumes (though the presumption is rebuttable) anyone who is sixteen years of age or older “to be competent to make health care decisions”.²⁶² “Health care decision” is in turn defined as “a consent, refusal to consent, or withdrawal of consent of any care, treatment, service, medication, or procedure to maintain, diagnose, treat, or provide for an individual's physical or mental health or personal care...”²⁶³ The *Advance Health Care Directives Act* benefits minors over the age of sixteen in that they are presumed competent to consent while still affording younger minors the opportunity to prove that they have decision-making capacity.

(x) Yukon

Under the Yukon’s *Care Consent Act*, minors and adults alike can consent or refuse health care if the individual understands “(i) the reason or reasons why the care is proposed, (ii) the nature of the proposed care, (iii) the risks and benefits of receiving and not receiving the proposed care that a reasonable person would expect to be told about, and (iv) alternative courses of care.” Some understanding of their present condition must

²⁶⁰ S.N.L. 1998, c. C-12.1.

²⁶¹ It is worth noting that the College of Physicians and Surgeons of Newfoundland and Labrador does provide physicians some guidance on how to interpret the common law mature minor rule by way of its “Guideline – Consent to Medical Treatment of Minors”, which can be found on its website at <<http://www.cpsnl.ca/default.asp?com=Policies&m=359&y=&id=11>>.

²⁶² *Supra* note 130, s. 7(b).

²⁶³ *Ibid.*, s. 2(b).

also be demonstrated.²⁶⁴ These criteria are similar but not as exhaustive as those set out by Abella J. in *A.C. v. Manitoba (Director of Child and Family Services)*.²⁶⁵ Whereas the common law mature minor rule and other consent to treatment legislation are silent, the *Care Consent Act* specifically states that it is the care provider who is proposing to provide care that determines whether or not an individual has the requisite capacity.²⁶⁶

The *Care Consent Act* defines “health care” as “anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health related purpose, and includes a course of health care”.²⁶⁷ This definition is similar to the definition of “health care” included within British Columbia’s *Infants Act* and the definition of “treatment” in Manitoba’s *The Health Care Directives Act* and Prince Edward Island’s *Consent to Treatment and Health Care Directives Act*.²⁶⁸

Read together, the provisions of the *Care Consent Act* mean that once found to be capable of consenting or refusing care, a minor residing in Yukon has the right to do so “on any grounds, including moral or religious grounds, even if the refusal will result in death.” She also acquires the right to choose between forms of care available.²⁶⁹ Implicitly, this means that under the *Care Consent Act*, minors can consent to or refuse care that is not in their “best interest.” As seen below, however, these rights may be curtailed somewhat under the *Child and Family Services Act*²⁷⁰, which deems the “best interests” of minors to be the paramount consideration under that statute.²⁷¹

²⁶⁴ *Care Consent Act*, *supra* note 229, ss. 5(e), 6(2).

²⁶⁵ See *supra* note 65 at para. 96.

²⁶⁶ *Care Consent Act*, *supra* note 229, s. 6(1).

²⁶⁷ *Ibid.*, s. 1.

²⁶⁸ *Infants Act*, *supra* note 29, s. 17(1); *The Health Care Directives Act*, *supra* note 215, s. 1; *Consent to Treatment and Health Care Directives Act*, *supra* note 256, s. 1(p).

²⁶⁹ *Care Consent Act*, *supra* note 229, ss. 3(a)-(b).

²⁷⁰ S.Y. 2008, c. 1 [*Child and Family Services Act* (Yukon)].

²⁷¹ *Ibid.*, s. 2.

(xi) **Northwest Territories and Nunavut**

The Northwest Territories and Nunavut do not have any laws that alter or displace the common law mature minor rule. Stated differently, until reaching nineteen years of age, minors residing in either of these two territories are presumed to lack the requisite capacity for autonomous decision-making.²⁷²

(xii) **Implications for Research**

The review of the provincial and territorial statutes that abolish, modify, or codify the common law mature minor rule set out above reveals how differently mature minors are treated across the country. There are those jurisdictions – Alberta, Northwest Territories, and Nunavut – that have not legislated in relation to consent to medical care by minors at all, meaning that the common law mature minor rule is unchanged. Amongst those remaining provinces and territories that have legislated with respect to consent to medical treatment by minors, variation is seen in three key elements of the statutory schemes.

Firstly, age is used by some provinces and territories. Specifically, in one jurisdiction – Saskatchewan – minors who are over the age of sixteen have capacity to consent to medical care. There are then a number of jurisdictions – Manitoba, New Brunswick, and Newfoundland and Labrador – that presume minors who are sixteen years and older to be competent. Finally, there are jurisdictions – British Columbia, Ontario, Nova Scotia, Prince Edward Island, and Yukon – that require an individualized assessment of capacity rather than using age to delineate rights.

²⁷² *Age of Majority Act*, R.S.N.W.T. 1988, c. A-2, s. 2; *Age of Majority Act*, R.S.N.W.T. (Nu.) 1988, c. A-2, s. 2 [*Age of Majority Act (Nu)*].

Secondly, two jurisdictions – British Columbia and New Brunswick – only permit minors to consent to treatment that is in their best interests, thereby explicitly incorporating the welfare principle into their respective statutory schemes. This means, however, that seven common law jurisdictions have expressly chosen not to impose a statutory best interest requirement and a further three others may or may not include the welfare principle under the common law mature minor rule.²⁷³ So, in the majority of provinces and territories, the welfare principle does not apply to medical decision-making by minors in circumstances where only consent to treatment legislation applies. If child protection legislation is triggered, even if there is no requirement to consider the minor’s best interest under consent to treatment legislation (or at common law where no consent to treatment legislation exists or applies), however, best interest must be considered.²⁷⁴ Consequently, in the case of research activities captured under consent to treatment legislation, minors have the same right to autonomous decision-making in the research realm as they do in the treatment context.

Thirdly, most jurisdictions have defined “treatment”, “medical treatment” or “health care”. In this regard, there is both different terminology (as in some jurisdictions define “treatment” or “medical treatment”²⁷⁵ while others define “health care”²⁷⁶) as well

²⁷³ Jurisdictions that make no mention of best interests under their statutory schemes are Saskatchewan, Manitoba, Ontario, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and Yukon. Jurisdictions with no legislation are Alberta, the Northwest Territories, and Nunavut. Interestingly, as noted earlier in this chapter, *C.(J.S.) v. Wren*, *supra* note 93 is a case decided based on the common law mature minor rule. That decision, which is admittedly dated, does not refer to best interests.

²⁷⁴ As noted in Ruth Sullivan, *Statutory Interpretation*, 2nd Ed. (Toronto: Irwin Law Inc., 2007) at 310, “in the event of a conflict between a specific provision dealing with a particular matter and a more general provision dealing with not only that matter but with others as well, the specific provision prevails”. Consent to treatment legislation provisions setting out the circumstances when a minor can consent to medical treatment are more general than child protection legislation provisions that allow for the apprehension of minors where refusal of treatment puts the life of the minor in jeopardy. Therefore, the latter class of provisions prevails over the former.

²⁷⁵ Jurisdictions defining “treatment” or “medical treatment” are Saskatchewan, Manitoba, Ontario, New Brunswick, and Prince Edward Island.

as what the definition of the chosen term states. The fact that not too much weight should be put on the specific term chosen by any legislature is aptly seen when one considers that British Columbia and Yukon define “health care” in the same way Manitoba and Ontario define “treatment”. Given that some legislatures have defined “treatment” and “health care” in much the same way, not much weight can be placed on a specific jurisdiction’s choice of term in determining if research activities are captured. However, when one looks at the substance of the definition, some of the definitions clearly capture some research activities. The phrase “health related purpose”, for example, is one way in which research activities are brought into the consent to treatment legislative regime. This notion must be reconciled with the general recognition that research and treatment are distinct entities.²⁷⁷ An attempt at such reconciliation is the framework proposed in Chapter 4 of this thesis.

C. Child Protection Legislation

Each provincial and territorial legislature has, whether intentionally or not, altered the common law mature minor rule, as that rule was defined earlier in this chapter, by enacting child protection legislation.²⁷⁸ As stated in the Nova Scotia *Children and Family Services Act*, the purposes underlying these statutes are to “protect children from

²⁷⁶ Jurisdictions defining “health care” are British Columbia and Yukon.

²⁷⁷ See discussion on distinguishing between research and treatment in Chapter 1.

²⁷⁸ *Child, Family and Community Service Act*, R.S.B.C. 1996, c. 46; *Child, Youth and Family Enhancement Act*, R.S.A. 2000, c. C-12; *Child and Family Services Act* (Saskatchewan), *supra* note 103; *Child and Family Services Act*, *supra* note 71; *Child and Family Services Act* (Ontario), *supra* note 101; *Family Services Act*, S.N.B. 1980, c. F-2.2; *Children and Family Services Act*, S.N.S. 1990, c. 5 [*Children and Family Services Act* (Nova Scotia)]; *Child Protection Act*, R.S.P.E.I. 1988, c. C-5.1; *Child, Youth and Family Services Act*, *supra* note 260; *Child and Family Services Act* (Yukon), *supra* note 270; *Child and Family Services Act*, S.N.W.T. 1997, c. 13 [*Child and Family Services Act* (NWT)]; *Child and Family Services Act*, S.N.W.T. 1997, c. 13, as duplicated for Nunavut by s. 29 of the *Nunavut Act*, S.C. 1993, c. 28 [*Child and Family Services Act* (Nunavut)].

harm, promote the integrity of the family and assure the best interests of children”.²⁷⁹ In striving to attain these ideals, child protection legislation governs a broad range of circumstances. That being said, only those provisions dealing with the role of minors in medical decision-making are discussed below. Also, given that there are twelve different statutes, unnecessary repetition has been avoided by discussing the three aspects that affect the applicability of these statutes to medical decision-making and medical research. The overall implications for research of these statutes are then set out.

(i) **Defining “Child”**

Given that these acts strive to “protect” children, arguably one of the most important provisions is how they have defined “child”. Interestingly, a review of the statutory definitions of “child” reveals that there exists considerable variation. Specifically, the statutes in force in the Saskatchewan, Ontario, Nova Scotia, Newfoundland and Labrador, Northwest Territories, and Nunavut define “child” as an individual below sixteen years of age.²⁸⁰ Alberta, Manitoba, and Prince Edward Island in turn, use eighteen years of age as the cut-off.²⁸¹ Finally, British Columbia, New Brunswick and the Yukon use nineteen years of age.²⁸²

Although some of this variation merely reflects the fact that the statutory age of majority varies between eighteen and nineteen years of age, it remains notable that nearly

²⁷⁹ *Children and Family Services Act* (Nova Scotia), *ibid.* at s. 2(1).

²⁸⁰ *Child and Family Services Act* (Saskatchewan), *supra* note 103, s. 2(1)(d); *Child and Family Services Act* (Ontario), *supra* note 101, s. 37(1); *Children and Family Services Act* (Nova Scotia), *supra* note 278, s. 3(1); *Children, Youth and Family Services Act*, *supra* note 260, s. 2(1)(d); *Child and Family Services Act* (NWT), *supra* note 278, s. 1; *Child and Family Services Act* (Nunavut), *supra* note 278, s. 1.

²⁸¹ *Child, Youth and Family Enhancement Act*, *supra* note 278, s. 1(1)(d); *Child and Family Services Act*, *supra* note 71, s. 1(1); *Age of Majority Act*, C.C.S.M. c. A7, s. 1 [*Age of Majority Act (Manitoba)*]; *Child Protection Act*, *supra* note 278, s. 1(h).

²⁸² *Child, Family and Community Service Act*, *supra* note 278, s. 1(1); *Family Services Act*, *supra* note 278, s. 1; *Age of Majority Act*, R.S.N.B. 1973, c. A-4, s. 1(1) [*Age of Majority Act (NB)*]; *Child and Family Services Act* (Yukon), *supra* note 270, s. 1.

half of the provinces and territories make it much harder if not impossible for authorities to force treatment on unwilling minors who are sixteen years of age and older. The conclusion flowing from this is that the legislatures in those jurisdictions felt that minors over the age of sixteen were in no more need of protection than adults. This point is raised at the outset of the discussion on the specific legislative provisions of child protection statutes because it casts doubt on one of the most often cited reasons for denying mature minors the right to consent to medical treatment; that being that they are vulnerable and are in need of protection.²⁸³ This means that, at least insofar as mature minors over the age of sixteen are concerned, there is a strong argument to be made that legislatures are prepared to presume that they need no more protection than adults and therefore should be allowed the right to consent to medical treatment unless there is sufficient evidence to rebut the presumption. The same logic applies to consent to research participation. This is not to say that there are not instances where individuals under the age of sixteen could be mature minors at common law and ought to also be afforded the right to consent to their own participation in research.

(ii) Defining “Health Care”

Not all medical treatment can be forced upon a “child”. Rather, each provincial and territorial legislature has opted to limit the degree of permissible interference with the rights of minors to those instances where the consequences of non-treatment are severe. Specifically, “health care” generally only includes medical, surgical, or other remedial

²⁸³ In the child protection context, the majority of the Supreme Court of Canada in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, were willing to accept that under the *Child and Family Services Act*, *supra* note 71, those minors who are sixteen and older were not subject to judicial override of their treatment decisions based on what was in their “best interest”.

services which are “essential”²⁸⁴ or “necessary”²⁸⁵ for the health or well-being of the child. Elsewhere, the “care or treatment” at issue must be required “to cure, prevent or alleviate physical harm or suffering.”²⁸⁶ For purposes of the present discussion, suffice it to say that the inter-jurisdictional variability as to how health care that can be forced upon minors is defined is more a matter of semantics than of one of substance.

As noted earlier, research consists of activities that are primarily aimed at generating generalizable knowledge. However, much like some activities could be carried out for a “health related purpose” under some consent to treatment statutes, some activities (not necessarily the same activities as under consent to treatment legislation) are medical, surgical or other remedial “care”. Specifically, although research carried out on healthy participants is unlikely to be captured, circumstances where the research participant may derive health benefits personally from participating would, in some circumstances, be found to be “care”.²⁸⁷ However, simply being “care” is not enough to trigger the application of child protection provisions. The research activities must also be “necessary” or “essential”. It is that criterion which greatly removes most, if not all research activities from the child protection realm. Stated differently, participation in

²⁸⁴ *Child, Youth and Family Enhancement Act*, *supra* note 278, s. 1(2.1)(b); *Child and Family Services Act* (Saskatchewan), *supra* note 103, s. 11(a)(iv); *Child, Youth and Family Services Act*, *supra* note 260, s. 14(g).

²⁸⁵ *Child, Family and Community Service Act*, *supra* note 278, s. 29(1); *Child and Family Services Act*, *supra* note 71, s. 17(2)(b)(iii); *Family Services Act*, *supra* note 278, s.31(1)(g); *Child and Family Services Act* (Yukon), *supra* note 270, s. 21(1)(g).

²⁸⁶ *Child and Family Services Act* (Ontario), *supra* note 101, s. 37(2)(e); *Children and Family Services Act* (Nova Scotia), *supra* note 278, s. 22(1)(e). Similar wording is also used in *Child Protection Act*, *supra* note 278, s. 9(o)-(p), *Child and Family Services Act* (NWT), *supra* note 278, s. 7(3)(n), and *Child and Family Services Act* (Nunavut), *supra* note 278, s. 7(3)(j).

²⁸⁷ I think this would be the case for those activities where the likelihood of participants deriving health benefits is thought to be quite high, or where a physician-researcher recommends participating in a research study over receiving the standard of care.

research is in all but the rarest of cases not “necessary” or “essential” because participants can opt to receive the standard of care or to do nothing.

(iii) Refusal of “Health Care”

Even where a minor meets the definition of “child” under the applicable act, state actors can only intervene with respect to medical treatment where the minor is in need of protection. Only two statutes include a minor’s refusal of health care as a ground for finding that the child is in need of protective services: British Columbia’s *Child, Family and Community Services Act* and the Yukon’s *Child and Family Services Act*.²⁸⁸ In all ten other common law jurisdictions in Canada, the need for protective services is only triggered when a parent, guardian, or other caregiver fails to provide a child with certain health care.²⁸⁹ Stated differently, the statutory provisions in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, the Northwest Territories, and Nunavut do not consider the possibility that consent may be sought from only a minor (whether they are a “child” or not) rather than a parent. Under those statutes, parental consent is seen as necessary.

(iv) Implications for Research

Ultimately then, in ten jurisdictions in Canada child protection statutes have little effect on the right of minors to autonomous decision-making under consent to treatment legislation or the common law mature minor rule because they only apply where a parent

²⁸⁸ *Child, Family and Community Service Act*, *supra* note 278, s. 29(1); *Child and Family Services Act* (Yukon), *supra* note 270, s. 33(1).

²⁸⁹ *Child, Youth and Family Enhancement Act*, *supra* note 278 at s. 1(2.1)(b); *Child, Youth and Family Services Act*, *supra* note 260 at s. 14(g); *Child and Family Services Act* (Saskatchewan), *supra* note 103, s. 11(a)(iv); *Child and Family Services Act*, *supra* note 71, s. 17(2)(b)(iii); *Child and Family Services Act* (Ontario), *supra* note 101, s. 37(2)(e); *Family Services Act*, *supra* note 278, s. 31(1)(g); *Children and Family Services Act* (Nova Scotia), *supra* note 278, s. 22(1)(e); *Child Protection Act*, *supra* note 278, s. 3(h); *Child and Family Services Act* (NWT), *supra* note 278, s. 7(3)(n); *Child and Family Services Act* (Nunavut), *supra* note 278 at s. 7(3)(j).

refuses to provide necessary care. Stated differently, in those ten jurisdictions, the statute does not apply to instances where consent is only sought from a minor where that care is not necessary. The fact that most child protection statutes only apply in such limited circumstances to medical treatment decisions and that the circumstances in which those statutes apply to research are even narrower facilitates the development of a framework defining the right to autonomous decision-making possessed by minors in the research realm.

D. Quebec Instruments

Quebec is a civil law jurisdiction, which means that all laws pertaining to matters falling to the provinces and territories under the division of powers are contained within the *Civil Code of Québec*. This means that, unlike all other provinces and territories in Canada which operate under a common law regime, the law of Quebec does not evolve by means of jurisprudential developments. As one author has put it, this means that a judge in Quebec “applies the law rather than creates it”²⁹⁰. It is also generally accepted that cases arising from common law jurisdictions are only relevant where the principles underlying the courts’ reasoning are also recognized under civil law.²⁹¹ Consequently, in order to understand the role – both present and potential – of mature minors in research in Quebec, it is necessary to examine the relevant articles of the *Civil Code of Québec*. To this end, the articles that address medical treatment and participation in research are as follows:

²⁹⁰ Robert Kouri & Suzanne Philips-Nootens, “Civil Liability of Physicians Under Quebec Law” in Jocelyn Downie, Timothy Caulfield, & Colleen M. Flood, eds., eds., *Canadian Health Law and Policy*, 3rd ed. (Markham: LexisNexis Canada Inc., 2007) 133 at 133 [Kouri & Philips-Nootens, “Civil Liability”].

²⁹¹ *Ibid.* at 133-134.

11.No person may be made to undergo care of any nature, whether for examination, specimen taking, removal of tissue, treatment, or any other act, **except with his consent.**

If the person concerned is incapable of giving or refusing his consent to care, a person authorized by law or by mandate given in anticipation of his incapacity may do so in his place.

12.A person who gives consent to or refuses care for another person is **bound to act in the sole interest of that person,** taking into account, as far as possible, any wishes the latter may have expressed.

If he gives his consent, he shall **ensure that the care is beneficial notwithstanding the gravity and permanence of certain of its effects, that it is advisable in the circumstances and that the risks incurred are not disproportionate to the anticipated benefits.**

...

14.Consent to care required by the state of health of a minor is given by the person having parental authority or by his tutor.

A minor 14 years of age or over, however, may give his consent alone to such care. If his state requires that he remain in a health or social services establishment for over 12 hours, the person having parental authority or tutor shall be informed of that fact.

...

17.A minor 14 years of age or over may give his consent alone to care not required by the state of his health; however, the consent of the person having parental authority or of the tutor is required if the care entails a serious risk for the health of the minor and may cause him grave and permanent effects.

...

21.A minor or a person of full age who is incapable of giving consent may not be submitted to an experiment if the experiment involves serious risk to his health or, where he understands the nature and consequences of the experiment, if he objects.

Moreover, **a minor** or a person of full age who is incapable of giving consent **may be submitted to an experiment only if, where the person is the only subject of the experiment, it has the potential to produce benefit to the person's health or only if, in the case of an experiment on a group, it has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap. Such an experiment must be part of a research project approved and monitored by an ethics committee.** The competent ethics committees are formed by the Minister of Health and Social Services or designated by that Minister among existing research ethics committees; the composition and operating conditions of the committees are determined by the Minister and published in the Gazette officielle du Québec.

Consent to experimentation may be given, in the case of a minor, by the person having parental authority or the tutor and, in the case of a person of full age incapable of giving consent, by the mandatary, tutor or curator. Where a person of full age suddenly becomes incapable of consent and the experiment, insofar as it must be undertaken promptly after the appearance of the condition giving rise to it, does not permit, for lack of time, the designation of a legal representative, consent may be given by the person authorized to consent to any care the person requires; it is incumbent upon the competent ethics committee to determine, when examining the research project, whether the experiment meets that condition.

Care considered by the ethics committee to be **innovative care required by the state of health of the person concerned does not constitute an experiment.**

...

33. Every decision concerning a child shall be taken in light of the **child's interests** and the respect of his rights.

Consideration is given, in addition to the moral, intellectual, emotional and physical needs of the child, to the child's age, health, personality and family environment, and to the other aspects of his situation. [Emphasis added]²⁹²

²⁹² *Supra* note 112, art. 11-12, 14, 17, 21, 33.

From the above provisions of the *Civil Code of Québec*, it is possible to draw several general conclusions. Firstly, minors over the age of 14 may consent to medical treatment, whether or not such treatment is required by their “state of health”. The only limitation on this relates to treatment not required due to a health condition that exposes the minor to serious risk and that may cause “grave and permanent effects”.²⁹³

Secondly, in a number of the articles cited above, fourteen years of age has been chosen as the age beyond which a minor can potentially be the sole individual to consent to treatment. When those articles are read in conjunction with article 11, it is clear that they should be interpreted as creating a rebuttable presumption of capacity. Stated differently, even if a minor is more than fourteen years old, if she lacks capacity, she cannot provide legally valid consent. Essentially then, minors over the age of fourteen are treated in the same manner as adults. No justification is given in the *Civil Code of Québec* for why fourteen years of age was chosen, though the choice appears to have been driven by a political compromise.²⁹⁴ The result of this arbitrary use of a fixed-age cut-off is two-fold. At first instance, the use of a fixed-age cut-off ignores the fact that minors of the same chronological age may have attained quite different levels of maturity. This directly contradicts the foundation of the mature minor rule at common law. The second consequence is that it assumes (although the assumption is rebuttable) that upon reaching 14 years of age, a minor is able to consent to all forms of medical treatment except that entailing a serious risk or severe consequences in cases of “care that

²⁹³ *Ibid.*, art. 14, 17.

²⁹⁴ Kouri & Philips-Nootens, “Civil Liability”, *supra* note 290 at 161. See also R. Kouri & S. Philips-Nootens, *Le corps humain, l’inviolabilité de la personne et le consentement aux soins* (Sherbrooke: Les Éditions RDUS, 1999) at 407 n0 292 *et seq* for further discussion on how the precise wording of articles 14 and 21 came to be passed by the Quebec legislature.

is not required by state of health”.²⁹⁵ Not only do all 14 year olds not demonstrate the same maturity, not all medical treatment is created equal. That is, some forms of treatment are minimally invasive while others are complex and are carried out over an extended period of time. Intuitively, one would expect a more sophisticated understanding to be required in order to consent to a more complex treatment.

Thirdly, and more germane to the role of mature minors in the research context, are the implications of article 21. In one sense, the *Civil Code of Québec* explicitly mandates greater involvement of minors in the research context than seen at common law by precluding that minor’s participation where she dissents.²⁹⁶ In order for such dissent to be respected, the minor must demonstrate an understanding of the “nature and consequences of the experiment”. It is interesting that the drafters would choose phraseology similar to that used in common law jurisdictions under the mature minor rule in the treatment context. It is equally striking that in the research context, minors need to show an appropriate level of understanding rather than merely having attained a specific age threshold. The result is that in Quebec, minors have a legislated right to dissent but can never consent to their own participation.

This is precisely the interpretation of article 21 that has been adopted in practice and that is endorsed by the ministère de la Santé et des Services Sociaux in a guide on research ethics disseminated amongst the research community.²⁹⁷ Despite the fact that all research involving minors carried out in Quebec is generally considered to be an

²⁹⁵ *Civil Code of Québec*, *supra* note 112, art. 17. The restriction on a minor over the age of fourteen providing consent seems quite narrow.

²⁹⁶ This is not recognized in legislation or jurisprudence emanating from any common law jurisdiction. It is, however, included in the *Tri-Council Policy Statement*, *supra* note 1, which applies nationally.

²⁹⁷ Franca Cantini *et al.*, “Formation en éthique de la recherche, Niveau 3 – Module 3.2, Questions pertinentes à certains types de participants à la recherche: enfants, majeurs inaptes et personnes en situation de vulnérabilité” (2004) at 16, online: Unité d’éthique, ministère de la Santé et des Services Sociaux <<http://ethique.msss.gouv.qc.ca/>>.

“experiment”, thereby bringing it under the ambit of article 21, Lévesque has argued that this need not be the case.²⁹⁸ Rather, she claims that only research projects that (1) affect bodily integrity and that (2) are “experiments” are captured under article 21.²⁹⁹

Lévesque’s argument is largely based on the fact that the term “experiment” is not defined in the *Civil Code of Québec* and is therefore open to interpretation. She goes on to note that article 21 falls under the heading of “Care” as well as refers to both “experiment” and “research project”. She takes the latter distinction to mean that “research project” is the broader of the two terms and as such that not all “research projects” are “experiments”.³⁰⁰

The major flaw with this argument is that Lévesque seems to be trying to carve out a third category; notably she appears to be saying that the real distinction ought to be between “research,” “treatment,” and “experiment” rather than the currently recognized “treatment” versus “research” dichotomy.³⁰¹ Her proposal ignores the reality of the medical research context. Specifically, time and resource constraints as well as a general lack of expertise in the law make it extremely unlikely that researchers and research ethics boards will embark upon a rather cumbersome exercise of distinguishing between “research” and “experiment”. Rather, they are merely likely to seek parental consent. Even if one assumes that judges would be able to appropriately distinguish between “treatment”, “research” and “experiment”, the availability of judicial review of the decisions made by the research community would do little to repair the beleaguered

²⁹⁸ Emmanuelle Lévesque, “Les exigences légales entourant le consentement dans la recherche avec des enfants et des adultes inaptes: une piste de solution aux difficultés posées par les articles 21 et 24 C.c.Q.” (2005-2006) 51 McGill L.J. 385 at 389.

²⁹⁹ *Ibid.* at 404.

³⁰⁰ *Ibid.* at 391, 398.

³⁰¹ Different meanings have been ascribed to “treatment” and “research” by the courts. Although none of those cases emanate from Quebec, it is highly likely that such precedents would be considered by a Quebec court when asked to interpret the rights of mature minors under article 21.

rights of mature minors as it is often too late to alter the course of events by the time the matter reaches the courts.³⁰²

The above concerns about Lévesque's argument should not be taken to mean that it should merely be assumed that parental consent is a *de facto* requirement for the participation of minors in medical research in Quebec. A strict interpretation of article 21 of the *Civil Code of Québec* precludes minors, be they immature or mature minors, from consenting to their own participation in medical research studies. Also, given the ability of mature minors to dissent to research participation as well as the distinction that has been drawn between research and innovative care in the *Civil Code of Québec*, some aspects of the framework proposed in Chapter 4 may nonetheless be applicable. Furthermore, it remains possible that in the right political atmosphere, amendments may be made to the *Civil Code of Québec* so as to allow mature minors to acquire the same rights as those proposed in this thesis for their peers living in other Canadian jurisdictions.

V. CONCLUSION

The above examination reveals that there are a significant number of legal instruments that speak to the ability of mature minors to make decisions that affect their

³⁰² Having found Lévesque's argument far from compelling, it is unnecessary to embark upon a lengthy analysis of the second criterion for exclusion from the ambit of article 21 she sets out, which deals with the effects on bodily integrity brought about through participation in research. My problem with that criterion is that it erroneously assumes that serious risk to health necessarily gives rise to a violation of one's bodily integrity. In *Quebec (Public Curator) v. Syndicat national des employés de l'hôpital St-Ferdinand*, [1996] 3 S.C.R. 211 at para. 97, Justice L'Heureux-Dube, on behalf of the Court, remarked that "common meaning of the word "inviolability" suggests that the interference with that right must leave some marks, some sequelae which, while not necessarily physical or permanent, exceed a certain threshold. The interference must affect the victim's physical, psychological or emotional equilibrium in something more than a fleeting manner." Obviously, not all research participation amounts to a violation of right to personal inviolability guaranteed under section 1 of the *Charter of Rights and Freedoms*, *supra* note 64.

persons, both physically and emotionally. The international and national instruments apply to minors residing in all Canadian provinces and territories, thereby ensuring a certain degree of uniformity. At common law, mature minors who wish to participate in medical research are entitled to consent, whether their participation is in their best interests or not. However, once one delves into areas under provincial territorial jurisdiction, it becomes evident that there are considerable differences in how minors are treated across Canada. Whereas some jurisdictions have consent to treatment legislation, others do not. The content of the legislation where it exists is also variable, with some setting a presumptive age of capacity at sixteen and others relying on individualized capacity assessments. Some legislative enactments restrict consent to circumstances where the treatment is in a minor's best interest and some statutes do not. Child protection legislation also varies between jurisdictions in how "child" is defined and how the effect of a refusing treatment is handled. Finally, the regime in Quebec is altogether different from that seen elsewhere and outright precludes minors from consenting to their own research participation. Beyond directly determining the rights of mature minors, many of these legal instruments also inform ethical instruments. The latter category of instruments is examined in the next chapter.

CHAPTER 3

ETHICAL INSTRUMENTS AND PRINCIPLES

I. INTRODUCTION

It is widely accepted that research must be conducted in accordance with applicable laws and ethical requirements.³⁰³ Having examined the legal constraints on the ability of mature minors to be the sole decision-makers in the previous chapter, the focus now shifts to the ethical principles and guidelines that govern medical research in Canada. Prior to looking at specific instruments and principles, it is necessary to briefly explore the different origins of law and ethics as well as how these two spheres relate to each other.

Legal and ethical instruments originated in different ways. The various statutes and quasi-legal instruments discussed in Chapter 2 were passed (or adopted) by Federal, Provincial and Territorial governments. The ethical instruments relevant to the issue of minors and consent to research participation, on the other hand, largely emanate from international bodies, such as the World Medical Association, and from other federal non-government bodies. There are two instruments falling into the latter category that guide most research involving humans in Canada: the *Declaration of Helsinki* and the *Tri-*

³⁰³ Precisely what activities or actions will be in “accordance with applicable laws and ethical requirements” will vary since, as is evident from the discussion in Chapter 2, the law differs between jurisdictions.

Council Policy Statement. General ethical principles, in turn, can be found within a formal document. They are also widely discussed in the academic literature and other secondary sources, which allow them to evolve in response to changing societal views.

The purpose underlying each of law and ethics is also different. Specifically, the law dealing with consent is primarily concerned with discerning if a physician (or researcher, although as noted in the previous chapter, there are few research cases) acted negligently, committed battery, or is guilty of professional misconduct. Medical ethics, in turn, involves deriving moral obligations that apply to a broad range of circumstances. It also is more responsive because the principles are continually refined through ongoing dialogue in the literature.³⁰⁴ Stated differently, the law is about setting the minimum basic parameters for acceptable conduct while medical ethics seeks to establish standards for “good” conduct.

This different evolutionary justification, along with the fact that legal and ethical instruments are passed at different times by different bodies, means that the two are not always reconcilable with one another. Although such conflicts may not be avoidable, it is desirable to minimize them and look for solutions where both legal and ethical norms can be upheld. Despite the aforementioned differences between law and ethics, there remains a similarity between the two concepts that goes to the heart of this thesis: the

³⁰⁴ Tom L. Beauchamp, “Informed Consent: Its History and Meaning”, in Tom L. Beauchamp, ed., *Standing on Principles: Collected Essays* (Toronto: Oxford University Press, 2010) 50 at 66-68. See also P.A. Komesaroff, “The Relationship between Law and Ethics in Medicine” (2001) 31 *Internal Medicine Journal* 413.

legal notion of competence and autonomy as an ethical principle. They are evaluated based on essentially the same criteria.³⁰⁵

With the above comments in mind, I now turn to the ethical instruments and principles. Unlike in Chapter 2 where the discussion was divided according to origin of the law (i.e. international, national, and provincial/territorial), the commentary below first provides a brief overview of existing ethical instruments and their origins. That is followed by a review of the literature on the three ethical concepts that are most engaged with regards to the consent process in medical research involving mature minors: autonomy and paternalism³⁰⁶ (which together make up respect for persons) and vulnerability. How these concepts have been incorporated into existing ethical instruments – the *Nuremberg Code*³⁰⁷, the *Declaration of Helsinki*, the *ICH GCP*, the *ICH CIMPPP*, and the *Tri-Council Policy Statement* – is then discussed.

II. OVERVIEW OF THE ETHICAL INSTRUMENTS

In order to properly understand how ethics informs the consent process in medical research involving minors, it is necessary to have a working understanding of how the ethical instruments that apply to the pediatric research setting in Canada have come to be and the limits on each of their spheres of applicability. To that end, a brief overview of how the *Nuremberg Code*, the *Declaration of Helsinki*, the *Tri-Council Policy Statement*,

³⁰⁵ Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics*, 6th ed., (Toronto: Oxford University Press, 2009) at 113 [Beauchamp & Childress].

³⁰⁶ As is discussed in the section on paternalism below, paternalism is not necessarily (and in fact is not according to the manner in which I have defined it in the present case) used as a disparaging term. I have chosen to use it rather than beneficence (which is also briefly discussed below) because at the heart of the issue in the consent process is the actions of researchers. Consequently, the ethical implications extend beyond a moral obligation (the term) to the intentional acts of researchers.

³⁰⁷ U.S. National Institutes of Health, Office of Human Subjects Research, *Nuremberg Code: Directives for Human Experimentation*, online: < <http://ohsr.od.nih.gov/guidelines/nuremberg.html> > [Nuremberg Code].

the *ICH GCP*, the *ICH CIMPPP* is detailed in this section. Then, following a discussion of the concepts of autonomy, paternalism, and vulnerability, the specific provisions that speak to capacity and the limits on a minor's ability to consent are set out.

A. **The Nuremberg Code**

Throughout the 1930s and 1940s, a number of physicians and public health officials were tried in Germany after they committed many horrific crimes against war-time prisoners by conducting a number of experiments on the prisoners without their consent.³⁰⁸ Ultimately, these prosecutions led to the creation of the *Nuremberg Code* in 1947. Although there were a number of lesser known documents that preceded the *Nuremberg Code*, the latter is widely considered to be the first set of ethical guidelines on human experimentation.³⁰⁹ The development of the *Nuremberg Code* marked the start of the process of ethical regulation of research on human subjects which continues to evolve today. Although it only considers the participation of individuals with legal capacity, it nonetheless is worth briefly discussing the *Nuremberg Code* as it helped to shape the *Declaration of Helsinki* and other modern ethics frameworks. To this end, it states at paragraph 1:

The voluntary consent of the human subject is absolutely essential.

This means that the **person involved should have legal capacity to give consent**; should be so situated as to be able to exercise free power of choice, without the intervention of any element of

³⁰⁸ J. Vollmann & R. Winau, "Nuremberg Doctors' Trial: Informed Consent in Human Experimentation before the Nuremberg Code" (1996) 313 B.M.J. 1445 at 1445.

³⁰⁹ See *ibid.* for a discussion on a non-legally binding directive concerning non-therapeutic research issued by the Prussian minister for religious, educational, and medical affairs issued in 1900. The authors note that much of the discussion prior to that directive being issued focused on the concepts of beneficence, autonomy, and the requirement for informed consent. Interestingly, over a hundred years later, these topics remain at the heart of many debates in research ethics.

force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconvenience and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment... [Emphasis added]³¹⁰

The reference to “legal capacity” in the above citation is significant in that it creates a direct link between ethical requirements and the law in the conduct of research involving humans. As discussed in greater depth below, ethical guidelines have since distinguished themselves somewhat from the law by specifying parameters that are to be read in conjunction with the applicable laws rather than merely relying on legal standards.

B. The *Declaration of Helsinki*

The *Declaration of Helsinki* was developed by the World Medical Association in 1964. Since that time, it has undergone a number of revisions, most recently in October 2008. As can be gleaned from the discussion below, this most recent amendment included a number of changes that are quite significant with respect to defining the potential role of minors in the research process. As this document applies to all forms of human experimentation, much of its contents are not strictly relevant to the consent process. That being said, prior to examining those relevant sections of the *Declaration of*

³¹⁰ *Supra* note 307 at para. 1.

Helsinki it is worth briefly considering how it fits into our national legal and ethical landscape.

As it applies to research carried out in a large number of countries, including Canada, the *Declaration of Helsinki* must necessarily be flexible enough so as to be adaptable to different cultural settings while still safeguarding the basic rights of research subjects. The World Medical Association has stated in paragraph 10 of the *Declaration of Helsinki* that this balance is best achieved by informing researchers of the need to be aware of applicable “ethical, legal and regulatory norms and standards...in their own countries”³¹¹, however, it then goes on to state that those norms and standards should not “reduce or eliminate any of the protections for research subjects set forth in this Declaration.”³¹² From a strictly legal standpoint, only failure to comply with relevant laws can result in legal sanctions. Therefore, unless the *Declaration of Helsinki* has been incorporated into applicable law, failure to comply with all of its protections will not result in legal repercussions for researchers nor is there a requirement imposed on legislatures to draft laws that are consistent with it (or any other ethical standard). However, where the law is somewhat vague or ambiguous, courts may (but need not) look to this and other ethical frameworks for guidance.³¹³

³¹¹ *Supra* note 41 at para. 10.

³¹² *Ibid.*

³¹³ This occurred in *Weiss v. Solomon* (1989), 48 C.C.L.T. 280, 1989 CarswellQue 72, where the Quebec Superior Court relied on article 6 of the Declaration of Helsinki (as well as other sources) to hold that the right of research subjects to protect their own bodily integrity must be respected by ensuring that informed consent is only given after potential risks have been disclosed. That case involved determining whether a physician had fulfilled his duty of care with regards to disclosure of the risk of research participation to a research subject who would not derive any direct benefit from participation. The physician and hospital were ultimately found liable.

C. The Medical Research Council Guidelines

In 1978, the *MRC Report No. 6, Ethics in Human Experimentation*³¹⁴ became the first medical research guidelines in Canada. The Medical Research Council subsequently replaced those guidelines with the *Guidelines on Research Involving Human Research Subjects*³¹⁵ in 1987. The stated purpose of the latter was “to sensitize and guide decision makers on the range of perceptions they should bring to bear and to describe the processes of decision making that must be observed.”³¹⁶ Compliance with the Guidelines was mandatory for all those in receipt of funding from the Medical Research Council.³¹⁷

D. The Tri-Council Policy Statement

The need for revisions to the Medical Research Council’s 1987 Guidelines emerged within only a couple of years of the Guidelines being in place. By the early 1990s, there was a real push towards the development of a single set of ethical guidelines to govern medical as well as social science and humanities research in Canada was gaining popularity amongst all stakeholders. The reasons underlying this need for change are many, including the significant increase in volume of research being carried out, the increase in interdisciplinary research that transcended the CIHR/SSHRC divide and the emergency of local human research protection policies that were being developed by individual institutions.³¹⁸ It is for that reason that in 1994 the presidents of the CIHR,

³¹⁴ No separate reference could be located for this report. However, this is the title given to it at page xi in Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Medical Research Council of Canada, 1987).

³¹⁵ *Guidelines on Research Involving Human Subjects, ibid.*

³¹⁶ *Ibid.* at xi.

³¹⁷ *Ibid.* at iii.

³¹⁸ Michael McDonald, “From Code to Policy Statement: Creating Canadian Policy for Ethical Research Involving Humans” (2009) 17(2-3) *Health Law Review* 12 at 13-14; Guy Rocher, “Origin and Development of the *Tri-Council Policy Statement* on the Ethics of Research Involving Humans” (1999) 9(2) *NCEHR Communiqué* 4.

NSERC, and SSHRC set up a working group to develop these guidelines. The process was not without its challenges but, after four years and four successive published draft versions of the guidelines and extensive consultation with the academic community throughout, the *Tri-Council Policy Statement (1998)*³¹⁹ became official.³²⁰ The *Declaration of Helsinki* had guided medical research in Canada prior to 1998.

From its inception, the *Tri-Council Policy Statement (1998)* was intended to be continually revised so as to ensure that it kept pace with developing technologies and societal views about different aspects of research. To this end, the Interagency Advisory Panel on Research Ethics was created by the three funding agencies in 2001. Since that time, this body set up a number of working groups to look into certain key areas covered by the *Tri-Council Policy Statement (1998)*. Reports from these working groups became publicly available in 2008. Following extensive consultation with interested parties, the second edition of the *Tri-Council Policy Statement* was released in December 2010.

The CIHR, NSERC, and SSHRC are three sources of research funding in Canada. In 2007-2008, CIHR awarded approximately \$975,000,000. This includes funding for 816 of the 3,625 operating grant applications submitted (i.e. less than one quarter). Similarly, NSERC's budget for 2008-2009 was approximately \$1,000,000,000.³²¹ SSHRC awarded approximately \$77,000,000 (twenty-three percent of funds requested), which amount includes funding for 904 of the 2,731 applications submitted (i.e.

³¹⁹ Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998* (with 2000, 2002, 2005 amendments), online: <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf> [*Tri-Council Policy Statement (1998)*]

³²⁰ Rocher, *supra* note 318.

³²¹ Canada Research Funding, "Federal Funding", online: <[http://canadaresearchfunding.org/federal-funding/](http://canadaresearchfunding.org/federal-funding/federal-funding/)>.

approximately one third).³²² The pharmaceutical industry also funds research in Canada. Notably, according to the Patented Medicine Prices Review Board, in 2005 companies holding drug patents spent approximately \$567,000,000 on clinical trials (out of \$1,187,000,000 spent on research and development).³²³

Under the Statement, all investigators conducting research at institutions receiving funding from CIHR, NSERC, or SSHRC must abide by the requirements set out therein.³²⁴ Based on the above figures, there is clearly a considerable amount of research being carried out in Canada that is not funded by CIHR, NSERC, or SSHRC. The *Tri-Council Policy Statement* also applies to some of that research by means of a reach-through provision. Specifically, as is explicitly welcomed by CIHR, NSERC, and SSHRC in the *Tri-Council Policy Statement*, bodies regulating researchers who do not work at institutions that receive funds from the Agencies and therefore fall outside the reach of the *Tri-Council Policy Statement* can choose to mandate compliance as a precondition to receiving funding from that body. To date, this has been done by a number of organizations, including Health Canada, the National Research Council, and the Community Research Ethics Board of Alberta.³²⁵ This results in the *Tri-Council Policy Statement* being the most persuasive statement on the ethics of research involving humans in Canada.

³²² Social Sciences and Humanities Research Council of Canada, “Competition Statistics: 2008-2009”, online: <<http://www.sshrc-crsh.gc.ca/results-resultats/stats-statistiques/index-eng.aspx>>.

³²³ Patented Medicine Prices Review Board, *Patented Medicine Prices Review Board: Annual Report 2005*, online: <<http://www.pmprb-cepmb.gc.ca/english/view.asp?x=667&all=true>>.

³²⁴ *Tri-Council Policy Statement*, *supra* note 1.

³²⁵ Government of Canada, Panel on Research Ethics, “Applicability of the TCPS to Agency-Funded Organizations as well as those not Funded by the Agencies”, online: <<http://pre.ethics.gc.ca/eng/policy-politique/tcps-eptc/interpretations/interpretation011/>>; Alberta Heritage Foundation for Medical Research, online <<http://www.ahfmr.ab.ca/creba/creba.php>>.

Given that this document is not binding legislation, the legal consequences for breaches of its ethical guidelines are limited. The possible penalties for failure to abide by the *Tri-Council Policy Statement* (and therefore breaching a Memorandum of Understanding) by an individual researcher include the loss or suspension of funding and the obligation to return all funds paid to date under a grant. Where the breach of the Memorandum of Understanding is by an institution, penalties include the suspension of funding and a declaration that the institute is not eligible for further funding.³²⁶ Since 2000, there have been eighty-four allegations of non-compliance with Tri-Agency policies, of which twelve were related to matters associated to the *Tri-Council Policy Statement*. None of these twelve allegations led to any funding actions being imposed by CIHR. It is unknown if any of the twelve allegations led to researchers being sanctioned by their own institution.³²⁷

E. The *ICH GCP* and The *ICH CIMPPP*

The *International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use* has released a series of statements that speak to the use of pharmaceutical products. The two most relevant such statements to this thesis are the *ICH GCP* and the *ICH CIMPPP*. Both have made their way into the Canadian ethical landscape, albeit in different ways.

Firstly, the *ICH GCP* was adopted in 1997 by Health Canada as a means of providing “assistance to industry and health professionals on how to comply with the

³²⁶ Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Agency Process for Addressing Allegations of Non-Compliance with Tri-Agency Policies* (2010), online: <http://www.nserc-crsng.gc.ca/NSERC-CRSNG/governance-gouvernance/process-processus_eng.asp>.

³²⁷ Canadian Institutes of Health Research, *CIHR Research Integrity Files: Report on allegations of non-compliance with Tri-Agency policies (fiscal 2000/01-2009/10)* (Updated May 11, 2010), online: <<http://www.cihr-irsc.gc.ca/e/29073.html>>.

policies and governing statutes and regulation”.³²⁸ The *ICH GCP* defines informed consent as “a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.”³²⁹ It also includes minors in the definition of “vulnerable subjects”.³³⁰

Secondly, in 2003 Health Canada adopted the *ICH CIMPPP*. This guidance document aims to “encourage and facilitate timely pediatric medicinal product development internationally.”³³¹ As is evident from its title, the *ICH CIMPPP* only applies to research involving minors.

III. ETHICAL CONCEPTS: AUTONOMY, PATERNALISM, & VULNERABILITY

The predominant ethical principle that governs how minors ought to be treated in the consent process is the principle known as respect for persons.³³² This broad principle includes two distinct requirements: the need to respect the autonomy of autonomous agents and the need to protect those with “developing, impaired, or diminished autonomy”.³³³ In light of these dual requirements, it is necessary to consider how it is

³²⁸ Canada, Health Canada, *Guidance for Industry – Good Clinical Practice: Consolidated Guideline (ICH Topic E6)* (Ottawa: Health Canada – Publications, 1997) at foreword. See e.g. *Food and Drug Regulations*, *supra* note 18, ss. C.05.001, C.05.012 for references to “good clinical practices”.

³²⁹ *ICH GCP*, *supra* note 55 at para. 1.28.

³³⁰ *Ibid.* at para. 1.61. The inclusion of minors in the definition of “vulnerable subjects” is discussed further below.

³³¹ *ICH CMPPP*, *supra* note 56 at para. 1.1.

³³² *Tri-Council Policy Statement (1998)*, *supra* note 319 at i.5; *Belmont Report*, *supra* note 32 at 4, 6. Although the principle of respect for persons remains central to the framework outlined in the *Tri-Council Policy Statement*, *supra* note 1, based on art. 1.1 and the introduction to Chapter 3 thereof, it is clear that respect for persons must now be considered in conjunction with two other principles – concern for welfare and justice – in issues of consent.

³³³ *Tri-Council Policy Statement*, *ibid.* at art. 1.1 and accompanying commentary.

determined whether a minor involved in medical research will be afforded the right to decide if she wants to participate. There is no one answer to this question as the answer ultimately depends on the capacity of the particular minor to consent to a specific research study. For that reason, this section contains a discussion of how the concepts of autonomy and beneficence have been applied to mature minors generally as well as how those concepts are informed by the notion of vulnerability.

A. Autonomy

There is considerable debate as to precisely what constitutes autonomy. On the one-hand, there is the traditional conception of autonomy that recognizes that individuals have a right to their own views and a right to have those views respected unless doing so will cause harm to others.³³⁴ Authors subscribing to this liberal individualistic conception of autonomy focus either on choice or on whether a person is autonomous.³³⁵ This is evident from the manner it has been defined in the literature and in the instruments discussed in this chapter. For example, Beauchamp and Childress remark that it “is behaviour which is governed by plans of action more or less clearly formulated through deliberation” and autonomous behaviour flows from intentional and voluntary “choices persons make based upon their own life plans.”³³⁶ Conversely, the authors of the *Tri-Council Policy Statement* have focused on whether a person is autonomous by defining autonomy as:

...the ability to deliberate about a decision and to act based on that deliberation. Respecting autonomy means giving due deference

³³⁴ Beauchamp & Childress, *supra* note 305 at 58.

³³⁵ Tom L. Beauchamp, “Who Deserves Autonomy and Whose Autonomy Deserves Respect” in Beauchamp, *supra* note 304, 79 at 80.

³³⁶ Terrence F. Ackerman, “Medical Ethics and the Two Dogmas of Liberalism” (1984) 5 *Theoretical Medicine* 69 at 70.

to a person's judgment and ensuring that the person is free to choose without interference. Autonomy is not exercised in isolation but is influenced by a person's various connections to family, to community, and to cultural, social, linguistic, religious and other groups. Likewise, a person's decisions can have an impact on any of these connections.³³⁷

It is similarly described in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's 1979 *Belmont Report*, which is the ethics guidance document that applies in the United States of America. It describes an autonomous person as "an individual capable of deliberation about personal goals and of acting under the direction of such deliberation."³³⁸

In recent years, the highly individualistic conception of autonomy has been criticized and other formulations of the concept have emerged. One such conception is known as "relational autonomy". According to the latter, when determining if an individual is capable of autonomous choice, consideration needs to be had to the social context in which that individual finds herself.³³⁹ Subscribers to the notion of relational autonomy seek solutions that adequately recognize that autonomy evolves within an individual as a result of social relationships and is shaped by a variety of social determinants, including age, gender, class, race, and ethnicity.³⁴⁰

For purposes of this thesis, I have adopted a liberal individualistic conception of autonomy. Although such a definition of autonomy has been criticized, it nonetheless remains the conception explicitly endorsed in Canadian public policy generally, and in

³³⁷ *Supra* note 1 at 8.

³³⁸ *Belmont Report*, *supra* note 32 at 4.

³³⁹ Carolyn McLeod & Susan Sherwin, "Relational Autonomy, Self-Trust, and Health Care For Patients Who Are Oppressed" in Catriona Mackenzie & Natalie Stoljar, eds., *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Shelf* (Toronto: Oxford University Press, 2000) 259 at 259-260 [Mackenzie & Stoljar].

³⁴⁰ Catriona Mackenzie & Natalie Stoljar, "Introduction" in Mackenzie & Stoljar, *ibid.*, 3 at 3-5.

ethical instruments governing medical research in Canada. Furthermore, I have chosen to focus the discussion on ‘autonomous choice’ rather than on whether a particular individual is an ‘autonomous person’. This is because an individual need not prove herself to be an autonomous person generally to be entitled to decide whether or not she will participate in a particular research study. Rather, she needs to establish that she is capable of making a specific choice – whether she possesses the requisite autonomy to make any number of other life choices is largely irrelevant.³⁴¹

In relation to minors specifically, autonomy raises two pragmatic questions. The first such question is what is required of minors in order for them to be deemed able to make autonomous choices? Some authors have questioned if decision-making capacity is in itself sufficient for autonomous medical decision-making. For example, Ross has argued that although decision-making capacity “is necessary and sufficient for adults”, it is “necessary but not sufficient” in the case of adolescents.³⁴² He does not specify precisely what additional traits or characteristics adolescents must possess in order to be entitled to make autonomous decisions. According to Foreman, another author, what is lacking is social independence.³⁴³

Requiring something more than capacity before an individual is capable of autonomous decision-making solely because they fall below a legislated age of majority

³⁴¹ She must, as is discussed further below, also maintain capacity throughout the study. As well, I say that her ability to make other decisions is “largely irrelevant” because, to the degree that her other life choices demonstrate her ability to make informed decisions based on her own life goals, they may be considered.

³⁴² Lainie Friedman Ross, *Children, Families and Health Care Decision Making* (Oxford, U.K.: Oxford University Press, 1998) at 56-74.

³⁴³ L. Steinberg & S. Silverberg, “The Vicissitudes of Autonomy in Early Adolescence” (1986) 57 *Child Development* 841 and R. Turner *et al.*, “Autonomy, Relatedness, and the Initiation of Health Risk Behaviors in Early Adolescence” (1993) 12 *Health Psychology* 200, both cited in D.M. Foreman, “The Family Rule: a Framework for Obtaining Ethical Consent For Medical Interventions From Children” (1999) 25 *J. Medical Ethics* 491 at 492.

is ethically problematic for two reasons.³⁴⁴ Firstly, it cannot be supported by the general conception of autonomy. Specifically, the *Tri-Council Policy Statement* refers to “person” and the Belmont Report refers to “an individual” and “individuals”. It is a tenuous stretch to suggest that these terms implicitly include only those persons or individuals over the age of majority. Had that limit been intended, it would have been explicitly stated.

Secondly, Foreman ignores the fact that making an autonomous choice requires capacity and voluntariness.³⁴⁵ Having capacity for autonomous decision-making does not necessarily mean an individual has made an autonomous choice in a particular instance. This is because in order for a decision to be autonomous, the individual must have the capacity to make the decision and the decision must be made voluntarily. All individuals, regardless of age, must make decisions voluntarily in order for them to be autonomous.³⁴⁶

The second question raised is what detriment to others warrants overriding a minor’s autonomy? Parents (or other legal guardians) are responsible for providing their minor children with the necessities of life. This notion serves as the basis for the child protection legislation discussed in Chapter 2. However, does this responsibility translate into a right to override a decision made by a mature minor solely because the parents disagree with the mature minor’s decision? I submit it does not. I would further argue that the detriment that must be demonstrated before overriding a mature minor’s decision with respect to research participation is much closer to (if not the same as) that required

³⁴⁴ Support from the psychological literature for my position that capacity cannot be determined based on age is set out in Chapter 4.

³⁴⁵ *Tri-Council Policy Statement*, *supra* note 1 at 27.

³⁴⁶ This thesis is only focused on the capacity component of autonomy. The point that voluntariness is also required is raised here because an alleged lack of voluntariness cannot ground a distinction between minors and adults because all persons are subject to a voluntariness requirement.

to override an adult's decision. An example here may be useful in proving this point. Imagine potential research participant 'A' who is seventeen years and three hundred and sixty-four days old and who has been found to have decision-making capacity. She wishes to participate in an oncology drug trial but her parents do not support her decision. Now, imagine potential research participant 'B' who is identical to 'A' in all respects except that she is eighteen years and one day old. Both live in a jurisdiction where the age of majority is eighteen years of age. It is quite difficult, if not impossible, to defend from an ethical standpoint overriding 'A's wishes but respecting 'B's decision.

Additionally, it is worth noting that in the case of an adult, the wishes of other individuals are not generally known at the time informed consent is sought. Consequently, any harm that will justify overriding a mature minor or an adult's autonomous decision should be readily ascertainable from the situation itself and be of a significant nature. The views of parents should therefore not be canvassed by researchers prior to determining if the minor has decision-making capacity. If she does, parental opinion becomes largely irrelevant (unless it brings into question the voluntariness of the minor's decision).

B. Paternalism

As noted above, according to the principle of respect for persons, where an individual lacks full autonomy, they are in need of protection. The moral obligation to act for the benefit of others, including the obligation to protect them from possible harm is known as the principle of beneficence.³⁴⁷ The means used to discharge this moral obligation is the principle of paternalism, which can be defined as "the intentional

³⁴⁷ Beauchamp & Childress, *supra* note 305 at 207.

overriding of one person's preferences or actions by another person, where the person who overrides justifies this action by appeal to the goal of benefitting or of preventing or mitigating harm to the person whose preferences or actions are overridden."³⁴⁸ Defined in this way, paternalism clearly serves beneficence. As well, although paternalism can carry a negative connotation or can be seen as prejudging interference as inappropriate, the formulation of the principle adopted here does neither.

Bearing this contextual backdrop in mind, I now return to looking at paternalism more closely. Some authors have divided paternalism into soft paternalism and hard paternalism. Whereas hard paternalism involves interfering with decisions made by individuals capable of autonomous decision-making to protect them from the consequences of their decisions, soft paternalism involves interfering with the decisions made by an individual whose decision-making is not voluntary or not autonomous (or presumed to be lacking in either of those traits).³⁴⁹ According to Miller, examples of circumstances that can give rise to soft paternalism include:

mistaken or inadequate factual beliefs, substantially impaired cognitive functioning, gross defects in rationality, impulsiveness, lack of self-control or weakness of will, distortions of judgment or appreciation relating to risks of harm – for example the tendency to underestimate long-term risks or overweight short-term benefits, and vulnerability to power or authority.³⁵⁰

Although age is not mentioned by Miller directly, it could be argued that minors as a group are captured within a number of the circumstances he cites.

³⁴⁸ *Ibid.* at 208.

³⁴⁹ Franklin G. Miller & Alan Wertheimer, "Facing Up To Paternalism in Research Ethics" (2007) May-June 24 at 26 [Miller & Wertheimer]; J. Feinberg, *Harm to Self* (New York: Oxford University Press, 1986) at 12.

³⁵⁰ Miller & Wertheimer, *ibid.* at 27.

The impulsiveness noted by Miller has been taken up by Levine as a reason to limit the ability of even mature minors to consent to their own research participation. Specifically, while he acknowledges that it is overly paternalistic to treat mature minors like children if they do in fact have the same capacity as adults, Levine goes on to argue that the authority of mature minors to provide informed consent to research should be limited somewhat because “many of them are more likely than adults to act impulsively.”³⁵¹ No proof is given by Levine for the claim that “many...act more impulsively”. Absent such supporting evidence, the claim ought not to be used to restrict the ability of mature minors to make their own decisions regarding participation in research.

Authors subscribing to this dichotomy generally agree that soft paternalism is relatively easy to justify. They disagree, however, as to whether hard paternalism can ever be justified. Feinberg, for example, claims that hard paternalism is never justifiable whereas Miller has adopted the position that, although it is harder to justify than soft paternalism, it is not impossible to justify.³⁵² Ultimately, in the case of younger minors, paternalism can be justified on the basis of soft paternalism.³⁵³ However, if one looks only at mature minors (rather than all minors), it becomes more difficult to bring the narrower group within one of Miller’s circumstances and impossible to prove Levine’s impulsiveness justification. This position is supported by the fact that, by definition mature minors have similar cognitive abilities to adults and they are capable of appreciating the harms and benefits of research participation. Mature minors ought

³⁵¹ Robert J. Levine, “Adolescents as Research Subjects Without Permission of Their Parents or Guardians: Ethical Considerations” (1995) 17 *J. Adolescent Health* 287 at 294.

³⁵² *Supra* note 349.

³⁵³ John H. Sorenson & Garrett E. Bergman, “Delineating Paternalism in Pediatric Care” (1984) 5 *Theoretical Medicine* 93 at 93.

therefore not to be presumed to be in need of protection merely because minors can generally be presumed to be incapable of autonomous decision-making.

Based on my position that mature minors are not (or cannot be presumed to be) lacking in autonomy or voluntariness, if mature minors are to be denied the right the consent, it must be justified on the basis of hard paternalism, not soft paternalism. Stated differently, if they are to have their decisions overridden, the reason for doing so would generally have to be worthy of overriding the autonomy rights of an adult in like circumstances.

C. Vulnerability

Despite my conclusion that only hard paternalism can ground overriding a mature minor's decision to participate in a research study, minors are frequently collectively classified as vulnerable.³⁵⁴ Given this historical classification, it is necessary to critically evaluate whether considering all mature minors as vulnerable is defensible on ethical grounds. In order to do so, an understanding of what constitutes vulnerability and how we determine whether it exists in a particular set of circumstances is needed.

Vulnerability can be succinctly defined as “an identifiably increased likelihood of incurring additional or greater wrong.”³⁵⁵ Vulnerability must therefore be related to a sufficiently specific wrong or harm, otherwise it is impossible to determine what protective measures, if any, are appropriate. In the research context, only vulnerabilities that affect an individual's ability to consent or render it doubtful that the individual

³⁵⁴ Beauchamp & Childress, *supra* note 305 at 90; European Union's Ad Hoc Group for the Development of Implementing Guidelines for Directive 2001/20/EC, “Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population” (2008) 15 Eur. J. Health L. 223 at 249 [E.U. Ad Hoc Group].

³⁵⁵ Samia A. Hurst, “Vulnerability in Research and Health Care: Describing the Elephant in the Room?” (2008) 22 Bioethics 191 at 195.

intended to give her permission to participate in the research need to be considered by researchers. Vulnerability in everyday life does not necessarily mean that an individual is a vulnerable research subject.³⁵⁶ This is because any vulnerability that does not affect a person's ability to consent is irrelevant to the determination of who should be afforded the right to consent to research participation.

Views as to who is truly vulnerable and how those individuals are identified differ. With respect to children, at one extreme there are those that claim that all children (which term is defined as including all minors) are vulnerable.³⁵⁷ For those groups and individual scholars, the vulnerability of children is an absolute truth that need not be questioned further.³⁵⁸ One author has attributed this vulnerability to the “lengthy experience with the incapacities of minors – some physical, some cognitive, some economic, some psychological and some social – that expose them to exploitation.”³⁵⁹

Fortunately, some ethicists are becoming increasingly critical of the labelling of specific subpopulations as vulnerable.³⁶⁰ There appear to be two primary reasons for this criticism. Firstly, labelling entire subpopulations ignores individual variations amongst members of that subpopulation.³⁶¹ Secondly, too many people end up being classified as vulnerable, thereby diminishing the utility of the concept (i.e. if nearly everyone falls

³⁵⁶ Kenneth Kipnis, “Seven Vulnerabilities in the Pediatric Research Subject” (2003) 24 *Theoretical Medicine* 107 at 109 [Kipnis].

³⁵⁷ See e.g. E.U. Ad Hoc Group, *supra* note 354 at 249.

³⁵⁸ See e.g. Gail E. Henderson, Arlene M. Davis, & Nancy M.P. King, “Vulnerability to Influence: A Two-Way Street” (2004) 4 *American J. of Bioethics* 50 at 51 [Henderson, Davis, & King].

³⁵⁹ Jonathan D. Moreno, “The Natural History of Vulnerability” (2004) 4 *American J. of Bioethics* 52 at 53. See also Amar D. Trivedi, “Rethinking Adolescent Assent: A Triangular Approach” (2005) 5 *American J. of Bioethics* 75 at 75 for claim that power imbalance between physicians (and arguably researchers) and adolescents leaves the latter vulnerable.

³⁶⁰ See e.g. Florencia Luna, “Elucidating the Concept of Vulnerability” (2009) 2 *International J. of Feminist Approaches to Bioethics* 121 at 121 [Luna]; Carol Levine *et al.*, “The Limitations of “Vulnerability” as a Protection for Human Research Participants” (2004) 4 *American J. of Bioethics* 44 at 47 [Carol Levine].

³⁶¹ Kipnis, *supra* note 356 at 107; Henderson, Davis, & King, *supra* note 358 at 50; Luna, *ibid.* at 123; Carol Levine, *ibid.* at 46-47.

within one group or another, are the means used to protect them really special protections or do they become standard elements of research?).³⁶²

The result of this growing body of critics has been the emergence of new means of ‘flagging’ potentially vulnerable individuals. One such tool that has been developed is Kipnis’ catalogue of seven vulnerabilities, which essentially sets out the seven types of vulnerability that may affect the permissibility of research involving minors. Those vulnerabilities are:

1. Incapacitational: Does the C[andidate]-S[ubject] lack the capacity to deliberate about and decide whether to participate in the study?
2. Juridic: Is the C-S liable to the authority of others who may have an independent interest in that participation?
3. Deferential: Is the C-S given to patterns of deferential behavior that may mask an underlying unwillingness to participate?
4. Social: Does the C-S belong to a group whose rights and interests have been socially disvalued?
5. Situational: Is the C-S in a situation in which medical exigency prevents the education and deliberation needed to decide whether to participate in the study?
6. Medical: Has the C-S been selected, in part, because of the presence of a serious health-related condition for which there are no satisfactory remedies?
7. Allocational: Is the C-S or proxy lacking in subjectively important social goods that will be provided as a consequence of participation in research?³⁶³

Although Kipnis’ taxonomy has been criticized on the basis that it leads to the same end as the subpopulation labelling approach – it creates fixed categories. However, even Luna who levels this criticism is prepared to concede that the taxonomy could be a useful guide.³⁶⁴ I agree. Kipnis’ seven vulnerabilities gives researchers and research

³⁶² Carol Levine, *ibid.* at 56; Henderson, Davis, & King *ibid.*

³⁶³ Kipnis, *supra* note 356 at 110.

³⁶⁴ Luna, *supra* note 360 at 135.

ethics boards a clear list of possible sources of vulnerability to consider when developing research protocols. This has great practical utility.

So what does this all mean for the use of protective measures (i.e. paternalistic intervention) to override a mature minor's consent to research participation?³⁶⁵ In the end, whether subpopulations are labelled as vulnerable or Kipnis' taxonomy is used to establish categories of vulnerability, the inquiry into vulnerability cannot be stopped there. Whether a particular potential research subject is in need of protection with respect to her involvement in a specific research project ought to then be evaluated by researchers on an individual basis as part of the consent process.³⁶⁶ In the framework I propose in Chapter Four, this assessment of vulnerability could be carried out as part of the individualized capacity assessment of each minor.

IV. ETHICAL INSTRUMENTS

A. *The Declaration of Helsinki*

When it revised the *Declaration of Helsinki* in 2008, the World Medical Association added the "right to self-determination"³⁶⁷ as one of the key considerations to be weighed when attempting to strike the appropriate balance between the need for research to improve society's collective ability to understand and treat various medical conditions against the various needs of research subjects. Beyond the right to self-

³⁶⁵ I am only referring to consent because minors with some understanding of the proposed research (i.e. threshold is lower than that to be deemed a mature minor) who decline research participation must have their dissent respected under art. 3.10 of the *Tri-Council Policy Statement*, *supra* note 1.

³⁶⁶ Joseph P. DeMarco, "Vulnerability: A Needed Moral Safeguard" (2004) 4 *American J. of Bioethics* 82 at 83.

³⁶⁷ *Supra* note 41 at para. 11.

determination, the other recognized needs of research subjects are the need to “protect the life, health, dignity, integrity,...., privacy, and confidentiality of personal information.”³⁶⁸

There is nothing in the *Declaration of Helsinki* that suggests that legally competent minors are to be treated any differently than legally competent adults. Specifically, the limits on the “right to self-determination” based upon whether an individual is competent are then set out in paragraphs 22, 24, 27, and 28, which state:

22.Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

24.In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

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.

³⁶⁸ *Ibid.*

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. [Emphasis added]³⁶⁹

Arguably what is most interesting from the above-cited paragraphs is the lack of mention of age or childhood as an example of incompetent research subjects. Prior to 2008, the predecessor to paragraph 27 referred to “a legally incompetent minor”³⁷⁰ while the equivalent to the current paragraph 28 stated, in part, “when a subject deemed legally incompetent, such as a minor child...”³⁷¹ Although both the previous and current versions of paragraphs 27 and 28 allow for the possibility that not all minors are incompetent, the 2008 revision seems to make this more obvious in that it implies that the minor’s capacity must be evaluated and only if found incompetent is third party consent to be obtained.

B. The Tri-Council Policy Statement

As noted in the introduction of this chapter, the guidelines set out in the Tri-Council Policy Statement are based on the principles of respect for persons, concern for welfare, and justice. In the case of mature minors and their ability to consent to research, it is primarily the principle of respect for persons that is engaged. Additionally, the potential vulnerability of individual mature minors is also directly addressed.

³⁶⁹ *Ibid.* at paras. 22, 24, 27-28.

³⁷⁰ *Ibid.* at para. 24.

³⁷¹ *Ibid.* at para. 25.

(i) **Mature Minors and Their Capacity to Consent**

The *Tri-Council Policy Statement* unequivocally affords mature minors the ability to consent to their own research participation. Support from this position is based on three key points. Firstly, the general statements on the principle of respect for persons do not limit an individual's ability to consent to her participation on the basis of age. The most relevant portions of those statements declare:

Respect for Persons implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible. **Where a person has the capacity to understand this information, and the ability to act on it voluntarily, the decision to participate is generally seen as an expression of autonomy.** The Policy refers to the process of seeking consent from prospective participants, which may result in either agreement or refusal to participate. This process is meant to emphasize Respect for Persons. Under no circumstances may researchers proceed to conduct research with anyone who has refused to participate. Subject to exceptions set out in this Policy, consent must be obtained from participants prior to the conduct of research.

Equally, **Respect for Persons implies that those who lack the capacity to decide for themselves should nevertheless have the opportunity to participate in research that may be of benefit to themselves or others. Authorized third parties acting on behalf of these individuals decide whether participation would be appropriate.**³⁷² [Emphasis added]

According to these statements, the three funding bodies (CIHR, NSERC, and SSHERC) as well as other organizations who have endorsed the *Tri-Council Policy Statement*, are satisfied that the ethical obligations arising out of the notion of respect for persons will be discharged so long as individuals who have capacity can determine whether or not they will participate in a research study. The principle only supports obtaining consent from a legally authorized third party if an individual (whether she is a minor or not) lacks

³⁷² *Supra* note 1 at 27.

capacity. Stated somewhat differently, capacity is both necessary and sufficient to be deemed able to consent to one's own participation. There is no separate 'maturity' requirement. Of course, the other requirements for informed consent including voluntariness must also be established before valid consent can be given.

Secondly, the only mention of children in the entire section on capacity is at article 3.10 which only applies when a minor lacks capacity. The *Tri-Council Policy Statement* describes capacity itself as:

...the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. The determination of capacity to participate in research, then, is not a static determination. It is a process that may change over time, depending on the nature of the decision the prospective participant needs to make, and on any changes in the participant's condition. Assessing capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.³⁷³

³⁷³ *Supra* note 1 at 40. It is worth noting that in the *Tri-Council Policy Statement (1998)*, *supra* note 319, the term "competence" was used instead of "capacity". The descriptions of the two terms are, however, quite similar. Specifically, in the *Tri-Council Policy Statement (1998)*, competence was characterized at s.2E as:

the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. This ability may vary according to the choice being made, the circumstances surrounding the decision, or the time in question. Competence to participate in research, then, is not an all-or-nothing condition. It does not require prospective subjects to have the capacity to make every kind of decision. It requires that they be competent to make an informed decision about participation in particular research. Competence is neither a global condition nor a static one; it may be temporary or permanent.

Given the wording, any doubt as to whether or not mature minors can consent to their own participation that existed when the *Tri-Council Policy Statement (1998)* was operative has now been removed.

Thirdly, and for still further certainty, the commentary that accompanies article 4.4 of the *Tri-Council Policy Statement* specifically states “where children have not yet attained the capacity to consent for themselves to participate in research, researchers shall seek consent from an authorized third party...”³⁷⁴ This again amounts to saying that where a minor has capacity, her consent is required and consent from a third party will not be sufficient.

(ii) Vulnerability of Mature Minors

The *Tri-Council Policy Statement's* clear endorsement of autonomy of all individuals with decision-making capacity regardless of age should not, however, be regarded as a failure to recognize that minors may be vulnerable and in need of different treatment.

In what looks at first glance to be the ‘labelling’ of children collectively as vulnerable, close examination of the section on children reveals that this is not in fact the case. Specifically, the role of children in research is discussed in “Chapter 4: Fairness and Equity in Research Participation”. The introductory comments of that section, state in part:

Children have varying degrees of maturity – metabolically, immunologically and cognitively – that may present important challenges for research design and the consent process, depending on the nature and complexity of the research. **In addition to the vulnerability that arises from their developmental stage,**

³⁷⁴ *Supra* note 1 at art. 4.4 and accompanying commentary.

children may also lack capacity to consent to participate in research (see Article 4.6).³⁷⁵ [Emphasis added]

Then, the commentary accompanying article 4.4 plainly states that all children are subject to article 4.6. Prior to setting out article 4.6, it is worth noting that “children” is not defined in the *Tri-Council Policy Statement*. However, it is unnecessary to attribute a specific meaning to the term because article 4.6 speaks to circumstances where immature minors can be included in research. It says nothing about mature minors:

Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

- (a) the research question can be addressed only with participants within the identified group; and
- (b) the research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
- (c) where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.³⁷⁶

Taken together, the immediately preceding extracts from the *Tri-Council Policy Statement* necessarily leads to the conclusion that according to the funding agencies, vulnerability does not in and of itself preclude an individual from consenting to research participation. The implications of this point are significant. It means that even if mature minors as a group are found to be potentially vulnerable (either through subpopulation labelling or the application of Kipnis’ taxonomy) and then a mature minor is found to be

³⁷⁵ *Ibid.* at 49.

³⁷⁶ *Ibid.* at art. 4.6.

individually vulnerable through an individualized capacity assessment, she may still be afforded the right to single-handedly decide whether she wishes to participate. Furthermore, researchers are required to make this process possible by ensuring that consent forms are appropriately drafted. The commentary accompanying article 4.7 makes this point clear:

The core principles of Respect for Persons, Concern for Welfare, and Justice entail special ethical obligations toward individuals or groups whose circumstances may lead to their vulnerability in the context of a specific research project and limit their ability to fully safeguard their own interests. Those who are owed special ethical obligations may include individuals who are institutionalized, those in dependent situations, or those whose circumstances (e.g., poverty or poor health status) may render even modest participation incentives so attractive as to constitute an inducement to take risks they would otherwise not take. Their situation may also compromise the voluntariness of consent in other ways. However, individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the group to which they belong. Their particular circumstances shall be considered in the context of the proposed research project.³⁷⁷

By preceding all references to vulnerability with the word “may”, the three funding agencies are essentially adopting Luna’s position that although groups may be more likely to be vulnerable, individual vulnerability still needs to be assessed.

C. The *ICH GCP*

As noted above, the *ICH GCP* includes minors as a class in its definition of “vulnerable subjects”. As well, statements contained within the *ICH GCP* clearly establish that all minors are to be active participants in the informed consent process, regardless of the type of research in which their participation is sought. However, in so

³⁷⁷ *Ibid.* at art. 4.7 and accompanying commentary. See also *ibid.* at 40-44.

doing, the drafters of the *ICH GCP* also add much confusion to the role of minors in research. The laudable yet also problematic provision reads:

when a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and if capable the subject should sign and personally date the written informed consent.³⁷⁸

The delineation of the role of minors in the informed consent process is not in itself problematic. Rather, the difficulty flows from the implicit assumption contained within paragraph 4.8.12 that no minor can consent to her own participation in a research study.³⁷⁹ This assumption is not necessarily true in the case of all minors. As is discussed in greater detail in Chapter Two, there is no explicit pronouncement in any common law jurisdiction in Canada that precludes mature minors from consenting to their own participation in at least some research studies. Admittedly, there is also no clear legal authority bestowing such a right on mature minors. Furthermore, although ethical frameworks may suggest limitations on when minors can consent to their own participation, such pronouncements are not legally-binding on researchers or the courts nor should they be taken as such.³⁸⁰

Seen in this light then, paragraph 4.8.12 of the *ICH GCP* can have one of two consequences. Firstly, it can serve to bolster the claim that minors (be they mature minors or not) can never consent to their own participation in research on a quasi-legal

³⁷⁸ *Supra* note 55 at para. 4.8.12.

³⁷⁹ This assumption follows from the clause “(e.g. minors, or patients with severe dementia)” which could be interpreted to mean that the consent of a substitute decision-maker is needed in all instances where minors are to be involved in research.

³⁸⁰ This comment is not intended to suggest that ethical guidelines are entirely irrelevant in legal proceedings. They may, for example, be considered by the courts in defining the standard of care owed by researchers and determining if a particular researcher has discharged her duty of care.

basis. Secondly, the provision can be deemed applicable only in instances where the consent of a substitute decision-maker is in fact needed in order for a minor to participate in a research study. Given that the *ICH GCP* is intended to help researchers comply with policies, regulations and statutes, it is doubtful that one poorly drafted paragraph contained therein would be sufficient to curtail the rights of mature minors that may otherwise exist, especially where it can bear two interpretations. As such, if there is a legal basis that enables a mature minor to consent to her own participation in a research study, paragraph 4.8.12 of the *ICH GCP* should not be found to alter this entitlement in any way. In fact, in the framework set out in chapter 5 of this thesis, I argue that there is in fact such a basis in law.

The meaning ascribed to paragraph 4.8.12 further affects the ambit of paragraph 4.8.14 of the *ICH GCP*, which sets out the instances where a substitute decision-maker can consent to a subject's participation in a study that is expected to be of no clinical benefit to study participants.³⁸¹

For purposes of this thesis, what is not captured by paragraph 4.8.14 is arguably of greater significance. Its application is restricted to research that is of no direct benefit to participants. No mention is made of any analogous limitations that may exist in the case of therapeutic trials anywhere in the *ICH GCP*. Based on this omission, there

³⁸¹ Paragraph 4.8.14 of the *ICH GCP*, *supra* note 55, reads:

Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

- (a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally.
- (b) The foreseeable risks to the subjects are low.
- (c) The negative impact on the subject's well-being is minimized and low.
- (d) The trial is not prohibited by law.
- (e) The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/favourable opinion covers this aspect.

appears to be no restrictions (beyond those imposed upon research participants generally) on the authority of a substitute decision-maker to consent to a minor's participation in research that will be of direct benefit to the minor.

D. The *ICH CIMPPP*

Although issued by the same body as the *ICH GCP*, the *ICH CIMPPP* improves upon some of the ambiguity found in the former. Most notably, it explicitly concedes that "...mature minors (defined by local laws) may be capable of giving autonomous consent".³⁸² Despite the fact that this acknowledgement is found at the end of a paragraph that begins "as a rule, a pediatric subject is legally unable to provide informed consent"³⁸³, it remains a welcome improvement upon paragraph 4.8.12 in the *ICH GCP*. The recognition that some minors may in fact be able to provide autonomous consent may also be taken as clarifying the confusing phraseology found within paragraph 4.8.12 of the *ICH GCP*. It also bolsters the argument that nothing within the *ICH GCP* (or likewise the *ICH CIMPPP*) is intended to curtail any legal rights that may otherwise exist.

The second element of the *ICH CIMPPP* of interest is the section on the timing of pediatric studies in relation to research involving less vulnerable populations. A list of factors to be considered when determining when pediatric studies should be initiated is set out in section 2.1 of the guidance document. Generally speaking, studies aimed at developing products to treat serious or life-threatening conditions for which there is no (or little) treatment should be initiated "early". Other pediatric studies should be started

³⁸² *Supra* note 56 at para. 2.6.3.

³⁸³ *Ibid.*

at “later phases of clinical development,” when at least some preliminary adult research data is available so that children will be exposed to fewer (or less severe) risks.³⁸⁴

V. CONCLUSION

Ethical frameworks have evolved considerably from the time the *Nuremburg Code* was passed to today with respect to their treatment of minors. Initially, minors were excluded from research altogether. They were then included but deemed vulnerable and/or incompetent and so parental consent was deemed necessary for their participation. Most recently, however, the *Declaration of Helsinki* has been amended to remove references to all minors being incompetent. As well, the *Tri-Council Policy Statement* now expressly recognizes that mature minors are able to (and must) consent to their own participation in research. Despite there being some potential vulnerability on the part of individual mature minors, such vulnerability (when established) does not in and of itself remove their right to autonomous decision-making. The recent changes to the *Declaration of Helsinki* and to the *Tri-Council Policy Statement* mean that the two ethical frameworks that have the most influence on how medical research is carried out in Canada now allow a broader recognition of the rights of mature minors.

Over time, the role of law and ethics has come to be recognized as different. As part of this process, ethical frameworks have come to prescribe conduct that may differ from what is required under the law. These different roles affect the penalties that can be imposed upon researchers. However, practically speaking, it is hoped that all those involved in the research enterprise strive to live up to the spirit of both legal and ethical requirements. Taken together, the various legal and ethical instruments that shape the

³⁸⁴ *Ibid.* at para. 2.3.

Canadian medical research landscape leave room for at least some minors to consent to their own participation in research if they are able to establish that they are competent. Now that the research setting has been examined from both perspectives, it is now possible to turn to the development of a framework that, while respecting the legal and ethical boundaries that exist, allows for the greatest role for mature minors in the consent process.

CHAPTER 4

THE FRAMEWORK: AN ALTERNATIVE PROPOSAL FOR CANADA

I. INTRODUCTION

In the two preceding chapters, I canvassed the legal and ethical instruments that apply to at least some research carried out in Canada. Readers will recall that following a review of the legal instruments, I concluded that the welfare principle has not been incorporated into the common law mature minor rule. As well, it was recognized that some research activities will be captured under consent to treatment legislation and child protection legislation in certain contexts. Given the lack of mention of research in both those types of statutes, their applicability seems far from an intended consequence. Quebec is the only province or territory to have explicitly legislated with respect to the role of minors in the medical research consent process. In terms of ethics documents, researchers carrying out research in Canada look to the newly released *Tri-Council Policy Statement*, which specifies how it is to be applied. The *Tri-Council Policy Statement* briefly discusses the need for researchers and research ethics board members to be aware of and comply with any applicable legal requirements. Rather than providing researchers with what the legal requirements are, the *Tri-Council Policy Statement* only gives researchers a list of the topics that may be captured by the law. Specifically, it states:

...These legal and regulatory requirements may vary depending on the jurisdiction in Canada in which the research is being conducted, and who is funding and/or conducting the research, and they may comprise constitutional, statutory, regulatory, common law, and/or international or legal requirements of jurisdictions outside of Canada. Where the research is considered to be a governmental activity, for example, standards for protecting privacy flowing from the *Canadian Charter of Rights and Freedoms*, federal privacy legislation and regulatory requirements would apply.

The law affects and regulates the standards and conduct of research involving humans in a variety of areas, including, but not limited to privacy, confidentiality, intellectual property and the capacity of participants. In addition, human rights legislation and most documents on research ethics prohibit discrimination on a variety of grounds and recognize equal treatment as fundamental...³⁸⁵

This lack of guidance is particular problematic. Given that many of those requirements (and the related legal standards) are rather vague and unclear to a legal scholar, it is doubtful that many researchers are able to make heads or tails of them, assuming they even knew where to look.³⁸⁶

In discussing the interaction between the *Tri-Council Policy Statement* and the law, it is also worth noting that in cases where there is a perceived (or actual) tension between the law and ethics, the *Tri-Council Policy Statement* are given the following guidance:

Researchers may face situations where they experience a tension between the requirements of the law and the guidance of the ethical principles in this Policy. In such situations, researchers should **strive to comply** with the law in the application of ethical principles. Researchers should consult with colleagues, the REB

³⁸⁵ *Supra* note 1 at 12.

³⁸⁶ The legal standard that is arguably the least clear is that pertaining to the capacity of minors in instances not captured by child protection legislation (which as I argued in Chapter 2 is in all research). Does it require that a maturity threshold be met? Can minors consent to their own participation that is not in their best interests and if so, when can they do so? How is capacity to be assessed and based on what information? These are only some of the questions that remain unanswered.

or any relevant professional body, and if necessary, seek independent legal advice to help resolve any conflicts between law and ethics, and guide an appropriate course of action. [Emphasis Added]³⁸⁷

With due respect to the authors of the Statement, striving to comply with the law will not shield them from liability. They need to actually comply with it; otherwise if they are found to have acted contrary to the law, researchers will be liable for damages that flowed from their actions.³⁸⁸ Fortunately, because of the suggestion to seek legal advice, any actions by a researcher or research ethics board with respect to the handling of a conflict between the law and the Tri-Council Policy Statement should be carried out knowing the consequences.

The result of years of developing vague and unclear standards has meant that those responsible for carrying out research have been left with few practical tools to carry out research on adolescents in an ethically and legally defensible manner. It is largely for that reason that this thesis has focused on providing all stakeholders with a perspective on the entire research landscape as it applies to one group – adolescents. Having painted a picture of this landscape, attention now shifts to proposing a framework that can be used in practice to ensure the role of adolescents in research is properly respected. The framework set out below is not an ethical instrument in its own right, nor is it a legal instrument; it is a practical tool to help bridge the gap between law and ethics. It is also intended to draw the attention of researchers to the possible capacity of minors involved in medical research.

³⁸⁷ *Tri-Council Policy Statement, supra* note 1 at 12.

³⁸⁸ I say “if they are found to have acted contrary to the law” because in cases where there is some ambiguity in the legal standard, researchers could raise the ethical standard as evidence of how the ambiguity in the law should be resolved.

Prior to setting out the framework, it is necessary to provide additional insight to readers as to how it was developed (beyond the contents of specific instruments) as well as the limits of the framework. The first noteworthy point in this regard is that I feel it is desirable to have a “national” model so as to ensure that the rights of adolescents are defined similarly across the country. The fact that minors residing in different jurisdictions are not treated the same way under the law, be it child protection or consent to treatment legislation, does not mean that they should not be treated in a more uniform manner when it comes to research. Simply stated, I have seized an opportunity to encourage a more just recognition of rights.

Developing such a framework is not an easy task; given that each common law jurisdiction has passed different child protection legislation and some also have consent to treatment legislation, not to mention the fact that Quebec law explicitly forbids minors from consenting to their own research participation. In light of this reality, the framework proposed herein recognizes the differences between common law jurisdictions and remains flexible enough so that it can be adapted to meet all legal requirements. With respect to Quebec, however, short of changing the law, there is no amount of modification to this framework that would allow minors to consent to their own research participation.³⁸⁹ The model set out later in this chapter cannot be applied to research being carried out in Quebec.

The second point is that even though some minors are afforded the right to provide autonomous consent under this framework, there is nothing requiring them to do so without consulting their parents, friends, and/or members of the research team. Those

³⁸⁹ In particular, article 21 of the *Civil Code of Québec*, *supra* note 112, would need to be amended.

minors are merely being extended a right afforded to all adults whose competence has not been challenged – the right to decide whether they wish to participate in a particular research study and the concomitant right to decide who they want to involve in their decision-making process.

This chapter begins by setting out reasons why the manner in which the role of teenagers is defined at present is no longer appropriate and why change is needed. The alternative framework is then set out to give readers a complete picture of the proposal. Thereafter, the key elements of the frameworks (i.e. the aim of the activity at issue and the capacity assessment) are described and justifications are given for their inclusion. Reasons why risk was not included as an element are provided. This chapter then concludes with suggestions as to precisely how institutions can go about implementing the proposed framework.

II. THE STATUS QUO: AN ARGUMENT FOR CHANGE

The lack of clarity and guidance in legal and ethical instruments as to the proper role for minors in the consent process has left researchers defining that role in vastly different ways. One issue is that there is no uniform way in which minors are approached for participation. In some research studies, researchers first seek consent from parents prior to involving the minor in any discussion about the research project. Thereafter, the research is discussed with the minor and the minor is asked in some studies to sign a consent form identical in content to that signed by her parent(s) while in others the minor is asked to sign an assent form.³⁹⁰ Asking minors to sign either type of form without first

³⁹⁰ See e.g. Marion E. Broome and Deborah J. Richards, “The Influence of Relationships on Children’s and Adolescents’ Participation in Research” (2003) 52 *Nursing Research* 191 at 193 where all minors over the age of twelve were required to sign a consent form that was identical in content to that signed by

assessing their capacity is problematic. Having them sign a consent form implies that they are able to understand and appreciate the information about the research study sufficiently well to consent. Stated differently, they have decision-making capacity. This begs the question why researchers proceeding in this manner also require parental consent (i.e. they are assuming minors are competent yet are not allowing them to exercise it). Conversely, having all minors participating in a given study sign an assent form assumes they are incompetent and does not afford minors the opportunity to prove they are competent. In other instances, parents and minors are approached by researchers at the same time.³⁹¹ This too is far from desirable because it denies the right of a competent minor to provide legally valid consent free from parental involvement. Admittedly, in the case of some minors, there is simply no way to avoid disclosing some basic information about the study to parents or authorized third party representatives because minors are contacted at home or arrive at the research site accompanied by the parent(s). This does not, however, mean that researchers need to discuss all study procedures in the presence of the minor's parents. As others have argued, disclosure of health information and treatment details (or I would suggest research activities) in instances involving older minors who are against such disclosure needs to be justified.³⁹²

their parents, without evaluating the capacity of the minor. See also Geert Pousset *et al.*, "Attitudes of Adolescent Cancer Survivors toward End-of-Life Decisions for Minors" (2009) 124 *Pediatrics* e1142 at e1143 [Pousset *et al.*] and John Pearce, "Consent to Treatment during Childhood: The Assessment of Competence and Avoidance of Conflict" (1994) 165 *British J of Psychiatry* 713 at 715 for additional examples of instances where researchers solicited parental authorization first. No explanation is given as to why parents were approached first. In order to know who to call, they necessarily had the names of the minors. This in turn means that researchers could likely have contacted minors first but chose to contact parents first.

³⁹¹ Broome & Richards, *ibid.* at 195.

³⁹² See e.g. Joan Loughrey, "Medical Information, Confidentiality and a Child's Right to Privacy" (2003) 23 *Legal Stud.* 510 at 535.

A second issue relates to how and by whom minors are engaged. Notably, the work of Unguru *et al.* reveals that parents were four times more likely than physicians to involve minors in the decision-making process. Given that parents only included minors forty-three percent of the time, researchers only rarely included minors in the process at all. This lack of inclusion left over half of the minors in the study feeling like they had “very little”, “little”, or “no role” in deciding whether to participate in a study.³⁹³ Even where a minor lacks capacity, they ought to be part of the discussion, if for no other reasons than to have their questions answered and to know what the research entails. Furthermore, under the *Tri-Council Policy Statement* researchers are required to look into the wishes with regards to research participation of minors who lack legal capacity but have “some ability to understand the significance of the research”.³⁹⁴

A third issue is the relative inability to know what role researchers are affording to minors in the decision-making process at present in Canada and elsewhere. This is because most studies involving adolescents merely state that informed consent was obtained from parents.³⁹⁵ This lack of disclosure on the process followed in obtaining consent raises three possibilities. Firstly, it could mean that capacity was appropriately assessed and all adolescents involved in a given study were found incompetent. Secondly, it could mean that the capacity of minors was not assessed. Thirdly, it could mean that researchers thought that parental consent was required even if the minors were competent. In oncology studies or other complex research projects, I am willing to

³⁹³ Yoram Unguru, Anne M. Sill & Naynesh Kamani, “The Experiences of Children Enrolled in Pediatric Oncology Research: Implications for Assent” (2010) 125 *Pediatrics* e876 at e880 [Unguru, Sill & Kamani].

³⁹⁴ *Tri-Council Policy Statement*, *supra* note 1 at art. 3.10.

³⁹⁵ This holding is based on my experience reading published medical literature for previous university studies as well as a recent perusal of a variety of medical journals.

concede that the first scenario is possible. However, in more straightforward studies, I am doubtful that the capacity of minors is being assessed when a parent is present. After all, if it was being assessed, one would expect at least some minors to be capable of autonomous decision-making. As well, with respect to the third possibility, as ought to be clear from the review of applicable legal instruments set out in Chapter 2, there is no requirement to seek parental consent unless the activities are captured under the applicable consent to treatment legislation or child protection statute. Regardless of which of the first two possibilities proves true for a given research study, greater transparency into the decision-making process should be encouraged. By requiring researchers to carry out a capacity assessment of each minor who is being asked to participate in a research study, it is my hope that the framework proposed herein will lead researchers to include more details on the consent process when publishing their research. Stated differently, I hope it will change the typical “informed consent was obtained” type statements to “the capacity of all participants was assessed and x number were found to have the capacity to give legally valid consent”.

Finally, as discussed at length in earlier chapters, in Canada there is no clear statement from the courts, the provincial or territorial legislatures, the Federal Government, or the principal funding agencies as to whether or not the mature minor rule applies to medical research. There is also only limited guidance on how the capacity of minors should be assessed, including whether there is a ‘best interest’ limitation.³⁹⁶

These misconceptions and problems in the role afforded to minors are not beyond

³⁹⁶ See discussion below on the capacity assessment for information on the tools available to researchers as well as the discussion in Chapter 2 on the welfare principle for my reasons why there is no ‘best interest’ limitation with respect to the right of minors to autonomous decision-making outside of the child protection context.

redress. They can and should be remedied by the adoption of a framework that clearly and unequivocally sets out for researchers and research ethics board members how minors are to be treated in the consent process. The framework proposed in this thesis sets out to do just that.

III. THE FRAMEWORK AS A WHOLE

At present, there is no legal or ethical statement that instructs researchers on how to undertake the consent process with minors. There is also no empirical evidence available as to whether researchers are presently respecting the rights of mature minors to consent to their own research participation or not. In light of this lacuna, it is proposed that the following statements be used to guide researchers carrying out research involving minors:

Researchers shall abide by the following guidelines with respect to capacity and minors in research:

- (a) All potential research participants who are under the age of majority will undergo a capacity assessment to determine if they are competent. If the researcher is satisfied that the minor understands and appreciates the nature and consequences of participating in research and the alternatives to research participation such that he/she is able to decide whether to proceed with it or not, the minor will be deemed competent.**
- (b) Researchers shall use an instrument that has been validated for use with minors involved in research activities when carrying out the capacity assessments under (a).**
- (c) Researchers shall discuss the specific research project as little as possible with a minor's parent(s) or authorized third party representative prior to assessing the minor's capacity under (a).**
- (d) Unless involvement from parent(s) or other authorized third party is requested by a competent minor, researchers shall not**

discuss the research with the competent minor’s parent(s) or other authorized third party. This applies prior to the signing of the consent form as well as during the life of the research study.

(e) Unless the law states otherwise, where the competent minor is able to provide free and informed consent, that minor’s consent to research participation shall be necessary and sufficient.

It may also be beneficial to include a graphic representation of the steps to be followed by researchers when engaging minors in the consent process. That diagram looks like this:

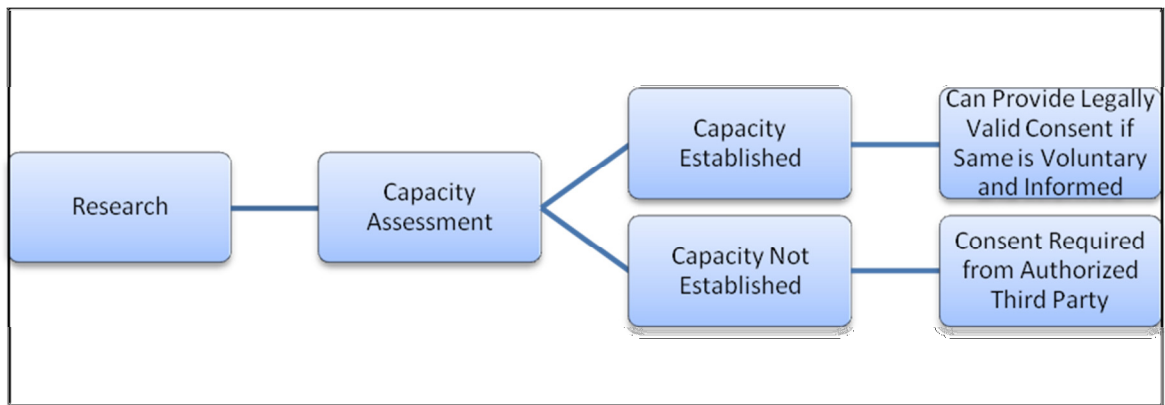


Figure 1. Schematic representation of the framework defining the role to be afforded to minors in the consent process for medical research studies.

I suggest that wording to this effect and the above diagram be incorporated into the section of the *Tri-Council Policy Statement* dealing capacity as soon as an instrument to assess the capacity of minors involved in research is developed and validated.³⁹⁷ Given that it may take some time for both of these events (i.e. the incorporation into the *Tri-Council Policy Statement* and the creation and validation of an instrument) to occur, individual research ethics boards are encouraged to require compliance with the above guidelines with the exception of (b), as soon as possible. Support from the Federal

³⁹⁷ The *Tri-Council Policy Statement*, *supra* note 1, does not provide an age at which capacity should be presumed.

Government of Canada (through the Office of Paediatric Initiatives) and provincial and territorial legislatures is also most desirable.

IV. AIM OF THE ACTIVITY

The framework proposed herein applies only to research. Despite the difficulties noted in Chapter 1 with respect to distinguishing between research and treatment, I feel it is imperative that researchers tease these two spheres of activity apart. The reasons for drawing the distinction between research and treatment, even where both involve interactions with the same physician-researcher are set out below.

Prior to looking at those reasons, however, it is helpful to consider the ways in which minors are involved in research. For purposes of this framework and the discussion throughout this chapter generally, it is necessary to recognize that minors may be involved in research in one of two ways. The research alone scenario includes studies designed primarily to “extend knowledge through a disciplined inquiry or systematic investigation”³⁹⁸ and consists solely of activities that the minor would not receive if she chose not to participate in the proposed study. This category generally involves research on healthy minors. The mixed research and treatment scenario, in turn, involves research (as defined above) as well as procedures that are aimed at benefiting the minor specifically and/or procedures that she would undergo even if she chose not to participate in the research.³⁹⁹ An example may be beneficial in explaining the two scenarios. Consider (a) a study looking at calcium consumption by minors and (b) a chemotherapy study that compares a new drug dosing regimen to the standard of care. While a minor participating in (a) may benefit from her participation by learning of a calcium

³⁹⁸ *Tri-Council Policy Statement, supra* note 1 at art. 2.1 and accompanying commentary.

³⁹⁹ See Schwartz, *supra* note 39, for further discussion on distinguishing between research and treatment.

deficiency, such a finding is not the primary purpose of the research. As well, any action by health care professionals as a result of this incidental finding would not be part of the study. The minor in (a) would therefore be asked to participate in research alone. On the other hand, the minor involved in (b) would receive some form of chemotherapy and the monitoring that goes along with such treatment (such as regular blood tests), whether or not she is enrolled in the study. She would consequently be involved in mixed research and treatment. Recognizing that there may be instances where researchers are uncertain if there is a treatment element (or if a specific procedure constitutes treatment or research), it is worth noting that when there any doubt, researchers and research ethics boards should ensure that any legal requirements applicable to treatment and research are respected. Where standards of disclosure differ, researchers should meet the more onerous standard. Any legal requirements contained in consent to treatment legislation (or very rarely in child protection legislation) must be respected.

The framework proposed here draws a distinction based upon the aim of the activity at the outset for number of reasons. Firstly, research and treatment are different. Research primarily seeks to generate generalizable knowledge. Like treatment it can also seek to improve the health status of a given patient/research participant. The difference is that in the case of research, the likelihood of improvement is unknown.⁴⁰⁰ Where research activities and treatment are delivered concurrently (be it by the same health care professional or not) both of these interests are at play. Besides the different primary aims of research and treatment, as well as the unknown efficacy of research interventions (and

⁴⁰⁰ See e.g. Hadskis, *supra* note 48 at 259-260.

consequently different risk to benefit profile), it is appropriate to treat minors involved in each of these types of activities differently.

Secondly, research and treatment are presently treated differently by legislation, by the common law, and by ethical instruments. As noted in Chapters 2, many legislatures have passed consent to treatment legislation, but those statutes do not mention research. Under the common law, all reported decisions involving minors in Canada have emerged out of the treatment realm. Finally, the principal statement on research ethics in Canada, the *Tri-Council Policy Statement*, only applies to research. There is no equivalent document that applies to treatment. Together, this means that in the eyes of politicians at the provincial/territorial and federal levels of Government, judges, and the authors of the *Tri-Council Policy Statement*, differential treatment is both necessary and appropriate.⁴⁰¹ Given this widely held belief and since the aim of this thesis is to develop a framework that can be applied nationally in the not-too-distant future, it is necessary to be respectful of the positions articulated in existing instruments and in the jurisprudence. This is best achieved by not addressing treatment in the framework. In the framework proposed in this thesis, efforts have been made to accord minors the most expansive recognition of rights possible under the current legal and ethical landscape.

Thirdly, although research and treatment are different, there are also many similarities between the actual procedures involved in each. For example, a blood test can be part of a research protocol, much like it can be part of a standard course of treatment. It is the reason why the test is carried out and the use that will be made of the

⁴⁰¹ The *Tri-Council Policy Statement*, *supra* note 1 at 1 was developed following extensive consultation with stakeholders, which include researchers, lawyers, and ethicists. It can therefore be said that at least some of those consulted were of the view that research and treatment differ.

result that is different between research and treatment. As a result, some of the individual procedures that need to be understood by minors are the same. The role of minors in the consent process for research cannot therefore be defined altogether differently from how their role with respect to treatment has been defined.

Fourthly, using aim of the activity as the first element in the framework simplifies the consent process for researchers. Specifically, even if minors and their parents are unable to distinguish between treatment and research, researchers and research ethics boards ought to be able to relatively easily determine if they are operating in the research realm or treatment-alone scenario or in the mixed research and treatment scenario as opposed to the treatment stream in most instances.⁴⁰² One easy way to make this distinction is for researchers to ask themselves if research ethics board approval was required. If so, there is at least some research component. Then, to distinguish between research alone and mixed research and treatment, researchers need only consider if the minor would undergo any of the procedures or receive any of the therapies included within the study protocol if she declined participation. If the answer is yes, then the work falls within the mixed research and treatment scenario and the researcher needs to consider all laws applicable to the treatment realm as well as those that apply to research. Again, researchers should ensure that they comply with the applicable legal requirements (i.e. the law that applies to treatment to treatment components and the law that applies to research to research components). If there is any doubt as to whether something is treatment or research, researchers should abide by the more onerous requirement. Doing so will reduce their potential exposure to liability.

⁴⁰² Unguru, Sill & Kamani, *supra* note 393 at e880-e881; Jeremy Sugarman *et al.*, “What Patients Say About Medical Research” (1998) 20:4 IRB: Ethics and Human Research 1 at 5-6 [Sugarman].

The clear separation of research from treatment, even when they are carried out concurrently will serve to remind researchers that research, due to its nature, sometimes carries certain risks that do not exist in the treatment realm. Potential research participants need to be informed of the risks flowing from research and those flowing from treatment (when applicable).⁴⁰³ That being said, in cases of mixed research and treatment, researchers-clinicians are urged to assess competence to consent to research and treatment elements simultaneously. Although the information to be understood and appreciated may be quite different for cases of research and treatment, the general test and criteria to be applied should be quite similar. As well, assessing capacity to consent to all interventions that will be delivered concurrently (or within a relatively short period of time) regardless of whether they constitute treatment or research recognizes the time-specific property of capacity determinations.

Based on the reasons discussed above, the creation of a framework applicable only to the consent process in medical research studies involving minors is appropriate. Although there are similarities between research and treatment, the differences between these two realms justify different approaches.

V. CAPACITY ASSESSMENT

The framework requires that a capacity assessment be carried out on all minors. There is, however, no specific template for this assessment provided here. Reasons for this omission are set out in greater detail below but generally pertain to the non-existence

⁴⁰³ Readers are reminded that the disclosure requirement for research and treatment differ. As noted by Hadskis, *supra* note 48 at 286-290, in the case of treatment, only material risks need to be disclosed whereas in research, all known risks must be disclosed.

of such a document at present and the inappropriateness of having a legal scholar draft one without the benefit of consultation with other interested parties.

Despite this apparent lack of guidance as to the content of the capacity assessment included within the framework, researchers are reminded that such assessments are (or ought to be) routinely carried out by clinicians who treat adolescent patients. Some institutions may also already have a process to be followed when evaluating capacity to consent. Those resources should be used until an instrument is specifically validated for use with minors involved in research activities.

The use of a validated instrument when assessing the capacity of all minors whose participation in research is sought does not mean that the degree of testing and time to carry out the assessment will be the same in all cases. Where young children are concerned, less testing will generally be required to determine competence. After all, once a researcher has conclusively determined that a minor lacks competence, it is unnecessary to go on with the remainder of the assessment. However, as a minor gets closer to reaching the age of majority, it becomes increasingly likely that she will be capable of autonomous decision-making and so more testing will be required to determine on which side of the capacity divide the minor falls. Regardless of the manner in which the capacity assessment is carried out, researchers should document all details regarding the assessment in writing. Such documentation would be of assistance in any legal proceeding brought against a researcher for failure to obtain legally valid consent.⁴⁰⁴

⁴⁰⁴ There is no actual evidence to suggest that parents (or other interested parties) would file law suits against researchers in cases where informed consent was not sought from them. There is likewise no evidence that minors denied the right to decide whether they wish to participate would sue. However, if and when such a case is brought, researchers would be better positioned to defend the claim if they can show to the court the steps they took in assessing capacity and the reasoning that underlies their ultimate conclusion of capacity or incapacity, as the case may be.

The discussion below begins by first looking at why the framework calls for an individualized assessment of each minor's capacity. It then situates the assessment within the broader consent process by looking at who is responsible for carrying out the assessment itself and with whom study-related information is shared. Thereafter, the discussion shifts to considering the types of activities that are to be assessed. Lastly, suggestions are given as to how a new tool could be developed.

A. Proving Capacity: Every Minor's Right

The primary aim of this thesis is to clarify the role of minors, particularly adolescents, in the decision-making process with respect to research participation. As it stands presently, the age of majority creates a bright line distinction between those who are presumed competent and those who are not. Although both presumptions are rebuttable in theory, it is unknown whether minors are being given the opportunity to rebut the presumption of incapacity in practice. Consequently, I propose that the rights of minors can be better respected by developing a framework that explicitly mandates researchers to assess the capacity of each minor as well as limiting the exchange of information with parents or authorized third parties prior to this assessment taking place.

The capacity assessment requirement included in the framework proposed herein applies to individuals who are less than eighteen or nineteen, depending on province of residence. Specifically, for persons living in Alberta, Manitoba, Ontario, Prince-Edward Island, and Saskatchewan, it applies if they are less than eighteen years of age.⁴⁰⁵ In all

⁴⁰⁵ *Age of Majority Act (Alberta)*, *supra* note 231; *Age of Majority Act (Manitoba)*, *supra* note 281; *Age of Majority and Accountability Act*, R.S.O. 1990, c. A.7, s. 1; *Age of Majority Act*, R.S.P.E.I. 1988, c. A-8, s. 1; *The Age of Majority Act*, R.S.S. 1978, c. A-6, s. 2(1).

other common law jurisdictions, the framework applies to individuals who are less than nineteen years of age.⁴⁰⁶

The discussion below sets out nine reasons why requiring that each minor undergo a capacity assessment leads to a better, more legally and ethically defensible definition of the role of adolescents in the consent process. Prior to looking at those reasons, I need to acknowledge the fact that some readers may not think it is necessary to assess the capacity of each minor. Those readers would argue that surely there is some minimum age below which capacity need not be assessed. My response to that argument is embedded in the reasons I set out below. Briefly stated though, it is that the breadth of research is so wide that an appropriate minimum age for one research study could be seen as being unnecessarily low with respect to another study and too high for yet another.

(i) Age Cannot Be Equated With Capacity

Age has long been used to define the rights, obligations, and responsibilities of classes of individuals within society. Historically, the ability to consent to one's own medical treatment has not been an exception. Notably, "the Rule of Sevens" was first laid out in *The Queen v. Smith*, (1845) 1 Cox C.C. 260 (Crim.)⁴⁰⁷ in 1845 in England. Under that rule, the legal capacity of minors is divided into increments of seven years. Specifically, minors under the age of seven do not have legal capacity, minors between the ages of seven and fourteen are presumed to lack capacity, but the presumption is rebuttable, and minors between fourteen and twenty-one are presumed (though again the

⁴⁰⁶ *Age of Majority Act*, R.S.B.C. 1996, c. 7, s. 1(1)(a); *Age of Majority Act (NB)*, *supra* note 282; *Age of Majority Act*, S.N.L. 1995, c. A-4.2, s. 2; *Age of Majority Act*, *supra* note 272; *Age of Majority Act*, R.S.N.S. 1989, c. 4, s. 2(1); *Age of Majority Act*, R.S.Y. 2002, c. 2, s. 1(1); *Age of Majority Act (Nu)*, *supra* note 272.

⁴⁰⁷ *The Queen v. Smith*, (1845) 1 Cox C.C. 260 (Crim.).

presumption is rebuttable) to be legally competent. Those over the age of twenty-one are presumed to have full capacity.⁴⁰⁸

Although the lives of minors have changed in many ways since 1845, capacity is still considered to evolve with age. Use of age as the basis for differential treatment persists today; as is evident when one considers that limits on when individuals can drive a car, vote in elections, or even the processes to be followed in criminal proceedings are all based on age. In some instances, it is necessary to confer rights upon individuals solely on the basis of age, despite the fact that doing so does not promote justice for all.⁴⁰⁹ Voting and driving are both examples of where this approach has been deemed necessary. In my view, it is not necessary to use age with respect to consent to research participation. The rights of minors can be respected by requiring that each minor have an equal opportunity to prove that they are competent. Minors involved in research, like those receiving medical treatment and those involved in the criminal justice system, should not all be treated in the same manner. The preservation of a minor's rights and the feasibility of looking at each individual in those contexts outweigh the need for bureaucratic efficiency. After all, chronological age does not guarantee a certain decision-making ability.⁴¹⁰

(ii) **Adolescents and Adults May Have Comparable Decision-Making Capacity**

Researchers have only recently begun looking at decision-making by minors in the research process. Consequently, much of the literature comparing the capacity of

⁴⁰⁸ Paul Arshagouni, "But I'm An Adult Now...Sort Of": Adolescent Consent in Health Care Decision-Making and the Adolescent Brain" (2006) 9 J. Health Care L. & Pol'y 315 at 332 [Arshagouni].

⁴⁰⁹ Susan E. Zinner, "The Elusive Goal of Informed Consent by Adolescents" (1995) 16 Theoretical Medicine 323 at 329-330 [Zinner].

⁴¹⁰ Ann Marie McCarthy *et al.*, "Psychological Screening of Children for Participation in Nontherapeutic Invasive Research" (2001) 155 Archives of Pediatrics & Adolescent Medicine 1197 at 1197 [McCarthy].

adolescents to adults emerges out of the medical treatment context. Despite the differences between the treatment and research setting, it is useful to look at what studies involving medical treatment have found with regards to the capacity of minors. Not only have few authors looked into the research context thereby leaving little evidence of the comparative capacities of minors and adults, there are also many instances where individuals are receiving treatment and involved in research concurrently. Finally, a thorough understanding of what is known from the treatment context is necessary because there is no clear reason why minors who are allowed to make treatment decisions should not possess the “parallel right” to decide whether they wish to participate in medical research.⁴¹¹

There is a growing body of research into the evolution of our decision-making ability from childhood through to adulthood. Subscribers to the view that minors of a certain age should be deemed competent point to the considerable body of literature that has found that the transition from incompetence to universal competence occurs somewhere between fourteen and fifteen years of age.⁴¹² As well, it has also been shown that from age fifteen onwards, the majority of adolescents are able to consent to medical treatment without being influenced by the opinion of others.⁴¹³

⁴¹¹ Zinner, *supra* note 409 at 323-326. At present, since the common law mature minor rule has not explicitly been found to apply to the research context, there is some uncertainty as to whether minors possess such a “parallel right”.

⁴¹² Committee on Bioethics, American Academy of Pediatrics, “Informed Consent, Parental Permission, and Assent in Pediatric Practice” (1995) 95 *Pediatrics* 314, which states that adolescents over the age of fourteen “may have as well developed decisional skills as adults for making informed health care decisions.”

⁴¹³ D. Bailly, “Problèmes liés au consentement chez l’enfant et l’adolescent” (2010) 17 *Archives de Pédiatrie* s7 at s12; Lois A. Weithorn & Susan B. Campbell, “The Competency of Children and Adolescents to make informed Treatment Decisions” (1982) 53 *Child Development* 1589 at 1595 [Weithorn & Campbell]; Thomas Grisso & Linda Vierling, “Minors’ Consent to Treatment: A Developmental Perspective” (1978) 9 *Professional Psychology: Research & Practice* 412 at 423.

Research suggests that adolescents and adults have comparable decision-making capacity in the treatment context. Notably, in the often-cited study by Weithorn and Campbell, children, adolescents and adults were presented with four hypothetical treatment dilemmas. They were then interviewed, with their responses to questions coded on the basis of understanding, choice, reasoned outcome, and rationale. Ultimately, this study revealed that fourteen year old adolescents did not differ from adults on any of the dimensions (understanding, choice, reasoned outcome, and rationale) assessed.⁴¹⁴ Although the fact that this study involved hypothetical scenarios cannot be ignored, it is necessary to ensure its significance is not overemphasized when trying to apply the findings to the research context given the inherent uncertainty of the research process. Such uncertainty includes in double-blind drug trials, for example, the fact that neither the investigator nor the participant know which investigational product the participant will receive at the time consent is obtained or even while the study is ongoing. Efficacy of the intervention is also unknown, which is not the case in the treatment context. Briefly stated then, hypothetical scenarios are more akin to the research context than they are to the treatment context.

Despite the above evidence, some researchers have nonetheless pointed to alleged differences in capacity between adults and minors to justify treating minors differently. For example, Koelch *et al.* have assessed the capacities for understanding, appreciation, and reasoning of children and adolescents with attention deficit/hyperactivity disorder (ADHD) or ADHD combined with oppositional defiant disorder. The capacities of the parents of participating minors were also examined. They found that just over two-thirds

⁴¹⁴ Weithorn & Campbell, *ibid.*

of minors and one-third of parents did not understand the primary objective of the research. Minors were also found to have difficulty understanding what a placebo was and the likelihood that they would receive it. Based on these results, those authors concluded that all minors are in need of protection because they have problems understanding complex research projects.⁴¹⁵

However, the study by Koelch *et al.* only involved minors between seven and fifteen years of age and so, at best the findings only apply to that age group.⁴¹⁶ Also, these authors were comparing the capacity of minors with a psychological ailment to their parents (whose own mental health status was not reported). Having failed to control for attention-deficit issues, the authors incorrectly attributed the differences in measures of capacity to age alone. Although age may explain the differences entirely, the research design does not allow for that conclusion to be drawn. Despite its flawed methodology, this study has been included in the discussion here to alert readers that some minors may have diminished capacity as compared to their parents.

(iii) Denial of Rights Based on Lack of Capacity Requires Proof

Those who argue that minors do not have the requisite capacity generally point to the greater amount of understanding into long-term consequences adults have acquired through knowledge and experience. They contend that minors have generally not had a

⁴¹⁵ Michael Koelch *et al.*, ““...Because I Am Something Special” or “I Think I Will Be Something Like a Guinea Pig”: Information and Assent of Legal Minors in Clinical Trials – Assessment of Understanding, Appreciation and Reasoning” (2009) 3(1) *Child and Adolescent Psychiatry & Mental Health* 2 [Koelch *et al.*, “Something Special”].

⁴¹⁶ I say “at best” because the MacCAT-CR (tool used to assess the capacity of the participants) has not been validated for use in children and adolescents and therefore may not correctly assess capacity in minors. In fact, in Koelch *et al.*, “Report of an Initial Pilot Study on the Feasibility of Using the MacArthur Competence Assessment Tool for Clinical Research in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder” (2010) 20 *Journal of Child and Adolescent Psychopharmacology* 63 at 66, Koelch and his colleagues concluded that the MacCAT-CR “seems to be feasible with children” but that further validation was required.

sufficient number of life experiences to make long-term projections about their health.⁴¹⁷ It has further been claimed that unlike adults, minors have the potential to improve their ability to make decisions that are in their best interest. Since their capacity has not reached its full potential, Ross argues minors should not be afforded the opportunity to make their own treatment decisions.⁴¹⁸

The view that minors lack experience and can improve their decision-making ability is flawed for two main reasons. Firstly, it ignores the fact that upon reaching the age of majority an individual is presumed competent. Consequently, even though intuitively most people would accept that a forty year old has had more life experiences than a sixteen year old, it is doubtful that an eighteen year old has a better understanding of long-term consequences based on life experience than a minor who is seventeen years and three hundred and sixty days old. After all, most would agree that many teenagers now continue to reside at home upon graduating from high school (which itself generally occurs between seventeen and eighteen years of age), are not married, and do not have children. They have also not likely had any more exposure to the health care setting.

Thirdly, denying all minors the right to consent on the basis of lack of experience and potential for improvement in their decision-making capacity means that minors will be held to a different standard than that expected of adults. Stated differently, even if they meet the criteria set out in law for mature minor status, such competency is necessary but not sufficient to bestow autonomy on a minor because the decisions they make today may limit their autonomy in the future.⁴¹⁹ Adults, however, are presumed

⁴¹⁷ Arshagouni, *supra* note 408 at 322.

⁴¹⁸ Lainie Friedman Ross, "Adolescent Sexuality and Public Policy: A *Liberal* Response" (1996) 15(1) *Politics & Life Sciences* 13 at 16-17.

⁴¹⁹ *Ibid.*

competent and entitled to make decisions unless that presumption is rebutted. Nothing further is required of adults. As such, adults are free to make decisions that will curtail their autonomy later in life. This blanket denial of rights is untenable from a legal standpoint. As readers will recall, any violation of section 7 rights to liberty and security of the person except in accordance with the principles of fundamental justice as well as to the section 15(1) right to freedom from discrimination on the basis of an enumerated ground must be justified under section 1 of the *Charter*. For reasons set out in Chapter 2 of this thesis, outright banning all minors from deciding whether they wish to participate in a research study would not withstand *Charter* scrutiny.⁴²⁰ Based on the reasoning in *A.C. v. Manitoba (Director of Child and Family Services)* as well as the jurisprudence on the common law mature minor rule reviewed in Chapter 2, the rebuttable presumption of incapacity that applies to all minors under the framework proposed herein, however, would be constitutional.

(iv) Mandating Capacity Assessments is Consistent with the Jurisprudence

It is doubtful that the courts would opt for a more expansive recognition of the rights of minors in the research setting as compared to the treatment setting, even when the two contexts can be distinguished from one another. This view is based on the great emphasis placed on the vulnerability of minors and on their need for protection by the majority of the Supreme Court of Canada in *A.C. v. Manitoba (Director of Child and*

⁴²⁰ As readers will recall, in its decision in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, the majority and the minority of the Supreme Court of Canada found that there was no *Charter* violation. Specifically, the majority and the minority concurred that there was no section 7 violation because no principal of fundamental justice had been violated. As well, there was no section 15(1) violation because, according to the majority, the presumption that those under the age of 16 lacked maturity to make treatment decisions was rebuttable. The minority, in turn, held that although a distinction had been made on the basis of age, there was no discrimination because the steps taken were ameliorative.

Family Services).⁴²¹ As readers will recall, under the common law, ‘mature minors’ are entitled to consent to their own medical treatment. This right is, of course, subject to any applicable consent to treatment legislation and child protection legislation. In the child protection context, however, the majority of the Supreme Court of Canada recently upheld the constitutionality of a section of Manitoba’s child protection statute that allowed treatment to be forced upon an unwilling minor under the age of sixteen where such treatment was in her “best interests”.⁴²² Faced with such a clear endorsement of the welfare principle from our highest court, the most that can be hoped for is a narrow reading of *A.C. v. Manitoba (Director of Child and Family Services)*, whereby the “best interests” criteria is restricted to the child protection context. That being said, one cannot deny the fact that some protection is still warranted in the research context, particularly in instances where the minor will not derive any direct benefit from her participation. One such source of protection is the requirement to use a validated tool for the capacity assessment of each and every minor whose participation is sought.

(v) **Existing Legislation Acknowledges That Not All Minors Have Equivalent Capacity**

Ten provincial and territorial legislatures already recognize that not all minors require the same protections. Specifically, the medical decision-making provisions contained within the child protection statutes of Newfoundland and Labrador, Nova Scotia, Nunavut, the North West Territories, Ontario, Prince Edward Island, and Saskatchewan only apply to minors under the age of sixteen.⁴²³ As well, Saskatchewan

⁴²¹ *Ibid.* at paras. 85-87, 97-117.

⁴²² *Ibid.* at paras. 97-117.

⁴²³ *Children, Youth and Family Services Act*, *supra* note 260, s. 2(1)(d); *Child and Family Services Act*, (NWT), *supra* note 278, s. 1; *Children and Family Services Act* (Nova Scotia), *supra* note 278, s.3(1);

allows all minors over the age of sixteen to consent to treatment, while Manitoba, New Brunswick, and Newfoundland and Labrador presume minors who are sixteen years and older to be competent.⁴²⁴ Five other jurisdictions (British Columbia, Ontario, Nova Scotia, Prince Edward Island, and Yukon) require an individualized assessment of capacity rather than using age to delineate rights.⁴²⁵ The ability of minors to consent to treatment in British Columbia, New Brunswick and Yukon may nonetheless be limited by child protection legislation, which in all three jurisdictions applies to minors under nineteen years of age.⁴²⁶

Without delving into the debate that occurred at the time that each of the relevant provisions were passed, politicians in those ten jurisdictions clearly felt that it was appropriate to draw a distinction with respect to capacity between minors based on age. In most cases, a bright line was drawn at sixteen years of age. This means that unlike the rebuttable presumption included within the framework proposed here, the bright lines included in the aforementioned statutes do not bestow care providers with the ability to override the decisions of minors over the legislated age that do not have the requisite understanding (i.e. those who would not be mature minors if an assessment was carried

Child and Family Services Act (Nunavut), *supra* note 278, s.1; *Child and Family Services Act* (Ontario), *supra* note 101, s. 37(1); *Child and Family Services Act* (Saskatchewan), *supra* note 103, s. 2(1)(d).

⁴²⁴ *The Health Care Directives and Substitute Health Care Decision Makers Act*, *supra* note 232, s. 2(1)(d); *The Health Care Directives Act*, *supra* note 215, s.1; *Medical Consent of Minors Act*, *supra* note 27, s. 3(1); *Advance Health Care Directives Act*, *supra* note 130, s. 7(b). In New Brunswick, the treatment must also be in the minor's best interests.

⁴²⁵ *Infants Act*, *supra* note 29, s.17(2)-(3); *Health Care Consent Act*, *supra* note 227, s.1, 4(1)-(3); *Personal Directives Act*, *supra* note 253; *Consent to Treatment and Health Care Directives Act*, *supra* note 256, s. 3; *Care Consent Act*, *supra* note 229, s.5(e), 6(2). In British Columbia, the treatment must also be in the minor's best interests.

⁴²⁶ *Child, Family and Community Service Act*, *supra* note 278, s. 1(1); *Family Services Act*, *supra* note 278, s. 1; *Age of Majority Act (NB)*, *supra* note 282; *Child and Family Services Act* (Yukon), *supra* note 270, s. 1.

out). They also do not afford minors under the age of sixteen to demonstrate that they are mature minors and should therefore be allowed to provide autonomous consent.

(vi) **The Capacity Assessment as a Measure of Protection**

One of the frequent reasons given for requiring parental consent rather than allowing minors to provide legally valid consent is that minors are vulnerable and consequently are in need of protection. Nowhere is this more succinctly stated than in the European Union's *Ethical Considerations for Clinical Trials on Medicinal Products Conducted in the Paediatric Population*⁴²⁷, which states that all minors are vulnerable and that even those who are not considered minors under national law may need "additional discussions and explanations."⁴²⁸

This justification for interfering with the rights of minors assumes that all minors are vulnerable. The basis for such vulnerability appears to be primarily their diminished decision-making capacity due to their age.⁴²⁹ So, if a minor is competent (i.e. is a mature minor), much (if not all) of the rationale for her vulnerability disappears.⁴³⁰ Any lingering vulnerability can be addressed through less constraining means than outright denying her the right to choose whether or not she wishes to participate in a research study prior to her parents being consulted.⁴³¹ Besides ensuring that appropriate means of

⁴²⁷ 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, "Ethical Considerations for Clinical Trials on Medicinal Products Conducted in the Paediatric Population" (2008) 15 Eur. J. Health L. 223.

⁴²⁸ *Ibid.* at 225, 231.

⁴²⁹ The notion of vulnerability is further discussed in Chapter 3 of this thesis.

⁴³⁰ Note that the majority in *A.C. v. Manitoba (Director of Child and Family Services)*, *supra* note 65, held in child protection proceedings, minors under the age of sixteen were vulnerable, whether or not they had decision-making capacity. They did not, however, go so far as to say all minors in all contexts remain vulnerable regardless of they have the capacity to provide legally valid consent.

⁴³¹ As noted in Chapter 3, minors must provide their assent in order to participate in a research study in circumstances where the *Tri-Council Policy Statement* applies. Article 3.10 of the *Tri-Council Policy Statement*, *supra* note 1, further requires that the dissent of incompetent minors must be respected when that individual has "some ability to understand the significance of the research". However, the present

communicating with the prospective research participants are used (as discussed further below), requiring that each minor undergo a capacity assessment is in itself a protective measure. Specifically, the individualized assessment means that no minors will be afforded rights that exceed their abilities because they have met some arbitrary age threshold.

(vii) No Evidence that Capacity Assessments are Routinely Carried Out

One cannot ignore the potential infringement of the rights of mature minors involved in research. The reality at present is that there is no guarantee that the right of mature minors to consent to their own research participation will be respected. The *Tri-Council Policy Statement's* silence on this point means that research ethics boards and researchers are not explicitly alerted to the need to turn their mind to any right to consent minors may possess. Some may suggest that there is no need for a provision that mandates a capacity assessment because such assessments are routinely carried out by researchers. My response to this is that there is no indication in any publication of research findings that I have read that gives any indication that capacity is being assessed, never mind that all researchers are evaluating the capacity of each and every minor they attempt to recruit into a study. Given this dearth of information, the thoroughness of any assessments, when assessments are even being done, is also unknown. Absent such proof and information on the accuracy of capacity assessments, I am of the view that minors are deserving of a guarantee that their rights will be respected in an appropriate manner.

process does not require that minors be approached first and without their parents present (unless the minor elects to have her parents there).

(viii) Standard Procedures Encourage Consistency and Predictability

Explicitly requiring a capacity assessment prior to any minor participating in a research study encourages consistency and fosters predictability. In a framework that is to be applied nationally, such characteristics are highly desirable. By leaving the presumption of capacity unchanged (i.e. at the age of majority) and requiring a capacity assessment on each minor, all minors have an equal opportunity to demonstrate that they are capable of autonomous decision-making. Minors will be informed of their right to establish that they are competent and researchers will be required to be able to point to specific reasons why a minor has been found to lack the capacity required to give legally valid consent.

(ix) International Perspective

Minors residing in other countries have been allowed to consent to their own participation in medical research studies. For example, New Zealand recently adopted a framework with respect to age of consent similar to that proposed here. Specifically, the Health Research Council of New Zealand's *Guidelines for Health Research with Children*⁴³² states:

7. Before undertaking research with children the investigator must ensure that legally valid consent is sought on the basis of the information provided:
 - i. The consent of a child of or over the age of 16 must be obtained and has the same effect as if the child were of full age, provided the child does not lack competence for reasons other than age.

⁴³² Health Research Council of New Zealand, *Guidelines for Health Research with Children, 2000* (updated 2007), online: <<http://www.hrc.govt.nz/assets/pdfs/publications/Appendix%201%20-%20Guidelines%20for%20Health%20Research%20with%20Children%20030407%20-%20Final.pdf>>.

- ii. If the child is below the age of 16, but has the competence to understand the nature, risks and consequences of the research:
 - (a) the consent of the child must be obtained, and
 - (b) that consent will have the same effect as if the child were of full age.⁴³³

In cases of mixed research and treatment, these guidelines are modified by the *Care of Children Act 2004*⁴³⁴, a statute that essentially combines what Canadian jurisdictions include in child protection and consent to treatment legislation. The *Care of Children Act* allows minors who are sixteen years of age or older to consent to “any medical, surgical, or dental treatment or procedure” that will benefit that minor.⁴³⁵ Upon reaching the age of eighteen, there are no restrictions on an individual’s ability to consent (i.e. the treatment or procedure need not be beneficial).⁴³⁶

As well, in the United Kingdom, young people who are sixteen years of age or older are afforded the right to consent to all forms of research. Those minors who are less than sixteen years of age can consent if (1) the research is of minimal risk, (2) participation is in their best interest, (3) they are found to be mature minors, and (4) they refuse parental involvement.⁴³⁷ Reasons as to why this author finds the use of the type of

⁴³³ *Ibid.* at principle 7. It is worth drawing the attention of readers to the fact that, unlike in the framework proposed here, New Zealand’s instrument does not explicitly mandate that contact is to be between the minor who is over sixteen years of age and the researcher.

⁴³⁴ (N.Z.), 2004/90.

⁴³⁵ *Ibid.* at s. 36(1).

⁴³⁶ *Ibid.* at s. 8.

⁴³⁷ National Health Service Central Office for Research Ethics Committees, *Multi-Centre Research Ethics Committees Guidance Notes, 2000*, Research on children (Manual II.7 & V27.1) cited in Sanci *et al.*, “Youth Health Research Ethics: Time For a Mature Minor Clause?” (2004) 180 *Medical Journal of Australia* 336 at 336 [Sanci *et al.*].

risk involved as a criterion for determining when minors have the right to consent problematic are set out below.

B. The Researcher's Role

Under the framework proposed herein, the researcher (when qualified) is expected to carry out the capacity assessment on each minor that the researcher seeks to recruit for a particular study. Fulfilling that obligation requires that researchers use appropriate means of communicating with prospective research participants so as to ensure that a minor found to be incompetent really lacks decision-making capacity as opposed to fails to understand the vocabulary used by the researcher. Both of these duties imposed on researchers are discussed in this section.

(i) Carrying Out the Capacity Assessment

There is no legal or ethical obligation on researchers in Canada to assess the competence of either potential or present research participants themselves.⁴³⁸ The principal researcher is, however, ultimately responsible for ensuring that anyone acting under delegated authority acts in accordance with all legal and ethical requirements.⁴³⁹ Obtaining valid consent is one such requirement. Given the breadth of research being carried out in Canada, requiring a certain class of individuals to assess competence for all types of research is inappropriate. Consequently, the discussion below sets out reasons why generally the researcher is likely best positioned to make the determination while still recognizing that in some instances, others may be a better choice. To this end, the comments below are only intended to provide researchers with some guidance as to who

⁴³⁸ Of course, if a researcher fails to allow a competent participant to consent, the researcher is exposing herself to a battery action.

⁴³⁹ *Tri-Council Policy Statement*, *supra* note 1 at art. 3.2 and accompanying commentary.

should carry out the capacity assessment. Ultimately it is individual researchers and research ethics boards who must decide who with respect to a particular study ought to carry out the assessment.

Although the *Tri-Council Policy Statement* is silent about the assessment of capacity itself, it does state that in any research captured by the instrument, the researcher or her “qualified designated representative” must seek consent from competent potential research subjects at the outset of the study.⁴⁴⁰ In the case of physician-researchers, one would expect the researcher to obtain consent since they are tasked with obtaining consent from their minor patients with respect to consent to treatment.⁴⁴¹ Researchers from other disciplines may or may not possess the same degree of skill.⁴⁴²

I would suggest that in most cases, the researcher responsible for the research should carry out the assessment. Where that individual feels she does not possess the necessary expertise, the assessment should be carried out by another properly skilled individual, such as a psychologist. The assumption that researchers have the requisite skills to obtain consent can be extended to the capacity assessment because the assessment is either a necessary precursor to the consent process, or alternatively is itself part of the consent process. Regardless of which way the role of the capacity assessment is framed, the fact that researchers are appropriately skilled to carry out the assessment is supported by the *Tri-Council Policy Statement*. Notably, in research involving minors

⁴⁴⁰ *Ibid.*

⁴⁴¹ I have used the phrase “seems sound” because there is no information available as to the frequency with which consent is obtained from mature minors in the treatment context. It is possible that physicians providing care to minors are merely seeking parental consent rather than undertaking a competence assessment.

⁴⁴² It is beyond the scope of this thesis to speculate as to the nature of the consent being obtained by various professionals. The point is being raised only to flag the possibility that it may be necessary to look to someone outside the research team, such as a psychologist, where no one within the team has the requisite expertise to properly determine if a minor is competent or not.

who are incompetent at the time informed consent is obtained, the researcher has a duty to obtain consent from that minor during the course of the study if the latter becomes competent.⁴⁴³ The researcher would only be able to fulfill that duty if she knew that the minor was now competent.

Beyond being a reasonable expansion of the *Tri-Council Policy Statement*, having the researcher carry out the assessment also has a number of significant advantages. These advantages include the fact that the researcher is more familiar with the study and so could more easily explain the study to the minor, answer questions, and evaluate how much information the minor understands. It may also be more cost effective since the researcher could then obtain consent at the same time.⁴⁴⁴ That being said, there are also some challenges in implementing this approach. Most notably, researchers would need to have a thorough understanding of the requirements for adolescents' informed consent and research ethics boards would need a thorough understanding of adolescent development.⁴⁴⁵ These hurdles are not insurmountable. Some researchers (particularly those who are also clinicians) likely have this understanding already. Others could acquire this knowledge through education.⁴⁴⁶

(ii) Using Appropriate Means of Communicating

Legislators and the Tri-Council are entitled to put in place processes to ensure minors are given an appropriate level of responsibility when it comes to healthcare decision-making. In doing so, however, the *Charter* requires that they use means that are

⁴⁴³ *Tri-Council Policy Statement*, *supra* note 1 at art. 3.9(e).

⁴⁴⁴ Thomas Grisso & Paul S. Appelbaum, *Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals* (New York: Oxford University Press, 1998) at 77-78 [Grisso & Appelbaum].

⁴⁴⁵ Sanci *et al.*, *supra* note 437 at 337.

⁴⁴⁶ Grisso & Appelbaum, *supra* note 444, is an example of a resource that could be used to educate researchers and research ethics board members.

minimally impairing.⁴⁴⁷ The Supreme Court of Canada has been clear: a complete ban on a specific activity will be more difficult to justify.⁴⁴⁸ As a result of this clear direction from our highest court, the framework proposed herein includes appropriate forms of protection: a focus on communication and an individualized assessment of capacity, the latter of which is discussed in a separate section above.

When one examines the literature on the way in which information is communicated to potential research participants and their decision-making capacity, it becomes evident that this is a topic that has garnered little attention. Specifically, the research comparing the decision-making capacity of adolescents to that of their parents makes no mention of the fact that differences may be due to the manner in which information was conveyed. No articles reviewed in the preparation of this thesis gave any detail on what subjects and their parents were told prior to signing a consent form or even included a copy of the form as an appendix. Rather, most articles merely report that informed consent was obtained from parents.⁴⁴⁹ Recently, however, Unguru *et al.* looked at the understanding of research-related treatment and the preferences for inclusion in decision-making of children with cancer. The mean age of the participants was just over thirteen and a half. They found that over two-thirds of minors found the trial-related information a “little hard” or “very hard” to understand. This was overwhelmingly attributed to their inability to understand the language used by their physician.⁴⁵⁰

⁴⁴⁷ *Charter*, *supra* note 64, s.1; *R. v. Oakes*, *supra* note 210. Further details on the test to be carried out when determining if a violation of s. 7 or s. 15(1) is justified can be found in Chapter 2 of this thesis and so will not be repeated here.

⁴⁴⁸ *Ramsden v. Peterborough (City)*, 1993 CanLII 60 (S.C.C.) at 26, [1993] 2 S.C.R. 1084.

⁴⁴⁹ See e.g. Weithorn and Campbell, *supra* note 413 and Koelch *et al.*, “Something Special”, *supra* note 415.

⁴⁵⁰ Unguru, Sill & Kamani, *supra* note 393 at e878-e879.

The mature minor test requires that a minor demonstrates “sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not.”⁴⁵¹ There is nothing in the previous statement that limits how information is conveyed to the minor (i.e. the same language as that used when discussing research procedures to parents need not be used). It is therefore essential that difficulty understanding the language used by a researcher not be equated to difficulty understanding the proposed research project.⁴⁵² Only the latter is evidence of a lack of capacity. Consequently, capacity should only be assessed after a minor has been presented with information in a manner that she can understand. Other forms of communication that should be considered by researchers include diagrams, graphs, and less sophisticated vocabulary.

C. The Limits on the Sharing of Study-Related Information

To ensure minimal interference with the privacy rights of minors, the framework proposed in this thesis requires that researchers discuss as few details of a specific research project with parents or authorized third party representatives of potential research participation as possible prior to carrying out the capacity assessment. This limit has been included in order to properly define the role of parents given the differences that may exist between their motivations and their child’s motivations with respect to research participation. It is also part of the process for practical reasons, which reasons include getting parents to bring young children to research sites. The use of the phrase “as possible” in part (c) of the framework also recognizes that the amount of information that

⁴⁵¹ Gilmour, “Children”, *supra* note 89.

⁴⁵² Research Ethics Boards review the language found in consent and assent forms to ensure the appropriateness of that language. However, there is no such review of the language used by researchers when they discuss the study either over the telephone or in person with potential research participants.

will need to be shared with parents prior to carrying out the capacity assessment will vary depending on the circumstances.

(i) **Different Reasons, Values and Choices**

Research has found that adolescents and their parents weigh different values and factors when deciding whether or not to consent to (or in the case of parents to their children's) participation in a particular research study. Notably, Brody *et al.* compared the views of adolescents, parents, and physicians with respect to participation in asthma research. Results revealed that more adolescents than parents were willing to enrol in greater than minimal risk asthma research. They also looked at the disagreement rate between adolescents and their parents, which earlier research had reported to be as high as 40%.⁴⁵³ Brody *et al.* found that most initial disagreements arose from the parent's wish to decline and the adolescent's willingness to participate. Such differing views were subsequently resolved in favour of the parent two-thirds of the time.⁴⁵⁴ Although this statistic does not tell us whether or not the minors were capable of giving legally valid consent, it does suggest that recruitment rates (and the participants recruited) differ depending on who is approached by researchers about a particular study and on who consents to research participation.

As well, Read *et al.* recently asked adolescents diagnosed with cancer and their parents from a number of sites, including three Canadian sites, to complete a

⁴⁵³ Janet L. Brody *et al.*, "Comparisons of Adolescent and Parent Willingness to Participate in Minimal and Above-Minimal Risk Pediatric Asthma Research Protocols" (2005) 37 *Journal of Adolescent Health* 229 at 234 [Brody *et al.*, "Comparisons"].

⁴⁵⁴ Janet L. Brody *et al.*, "Enrolling Adolescents in Asthma Research: Adolescent, Parent, and Physician Influence in the Decision-Making Process" (2009) 46 *Journal of Asthma* 492 at 495-496.

questionnaire about health research participation.⁴⁵⁵ The most frequently given reason for agreeing to participate by both the young adults (median age was 18 years) and the parents asked to consent on their minor child's behalf was to help others. However, the reasons for declining participation differed between the groups; the young adults pointed to time commitment while parents' reasons included travel barriers, wanting the best proven treatment, and not being ready to tell the child the diagnosis.⁴⁵⁶ Young adults were also found to place greater emphasis on the recommendations of friends and family to participate than did their parents.⁴⁵⁷ Merely being interested in the views of others does not mean a minor lacks capacity. Allowing minors to consent still affords them the option to consult with friends and family, it just does not require it. Admittedly, having different reasons for declining participation does not necessarily lead to a different result (i.e. both parents and adolescents could refuse for different reasons), it is nonetheless possible. As noted previously, researchers are obligated to respect the right of minors to decline to participate in research and so disagreement between an adolescent's wishes and those of her parent(s) with respect to participation is less problematic. However, where a minor wishes to participate and her parent(s) disagrees, unless she can provide autonomous consent, the minor's rights are infringed.

The effect of different views is further seen in a study by Pousset *et al.* In that study, answers about hypothetical end-of-life decisions given by adolescent cancer survivors (who were between 11 and 18 years old) during an interview were compared to

⁴⁵⁵ The fact that three sites included in the study were in Canada is mentioned because the participants in that study had been enrolled in a manner consistent with the *Tri-Council Policy Statement, supra* note 1. It also demonstrates that Canadian minors and their parents hold discordant views. Stated differently, this is not merely an issue that has presented itself in other countries.

⁴⁵⁶ Kate Read *et al.*, "Decision-making by Adolescents and Parents of Children with Cancer Regarding Health Research Participation" (2002) 124 *Pediatrics* 959 at 962-963.

⁴⁵⁷ *Ibid.* at 963.

answers from children with no experience of chronic illness. At the outset, parents were sent a letter explaining the research objectives and asked to consent to their child's participation, which 179 of 198 did. Children whose parents had consented were then asked to consent, which only 83 of the 179 did.⁴⁵⁸ These numbers are striking in that more than half of the minors did not want to participate in a study their parents wanted them to participate in. Although not required under the framework proposed here, one way in which researchers could ensure that the study is discussed as little as possible with a minor's parent(s) or authorized third party while also saving time and money would be to make minors over the age of sixteen the first point of contact, rather than their parents.⁴⁵⁹

(ii) The Role of Parents

It is sometimes assumed that the vulnerability of minors is best protected by removing the right of minors to consent and instead requiring researchers to obtain parental consent and assent from the potential subjects. The flaw with this reasoning is although intuitively it seems reasonable to expect parents to safeguard the interests of their minor children, research is now emerging that brings into question whether parents are better-positioned than mature minors and older adolescents to make decisions about research participation.⁴⁶⁰

⁴⁵⁸ Pousset *et al.*, *supra* note 390 at e1143-e1144.

⁴⁵⁹ For example, if Pousset *et al.* had contacted the minors who were sixteen years of age or older first, all costs associated with mailing letters to parents as well as the weeks between the time the letter was mailed to parents and consent was sought from those minors would be saved.

⁴⁶⁰ All child protection statutes discussed in Chapter 2 are premised at least in part on the duty parents owe to their children to protect them. When parents fail to meet this obligation, the statutes allow for the State to intervene. It is beyond the scope of this thesis to examine whether parents are best positioned to afford such protection in circumstances beyond the realm of medical research where such legislation applies.

Beyond the fact that mature minors by definition have the capacity to make their own decisions and so arguably are in no more need of protection than a healthy adult, their parents' understanding of the research process is not necessarily any better than their own.⁴⁶¹ In fact, Tait *et al.* have found that only one-quarter of parents participating in an internet survey had an "adequate understanding" of the benefits of a hypothetical study.⁴⁶² Similarly Sugarman *et al.* found that nearly half of adult research participants did not know or recall that the 'treatment' they were receiving was in fact clinical research.⁴⁶³ These studies do not tell us whether the understanding of minors in those circumstances would have been better, the same, or worse. They do, however, suggest that turning to parents for consent to their child's research participation, may mean that consent is being obtained from individuals who themselves do not possess decision-making capacity.

If minors are being 'protected' by individuals who themselves lack an understanding of the research, they are not the beneficiaries of any real protection. Furthermore, not only are they not protected, all those involved in the research enterprise are proceeding on the mistaken belief that minors are being protected. In my opinion, more harm can result from proceeding on the assumption that mature minors are being protected when they are not than if they are allowed to provide autonomous consent. The obvious question then becomes: how can we respect the rights of mature minors while

⁴⁶¹ Although not understanding is not the same as not having capacity, since capacity requires both an understanding and appreciation of the nature and consequences of research participation and alternatives to participation, a lack of understanding of the research process generally gives rise to the possibility that parents may not in fact have capacity to consent. I was unable to find any reported study in which the capacity of parents to consent was evaluated. Rather, it seems to be often taken for granted.

⁴⁶² Alan R. Tait *et al.*, "Effect of Various Risk/Benefit Trade-offs on Parents' Understanding of a Pediatric Research Study" (2010) 125 *Pediatrics* e1475 at e1480.

⁴⁶³ Sugarman, *supra* note 402.

still safeguarding their interests? Contrary to the conclusion reached by Koelch *et al.* that all minors are in need of protection and that such protection is best provided by their parents even when the latter has a questionable understanding of a particular research study, I believe that this can be achieved through better communication and a validated process to assess decision-making capacity in minors who are less than sixteen years of age.⁴⁶⁴

(iii) The Practical Reality

Recognizing that minors may not attend at a research site without a parent or authorized third party present (or at least without such an individual knowing of their planned attendance), researchers are permitted some communication with the parent or authorized third party under the framework. However, discussions about the details of the specific research project should be as limited as possible, bearing in mind the need to get young children to attend research sites.

Once the capacity assessment has been completed, if the minor has been found to have decision-making capacity, it is up her to decide with whom she wishes to discuss the study. However, it is worth reminding readers that even if a minor is found to be incompetent to provide legally valid consent, she may still possess sufficient understanding and appreciation of the research procedures to assent to her own participation. When this is the case, if the minor declines participation, that decision is binding on the researcher, regardless of whether or not parental consent had been obtained.⁴⁶⁵

⁴⁶⁴ Koelch *et al.*, “Something Special”, *supra* note 415.

⁴⁶⁵ *Tri-Council Policy Statement*, *supra* note 1 at art. 3.10.

The limitation on discussing specific study-related procedures should not be taken as precluding researchers from discussing the general process involved in obtaining consent to parents and minors. Specifically, researchers remain free to explain to all interested parties how things will unfold, including that the minor's capacity will be assessed and that consent will be sought from the appropriate individual. Researchers can also tell a minor and her parents the general reason for the study because precluding the sharing of such general information would likely make the recruitment process close to impossible. As well, in some instances, such information is available to the general public through study-specific advertisements.

D. Activities That Are To Be Assessed

Under the framework proposed herein, the capacity of all minors must be assessed to determine if they are competent to provide autonomous consent to participate in a particular study. Capacity is situation-specific and so the assessment must be carried out in relation to the research study in question rather than with respect to research participation generally.⁴⁶⁶ A minor who is found to have the requisite capacity to consent to her own participation in one study may not be competent to consent to her participation in another study. Simply stated, different research studies will require different levels of decision-making skills.

In considering what is to be included in assessing the capacity of minors, one must be mindful not to set a threshold for competence that is, as one author has put it,

⁴⁶⁶ *Tri-Council Policy Statement, supra* note 1 at 37-40.

“sufficiently exacting that many adults might fail it.”⁴⁶⁷ So, precisely what needs to be assessed then? According to the jurisprudence, the assessment is aimed at determining whether the minor in question is a “mature minor”. That is, whether the minor has “sufficient understanding and appreciation of the nature and consequences of treatment and its alternatives to be able to decide whether to proceed with it or not.”⁴⁶⁸

One way that has been proposed to determine if the legal requirements for competence (i.e. mature minor standard in the case of minors) have been met is by examining an individual’s functional ability in four areas. According to Grisso and Appelbaum, the leading scholars on the assessment of competence to consent to treatment, these abilities are:

- The ability to *express a choice*;
- The ability to *understand* information relevant to treatment decision-making;
- The ability to *appreciate* the significance of that information for one’s own situation, especially concerning one’s illness and the probable consequences of one’s treatment options; and
- The ability to *reason* with relevant information so as to engage in a logical process of weighing treatment options. [Emphasis in original]⁴⁶⁹

Each of these abilities is framed in reference to treatment decisions, but they nonetheless seem to be equally applicable to the research context.

Prior to looking at tools that have been developed to assess decision-making skills, it is worth mentioning that some authors have suggested that different levels of

⁴⁶⁷ Andrew Bainham, “The Judge and the Competent Minor” (1992) 108 Law Quarterly Review 194, cited in Carolyn Johnston, “Overriding Competent Medical Treatment Refusal By Adolescents: When “No” Means “No”” (2009) 94 Archives of Disease in Childhood 487 at 487.

⁴⁶⁸ Gilmour, “Children”, *supra* note 89.

⁴⁶⁹ Grisso & Appelbaum, *supra* note 444 at 31. Each of these categories is further discussed in Paul S. Appelbaum & Thomas Grisso, “The MacArthur Treatment Competence Study. I: Mental Illness and Competence to Consent to Treatment” (1995) 19 Law Hum Behav 105.

competence ought to be required depending on the type of research at issue. Specifically, it has been argued that minors would need to demonstrate “a higher level of competency prior to being afforded the right to consent to non-therapeutic research procedures than is ordinarily required for therapeutic procedures”.⁴⁷⁰ However, given the current lack of clarity as to how competence should be evaluated, it would seem that adding degrees of competency would only further confuse the matter. Furthermore, degrees of competence are already indirectly included in the current approach in the treatment context (and in the research framework proposed herein) because as procedures become more complex, minors must demonstrate a more sophisticated understanding. Consequently, I propose that for the time being, a binary classification system be used (i.e. is the minor competent to make the particular decision at issue or not).

E. Using Existing Instruments to Develop a New Instrument

The competence assessment is only as sophisticated as those carrying it out choose to make it.⁴⁷¹ Based on the complete absence of a validated instrument to assess the competence of minors in the research context, it is likely that at present there is considerable variation in the thoroughness of assessments. Although the criteria will always require subjective evaluation, if the process to be followed in making the subjective determinations is spelled out, minors under the age of sixteen will at least be able to gain some comfort from the fact that they all have the same opportunity to rebut the presumption of incompetence.

⁴⁷⁰ Rodney K. Adams, “Live Organ Donors and Informed Consent: A Difficult Minuet” (1987) 8 J. of Legal Med. 555 at 577.

⁴⁷¹ Michelle Oberman, “Minor Rights and Wrongs” (1996) 24 J.L. Med. & Ethics 127 at 129.

Many authors have identified a need for a tool to assist in the assessment of capacity of minors.⁴⁷² Recognition by scholars that such an instrument is lacking suggests that it may be inappropriate to use adult criteria to assess the competence of minors. It also implies that some clinicians and researchers may be opting to informally assess competence rather than using a flawed tool. Although there is no research available to confirm or reject these possibilities, it is irrefutable that the use of a properly designed and validated tool is more likely to yield results that are representative of a given adolescent's actual functioning and competence.⁴⁷³

Unfortunately, it is not possible to include an instrument that can be used to assess the competence of minors to consent to their own research participation within the framework here because no such tool exists at present and one could only be developed after extensive consultation with physicians, researchers, ethicists, psychologists, and lawyers. Each of these classes of individuals would bring a necessary expertise to the process. For example, lawyers could help ensure that the instrument was of assistance to researchers in any legal proceedings arising from a finding that a minor had the requisite capacity to provide autonomous consent to her participation in research.⁴⁷⁴

Despite being unable to provide researchers with a resource that is ready for use, it would nonetheless seem appropriate to refer readers to two existing resources that could be used as the basis for a new instrument. The first such instrument is the MacArthur Competence Assessment Tool – Treatment (MacCAT-T). This instrument

⁴⁷² See e.g. Sari Leanne Kives, "Opinions in Pediatric and Adolescent Gynecology" (2008) 21 J Pediatr Adolesc Gynecol 47 at 50 [Kives] and Arshagouni, *supra* note 408 at 338.

⁴⁷³ Frances J. Lexcen & N. Dickon Reppuci, "Effects of Psychopathology on Adolescent Decision-Making" (1998) 5 U. Chicago L. Sch. Roundtable 63 at 64.

⁴⁷⁴ Kives, *supra* note 472 at 49.

was developed by Grisso and Appelbaum to provide clinicians with a way of obtaining and organizing information about patients' decision-making abilities.⁴⁷⁵

The second tool has been developed by McCarthy *et al.*. It consists of a psychological screening protocol to screen children involved in non-therapeutic, invasive research to determine those children who may be at risk of developing psychological distress. Although not focused solely on assessing competence, this tool does include an evaluation of cognitive abilities, thereby making certain elements of it relevant to the present discussion. It is also worth noting that data was only collected on twenty children (whose mean age was 10.6) and that the screening tool as a whole has not yet been validated.⁴⁷⁶ So, despite it not being ripe for competence assessments, elements of it may be of interest to those involved in the development of a new instrument.

VI. RISK

The *Tri-Council Policy Statement* sets out different requirements based on the magnitude and type of risk involved in a particular study for research involving individuals who lack legal competence.⁴⁷⁷ Risk has also been used in the United Kingdom as well as in Australia through the *National Statement on Ethical Conduct in Human Research (2007)*⁴⁷⁸, the framework recently developed in Australia that sets out when minors can consent to their own participation. Notably, the latter does not divide minors according to age but rather into four more ambiguous categories: (1) infants (who

⁴⁷⁵ See Grisso & Appelbaum, *supra* note 444 at 101-147, 173-200. As these authors have written extensively on how the MacCAT-T was developed and how it is to be used to assess the competence of individuals, readers seeking to know more about the instrument are encouraged to refer to this source.

⁴⁷⁶ McCarthy *et al.*, *supra* note 410.

⁴⁷⁷ *Tri-Council Policy Statement*, *supra* note 1 at arts. 3.9, 4.6.

⁴⁷⁸ National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research (2007)*, online: <http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e72-jul09.pdf>.

cannot give autonomous consent), (2) young children (whose consent is required but not sufficient), (3) young people “who are mature enough to understand and consent and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian”, and (4) adults (who are presumed competent).⁴⁷⁹ Additionally, the relevant review body can deem the consent of a young person to be sufficient where the young person understands the risks and benefits of participation but is nonetheless vulnerable because of relative immaturity in other respects where (i) the research is of low risk, (ii) the research will benefit the specific category of children within which the young person falls into, and (iii) the young person is either estranged from his or her parents or it is not in his or her best interest to obtain parental consent.⁴⁸⁰ Given this use in other instruments and in anticipation of suggestions from others that risk ought to have been used as a determinant in the framework proposed herein, the concept of risk is reviewed briefly below, following which I provide the two primary reasons why risk has not been used are briefly set out below. However, before proceeding further, I must state explicitly that I am not advocating removing the minimal risk criteria from the *Tri-Council Policy Statement*. Rather, it is merely not being applied in a situation where the authors of the *Tri-Council Policy Statement* have not explicitly imposed the minimal risk requirement. Under the framework proposed here, when a minor is found to be incompetent and consent is sought from a parent or an authorized third party representative, the minimal risk rules are triggered and must be met.

⁴⁷⁹ *Ibid.* at chapter 4.2.

⁴⁸⁰ *Ibid.* at guideline 4.2.9.

A. Overview of Risk

(i) Acceptable Risks

Society has come to accept that risk exists in medicine, regardless of how frequently a treatment has been used and how much skill a physician possesses.⁴⁸¹ The research enterprise is no exception. Although research participants, be they adults or children, are not assured that they will not encounter any risks whatsoever, there are limits on tolerable exposure. Only research in which the potential benefits for the individual participant and society outweigh the foreseeable risks is legally permitted in Canada.⁴⁸² Beyond this general requirement for a potential positive benefit-to-risk balance, little guidance as to the threshold of acceptable risk is provided in legislative instruments. This is somewhat unsurprising, given the relative absence of law generally in relation to those aspects of medical research extending beyond the drug approval process.

Fortunately, ethical frameworks compensate *somewhat* for the lack of guidance from the legal realm as to the risks research participants can face. As well, no research participant can be subjected to unnecessary risks of harms though there is no clear upper threshold beyond which risks are no longer acceptable.⁴⁸³ The only restriction is that any harms to which a subject may be exposed must not outweigh the benefits that are anticipated to flow from the research (i.e. there must be a positive balance between the benefits and harms, as required under the law).

⁴⁸¹ Órlaith Molloy, “Autonomy and Consent: The Lack of Protection for Incompetent Individuals in the Healthcare Context” (2007) 15 ISLR 65 at 68-69.

⁴⁸² *ICH GCP*, *supra* note 55 at para. 2.2.

⁴⁸³ Neither the *Tri-Council Policy Statement*, *supra* note 1 at 10 nor the *Declaration of Helsinki*, *supra* note 41, provides an explicit upper limit of acceptable risk.

Beyond these few limitations, adult research participants are generally able to decide what risks they are willing to assume.⁴⁸⁴ The same is true for mature minors. Presumably based on the perceived need for greater protection, there are more stringent restrictions for research involving immature minors. Specifically, immature minors can only participate in research that poses greater than minimal risk if they may derive direct benefits from the research. For minimal risk research, immature minors can participate if the research is potentially beneficial to the immature minor or to a group to which the immature minor belongs.⁴⁸⁵

(ii) Minimal Risk

The law in Canada makes no mention of the concept of “minimal risk” in defining the scope of acceptable research. However, this concept underlies many of the boundary lines drawn in the *Tri-Council Policy Statement*, the most extensively used ethical framework in Canada. There, “minimal risk” is defined as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research”⁴⁸⁶ [emphasis added]. Note that the risks to be considered when determining if research poses minimal risk or if the overall balancing of potential risks and benefits is appropriate are those related to the research. Stated differently, risks related to treatment that would exist regardless of whether or not the minor participates in the research are not relevant to the evaluation of the research. Those risks associated

⁴⁸⁴ Kopelman, “Group”, *supra* note 46 at 177.

⁴⁸⁵ *Tri-Council Policy Statement*, *supra* note 1 at art. 4.6.

⁴⁸⁶ *Supra* note 1 at 23. This definition is essentially unchanged from that found in the first edition of the *Tri-Council Policy Statement (1998)*, *supra* note 319 at para. 1.5, which stated “if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.”

with treatment are, however, to be considered when selecting an appropriate course of treatment.⁴⁸⁷

Even though the definition of minimal risk set out above has not proven to be entirely straightforward, it marks Canada's most recent attempt at providing guidance to the research community as to what constitutes minimal risk. Furthermore, the definitions of minimal risk adopted by other countries have garnered similar criticism. For example, the legislated American definition states that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [emphasis added].⁴⁸⁸ Although very similar to the Canadian definition, the current view is that risks in the United States must be assessed from the perspective of the healthy child (rather than from the potential subject's perspective under the Canadian definition).⁴⁸⁹ A somewhat different approach to defining minimal risk has been endorsed by the United Kingdom's Medical Research Council and Royal College of Paediatrics and Child Health's Ethical Advisory Board. Those organizations have opted to provide researchers with specific examples of activities at each of minimal, low, and high risk thresholds.⁴⁹⁰ Under the United

⁴⁸⁷ The need to consider research-related risks separate and apart from treatment-related risks bolsters my earlier argument that research and treatment need to be distinguished, even when they are to be delivered concurrently by the same physician/researcher.

⁴⁸⁸ *Protection of Human Subjects*, 45 CFR §46.101(i) (2009).

⁴⁸⁹ Robert M. Nelson, "Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study" (2001) 23(6) IRB 7 at 8.

⁴⁹⁰ Loretta M. Kopelman, "What Conditions Justify Risky Nontherapeutic or "No Benefit" Pediatric Studies: A Sliding Scale Analysis" (2004 Winter) *The Journal of Law, Medicine & Ethics* 749 at 749 [Kopelman, "Conditions"]. See also Medical Research Council, "MRC Ethics Guide: Medical Research Involving Children", online: <www.mrcac.uk> [Medical Research Council].

Kingdom regime, high risks studies can only be carried out where there is a prospect of direct benefit.⁴⁹¹

The fact that no country has defined minimal risk in a way that elicits praise rather than criticism largely speaks to the fact that researchers (and particularly research ethics board members) are not actuaries and are rarely provided with documentation as to the probability and magnitude of risks occurring.⁴⁹² As such, the comparison between research risks and risks encountered in everyday life may at times be based on little more than perception and speculation. This has, rather unsurprisingly, led to a great degree of discrepancy in risk assessment between research ethics boards.⁴⁹³

The restriction on research participation based on magnitude of risk that flows from the distinction between “minimal risk” and other risks has two noteworthy implications.⁴⁹⁴ Firstly, it allows researchers to recruit minors for ‘riskier’ research where participants may benefit from their participation. More specifically, assuming the other requirements of free and informed consent have been met, children, including mature minors, can be asked to participate in such research so long as there is a potentially favourable risk-benefit balance. Without embarking upon an exhaustive discussion on how risks and harms are weighed and balanced against one another, the participation of minors in oncology trials appears to be an instance in which there is

⁴⁹¹ Medical Research Council, *ibid.* at 15.

⁴⁹² Research ethics board members are not the only individuals involved in the research process who have difficulty quantifying risks associated with everyday activities. Both parents and children have also been shown to have a poor understanding of such harms. See David Wendler & Tammara Jenkins, “Children’s and Their Parents’ Views on Facing Research Risks for the Benefit of Others” (2008) 162(1) *Arch Pediatr Adolesc Med.* 9 at 13, for further elaboration on this point as well as for a discussion on how the description of risk affects willingness to participate in non-beneficial research.

⁴⁹³ Shah, *supra* note 3 at 477, 479.

⁴⁹⁴ There are other implications, such as whether informed consent is required for secondary use of the data collected, the nature of the ongoing review process, and who should explain research to potential participants.

likely more than minimal risk. Such additional risk is due to the drugs used as well as to the fact that the standard treatment is often quite effective.

Secondly, research ethics board members must evaluate the risks of proposed research on a case-by-case basis and determine if these risks fall within an acceptable range. Given the highly subjective nature of such an exercise, it is possible that research ethics boards overestimate the magnitude of research risks as well as the likelihood that such risks will materialize. Such a flawed evaluation of risk (assuming it is in fact flawed) leads to unjustified intervention into the research enterprise.

From the above discussion, it is clear that although participation in research studies is likely to bring about some exposure to risks that may not have been encountered in the course of standard treatment, all research participants can derive *some* protection from both legal and ethical frameworks that have been developed to limit the scope of acceptable risks. It is equally evident that, like other countries, the use of the term “minimal risk” is problematic and may be leading to inconsistent research practices across the country. Nonetheless, because of its use as an additional means of protection in research involving children, it must be considered when devising a framework that better defines the roles of mature minors in the research process. Furthermore, when canvassing the approaches adopted in foreign jurisdictions, it is of great importance to consider the situations in which minors in those jurisdictions can participate in research, regardless of whether they consent to their own participation or if consent is sought from their parents.

(iii) Disclosure of Risk

It is worth briefly mentioning that researchers must disclose risks and anticipate anticipated benefits to potential research participants (or their legally authorized representative) at the time consent is obtained.⁴⁹⁵ When applicable, the federal *Food and Drugs Regulations* further require that research sponsors ensure that such disclosure is made.⁴⁹⁶ Although there is a clear obligation to provide some disclosure, as noted above, different views as to precisely what needs to be disclosed have been articulated in the literature.⁴⁹⁷ This difference in opinion is based on different interpretations of *Halushka v. University of Saskatchewan* and *Weiss v. Solomon*. That said, in relation to risk and for purposes of the present discussion, it is sufficient to state that the disclosure standard is at least as onerous as that found within the treatment context.⁴⁹⁸

B. Reasons Why Risk Is Not In The Framework

The first reason is that risk determinations are highly arbitrary and the process as a whole has been criticized. Researchers simply do not have the expertise to quantify specific risks involved in research relative to risks faced by individuals in everyday life. They would, however, be called upon to make precisely that assessment if risk had been included as an element of this framework. Specifically, the researcher would have to determine what level of risk is involved in a particular research study prior to obtaining research ethics board approval because the type of risk would affect the manner in which consent would be obtained, a fact which needs to be spelled out in the research protocol that is submitted for approval. It is also within the jurisdiction of research ethics boards

⁴⁹⁵ *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 at 444 (Sask. C.A.).

⁴⁹⁶ *Food and Drug Regulations*, *supra* note 18 at C.05.010.

⁴⁹⁷ See Kopelman, "Conditions", *supra* note 490.

⁴⁹⁸ Hadskis, *supra* note 48 at 286-290.

to assess the risks.⁴⁹⁹ In cases of mixed research and treatment, the situation would be further complicated in that researchers have to also tease out the risks attributable to research from those linked to treatment. The research risks would need to be weighed as whole to determine if the total risk is minimal or greater than minimal.

The second reason is that it was not necessary to include risk in the framework proposed herein to strike a legally and ethically defensible balance between the rights of minors to provide autonomous consent and the concordant need to protect the vulnerable and incompetent. None of the applicable legal instruments discussed at length in Chapter 2 make any mention of minimal risk as a tool to be used in delineating the bounds of acceptable research. There are boundaries set on when consent can be sought but none of those pertain to minimal risk specifically. Similarly, although a number of ethical instruments, including the *Tri-Council Policy Statement* refer to minimal risk, there are no restrictions based on risk on a competent minor's right to consent to research participation. Under the framework, where minors fail to prove themselves to be mature minors, the protections extended to them by child protection legislation, consent to treatment legislation, and the *Tri-Council Policy Statement* apply.

VII. CONCLUSION

The framework proposed herein represents a balance between respecting the rights of mature minors while still ensuring that those minors who lack capacity receive appropriate protection. This is achieved in three steps. At the first step, researchers are required to consider the aim of the activity involved (i.e. research alone or mixed research and treatment). This provides a straightforward way for them to identify if consent to

⁴⁹⁹ *Tri-Council Policy Statement*, *supra* note 1 at 22-27.

treatment and child protection legislation applies and needs to be considered. At the second step, all minors are to undergo an individualized capacity assessment carried out in accordance with parameters set out in a validated instrument.

The framework proposed above focuses on consent and so, since consent from the legally authorized individual must be maintained throughout the life of a research study, this framework can and should be used by researchers throughout the entire life of the study. This, in turn, means that researchers ought to be encouraged to apply the framework to research that is ongoing at the time a particular institution chooses or is required to incorporate it into its research practices. Although efforts have been made to keep the framework as simple and user-friendly as possible, institutions will nonetheless have to expend resources to educate researchers about how the framework is to be applied in their institution. Consequently, despite the fact that from the perspective of the adolescents participating in research, it is desirable that the framework be adopted as soon as possible and be applied to all research, whether a study has already started or not, I suggest that institutions take the time to ensure the framework is properly understood by researchers prior to incorporating it into their research practices.

CHAPTER 5

CONCLUSION

The preceding analysis of the role of mature minors in the medical research consent process has sought to correct an emerging wrong – the exclusion of mature minors in medical research without proper regard to what their rights are and how they ought to be treated. This thesis proposes that this wrong can be corrected by implementing a two-step framework that balances respecting the rights of mature minors and ensuring that those minors who lack capacity receive appropriate protection. At the first step, researchers are required to consider the aim of the activity involved (i.e. research alone or mixed research and treatment). This provides a straightforward way for them to identify if consent to treatment and child protection legislation applies and needs to be considered. At the second step, all minors are to undergo an individualized capacity assessment carried out in accordance with parameters set out in a validated instrument.⁵⁰⁰ If the minor is found to have capacity (i.e. is a mature minor), her consent, provided it is informed and voluntarily given, is necessary and sufficient. According to the framework proposed here, the degree of parental involvement is determined by the minor such that if

⁵⁰⁰ Ideally the instrument would be validated for all ages. However, in recognition of the expense and difficulty associated with validating an instrument for use on infants and very young children, at least initially, researchers should strive to validate an instrument that can be used to assess the capacity of children and adolescents.

she wishes to involve her parents in discussions about the research, she is free to do so. She is, however, not required to so include them.

The proposed framework is consistent with the law and ethical instruments and principles that apply in all jurisdictions except Quebec, where the *Civil Code* specifically requires parental consent. Turning firstly to the applicable law, much of the discussion in this thesis focuses on the Supreme Court of Canada's decision in *A.C. v. Manitoba (Director of Child and Family Services)*. In that decision, the Majority outlines seven factors that could be (the list is not exhaustive) considered when evaluating the maturity of a minor. While the decision is somewhat confusing and has been subject to differing interpretations, I have argued that, there is nothing in that list or elsewhere in any of the three sets of reasons included in the decision that restricts a mature minor's ability to consent to her own medical research participation. In my view therefore, at common law mature minors remain able to consent where they have sufficient understanding and appreciation of the nature and consequences of the research and its alternatives to be able to decide whether to participate in the particular study or not.

Beyond the common law, one finds international, national, and provincial/territorial instruments. While one instrument, the United Nations' *Convention on the Rights of the Child*, applies to all medical research involving minors, all other codified instruments only apply to a subset of research. Limits on their applicability are both due to their origin (e.g. a provincial/territorial statute necessarily only applies within that jurisdiction) as well as how certain terms such as "health care" have been defined. A cross-country review of consent to treatment revealed that three jurisdictions (Alberta, Northwest Territories, and Nunavut) have not passed legislation of this type, meaning

that the common law mature minor rule is unchanged. The remaining common law jurisdictions (British Columbia, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and Yukon) use a combination of age, a best interest requirement, and definition of terms to modify or codify the mature minor rule. Child protection statutes which exist in each common law jurisdiction have less bearing on medical research, largely because ten such statutes only apply when a parent refuses to provide necessary care. This has two implications: firstly, research is rarely if ever “necessary” and secondly, the legislation is not triggered if consent is only sought from the minor.

A review of the ethical instruments and principles leads to the same conclusion. In the past, minors were deemed incompetent and therefore unable to consent to their own participation. Recently, however, both the *Declaration of Helsinki* and the *Tri-Council Policy Statement* have been revised to allow for a broader recognition of the rights of minors. As is clear from the literature on autonomy, paternalism, and vulnerability, broader recognition does not mean treating minors like adults. It means affording them the opportunity to demonstrate that they are able to decide whether they wish to participate in a particular research study by requiring researchers to carry out an appropriate capacity assessment. Mature minors will be found to have capacity. In the case of non-mature minors, on the other hand, their vulnerability or their need for protection will mean that parental consent will be necessary.

Having developed a framework that is defensible from both a legal and an ethical standpoint, the next steps in properly respecting the rights of minors involved in medical research are the validation of an instrument to be used to assess the capacity of minors

and the implementation of the framework. The latter first requires making institutions aware of its existence, which I will endeavour to do through subsequent publications. Once that is done, the burden will shift to institutions and individual researchers. The framework proposed herein has the potential to benefit many minors: both the mature minors whose rights are better respected, and other minors who will subsequently benefit from the research findings. As well, since consent from the legally authorized individual must be maintained throughout the life of a research study, this framework can and should be used by researchers throughout the entire life of the study. This, in turn, means that researchers ought to be encouraged to apply the framework to research that is ongoing at the time a particular institution chooses or is required to incorporate it into its research practices. Although efforts have been made to keep the framework as simple and user-friendly as possible, institutions will nonetheless have to expend resources to educate researchers about how the framework is to be applied in their institution. Consequently, despite the fact that from the perspective of adolescents participating in research, it is desirable that the framework be adopted as soon as possible and be applied to all research, whether a study has already started or not, I suggest that institutions take the time to ensure the framework is properly understood by researchers prior to incorporating it into their research practices.

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