

# Legal and Ethical Issues in ART “Outcomes” Research

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## I. Introduction

Assisted reproductive technologies (ARTs) have become almost commonplace in the developed world. It is estimated that 1% of American children are now conceived using some form of assisted reproduction,<sup>1</sup> and that over a million children have been born as a result of the use of ARTs.<sup>2</sup> In the past several years, however, scientists have begun to sound a cautionary note about the health outcomes of ARTs, as it appears that children conceived using ARTs may be at higher risk of birth defects and certain genetic anomalies than those conceived naturally.

As a result of these new findings, a consensus appears to be emerging that research into the safety of assisted reproductive technologies (ARTs) is required. Such research will require a longitudinal, prospective design in order to answer questions about short and long-term health outcomes for those conceived using ARTs. There are a number of scientific issues that require attention before ART outcomes research can be successfully conducted; these include: sample size limitations, the diversity of both types of ARTs and birth defects, and confounding variables such as maternal age and folic acid consumption.<sup>3</sup> But a substantial non-scientific impediment to the conduct of this research also demands consideration: legal and ethical constraints that have the potential to complicate the research enterprise. In particular, given the research context, law and policy relating to the research participation of pregnant women and children must be attended to. The question of whether and to what extent pregnant women and children may participate in health research has been a persistent concern in both legal and ethical

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<sup>1</sup>Christine K. Olson *et al.* “In vitro fertilization is associated with an increase in major birth defects” (2005) 84:5 Fertility and Sterility 1308. The numbers are still higher in some countries as Reija Klemetti *et al.* note, “[i]n the Nordic countries, 2.2% – 3.9% of children were born with the help of IVF.” Reija Klemetti *et al.*, “Increasing evidence of major congenital anomalies in children born with assisted reproduction technology: what should be done?” (2005) 84:5 Fertility and Sterility 1327.

<sup>2</sup>See e.g. Robert M. L. Winston & Kate Hardy, “Are we ignoring potential dangers of in vitro fertilization and related treatments?” (2002) Fertility Supplement: Nature Cell Biology & Nature Medicine S14-S18; Leonard I. Zon, Laurie Zoloth & Suzanne Kadereit, “Taking the Stem Cell Debate to the Public” (2004) 2:6 PLoS Medicine e188, online: PubMed Central <<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=423156&tools=bot>>.

<sup>3</sup>See Laura A. Schieve, Sonja A. Rasmussen & Jennita Reefhuis, “Risk of birth defects among children conceived with assisted reproductive technology: providing an epidemiologic context to the data” (2005) 84 Fertility & Sterility 1320.

circles.<sup>4</sup> On the one hand, current ethical guidelines exhort researchers to include these populations where possible;<sup>5</sup> on the other, the law seems to pose a barrier to their participation.

In this article, the intent of which is to raise issues requiring further consideration, I will examine legal and ethical standards relating to consent in the Canadian context, and highlight the legal and ethical concerns that arise at different stages of longitudinal prospective research studies in the ART context. In Part II, I explain the ART context and highlight the concerns that have led to calls for long-term follow-up of children conceived using ARTs. In Part III, I discuss consent to research participation along the continuum of participants in longitudinal ART outcomes research, and in Part IV, I move on to consider legal and ethical regulation of health research generally. I conclude by noting that the legal and ethical parameters around consent to longitudinal ART research must be clarified in order to permit rather than hinder the conduct of this important research.

## II. The Context: Assisted Reproductive Technologies

In the almost 30 years since the birth of the first “test-tube baby,”<sup>6</sup> the science around reproductive and genetic technologies has exploded, giving rise to new tests and technological breakthroughs on a routine basis. Preimplantation genetic diagnosis (PGD), for example, permits scientists to diagnose genetic conditions in an in vitro embryo,<sup>7</sup> prior to it being implanted in a woman’s uterus through in vitro fertilization (IVF), a technology in which an ovum is fertilized with a

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<sup>4</sup> See e.g. R. Alta Charo, “Protecting us to Death: Women, Pregnancy and Clinical Research Trials” (1993) 38 St. Louis U. L. J. 135 at 158-67 [Charo]; Anna C. Mastroianni, “HIV, Women and Access to Clinical Trials: Tort Liability and Lessons from DES” (1998) 5 Duke J. Gender L. & Pol’y 167 at 178-80 [Mastroianni]; Vanessa Merton, “The Exclusion of Pregnant, Pregnable, and Once-Pregnable People (a.k.a. Women) from Biomedical Research” (1993) 19 Am. J. L. & Med. 369; Paul B. Miller & Nuala P. Kenny, “Walking the Moral Tightrope: Respecting and Protecting Children in Health-Related Research” (2002) 11:3 Cambridge Q. Healthcare Ethics 217 [Miller & Kenny]; Loretta M. Kopelman, “Children as Research Subjects: A Dilemma” (2000) 25:6 J. Med. & Philos. 745 [Kopelman]; Sujit Choudhry, “Review of legal instruments and codes on medical experimentation with children” (1994) 3 Cambridge Q. Healthcare Ethics 560; and Françoise Baylis & Jocelyn Downie, “An Ethical and Criminal Law Framework for Research Involving Children in Canada” (1993) 1 Health L.J. 39 [Baylis & Downie].

<sup>5</sup> Canada, Medical Research Council of Canada, Natural Sciences and Engineering Research 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 and 2005 amendments), online: <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>> [*Tri-Council Policy Statement*] (Art. 5.2 states that “Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.”); see also Rosamund Rhodes, “Rethinking Research Ethics” (2005) 5 American Journal of Bioethics 7 [Rhodes].

<sup>6</sup> Patrick C. Steptoe & Robert G. Edwards, “Birth after the reimplantation of a human embryo” (1978) 2 Lancet 366.

<sup>7</sup> Peter Braude *et al.*, “Preimplantation Genetic Diagnosis” (2002) 3:12 Nature Reviews Genetics 941 at 941; Jeffrey Botkin, “Ethical issues and practical problems in preimplantation genetic diagnosis” (1998) 26:1 Journal of Law, Medicine & Ethics 17.

sperm cell outside the woman’s body.<sup>8</sup> And if IVF alone will not suffice to assist a couple to conceive, because of very low sperm count or immotile sperm, a procedure termed intra-cytoplasmic sperm injection (ICSI) might be appropriate – a single sperm cell can be injected directly into the ovum to ensure that fertilization takes place.<sup>9</sup> Other variations on the IVF theme include a procedure called in vitro maturation (or IVM), in which immature oocytes are matured in vitro for 24-48 hours, eliminating the need for risky hormonal stimulation of the ovaries prior to harvesting eggs,<sup>10</sup> and IVF with blastocyst embryo transfer, which involves waiting for five to six days post-fertilization to transfer the embryo(s) to the woman’s uterus, which, it is hoped, will lead to a greater likelihood of implantation.<sup>11</sup> Reproductive cloning, perhaps the most ‘high tech’ of the new reproductive technologies (and certainly the most controversial), allegedly looms on the horizon as well.<sup>12</sup>

While the science continues to drive forward, concerns have begun to emerge that children born of ARTs are at higher risk of birth defects<sup>13</sup> and certain genetic anomalies than children conceived naturally. These concerns are exacerbated by the reality that comprehensive safety and efficacy studies were not conducted prior to the adoption of most reproductive technologies into clinical practice.<sup>14</sup>

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<sup>8</sup>Roxanne Mykitiuk & Albert Wallrap, “Regulating Reproductive Technologies in Canada” in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Toronto: Butterworths, 2002) 367 at 376.

<sup>9</sup>*Ibid.*

<sup>10</sup>Ri-Cheng Chian *et al.*, “Natural-cycle in vitro fertilization combined with in vitro maturation of immature oocytes is a potential approach in infertility treatment” (2004) 82:6 *Fertility & Sterility* 1675; Ri-Cheng Chian, Jin-Ho Lim & Seang-Lin Tan, “State of the art in-vitro oocyte maturation” (2004) 16:3 *Current Opinion in Obstetrics and Gynecology* 211. The most serious risk of these medications appears to be “ovarian hyperstimulation syndrome”(or OHSS) which can, in rare cases, be fatal. See American Society for Reproductive Medicine, *Assisted Reproductive Technologies: A Guide for Patients* (Birmingham, Alabama: American Society for Reproductive Medicine, 2003) at 13; “Woman dies from rare IVF side effect” *BioNews* (13 April 2005), online: Progress Educational Trust <<http://www.bionews.org.uk/new.lasso?storyid=2532>>.

<sup>11</sup>Michael Wilson *et al.*, “Integration of blastocyst transfer for all patients” (2002) 77:4 *Fertility & Sterility* 693.

<sup>12</sup>Julian Savulescu, “Equality, cloning and clonism: why we must clone” *BioNews* (16 May 2005) , online: Progress Educational Trust <<http://www.bionews.org.uk/commentary.lasso?storyid=2571>>; David Oderberg, “Cloning is an affront to human dignity” *BioNews* (18 May 2005) , online: Progress Educational Trust <<http://www.bionews.org.uk/commentary.lasso?storyid=2572>>.

<sup>13</sup>Including cardiovascular and musculoskeletal birth defects and birth defect syndromes: see Olson *et al.*, *supra* note 1.

<sup>14</sup>As William M. Buckett and Seang Lin Tan note, “[t]he first studies comparing rates of congenital abnormalities in children conceived as a result of assisted reproductive techniques with those in children conceived spontaneously were published ... some 10-15 years after the advent of IVF.” William M. Buckett & Seang Lin Tan, “Congenital abnormalities in children born after assisted reproductive techniques: how much is associated with the presence of infertility and how much with its treatment?” (2005) 84:5 *Fertility & Sterility* 1318 at 1318 [Buckett & Tan]. See also M. De Rycke, I. Liebaers & A. Van Steirteghem, “Epigenetic risks related to assisted reproductive technologies: Risk analysis and epigenetic inheritance” (2002) 17:10 *Human Reproduction* 2487 at 2488 [De Rycke, Liebaers & Van Steirteghem] (“The widespread, almost immediate clinical application of IVF and ICSI in assisted reproduction, without any adequate experimental phase, as well as the invasive nature of some of the

Birth defects are more common in multiple gestation pregnancies,<sup>15</sup> and ARTs often lead to multiples, but recent studies have also found increased rates of birth defects in single gestation pregnancies as well.<sup>16</sup> There are a number of possible points on the ART-treatment continuum at which problems may arise, including ovarian stimulation, fertilization and early embryonic development (in the culture medium), and the embryo transfer process. In addition, it has been suggested that both fetal and placental development can be affected by ART procedures, and both of these possibilities have implications for health outcomes.<sup>17</sup> Finally, it remains uncertain whether the procedures themselves, or the underlying infertility, cause these developmental errors.<sup>18</sup>

Some of the reproductive technologies, such as ICSI<sup>19</sup> and assisted hatching<sup>20</sup> (a procedure that involves thinning or making a small hole in the protective layer that surrounds the embryo<sup>21</sup>) involve invasive procedures. It has been suggested, for example, that ICSI might theoretically damage sperm cells and oocytes, and that further study is needed in order to allay concerns about its safety.<sup>22</sup> Although the available evidence points to no association between ARTs and "serious malformations,"<sup>23</sup> there have been indications that ARTs may be associated with conditions caused by epigenetic changes and imprinting disorders, which play a role in congenital syndromes and which may contribute to an increased risk of cancer.<sup>24</sup> As a result of these suggested associations, as well as other concerns raised by specific technologies and potential developmental and psychosocial issues related to ART-caused multiple births,<sup>25</sup> a number of commentators have acknowledged

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techniques, have led to a debate concerning the safety of these techniques."); Laura Shanner, "The Right to Procreate: When Rights Claims have gone Wrong" (1995) 40 McGill Law Journal 823 at 870.

<sup>15</sup> Olson *et al.*, *supra* note 1.

<sup>16</sup> *Ibid.*; Reija Klemetti *et al.*, "Children born after assisted fertilization have an increased rate of major congenital anomalies" (2005) 84 Fertility & Sterility 1300; Michèle Hansen *et al.*, "Assisted reproductive technologies and the risk of birth defects – a systematic review" (2005) 20:2 Human Reproduction 328 [Hansen *et al.*].

<sup>17</sup> See *e.g.* I. Cetin, V. Cozzi & P. Antonazzo, "Fetal Development after Assisted Reproduction – A Review" (2003) 24: Supp. 2 Placenta S104.

<sup>18</sup> *Ibid.* at S109; see also Buckett & Tan, *supra* note 14.

<sup>19</sup> Shi Wu Wen *et al.*, "Intracytoplasmic sperm injection: promises and challenges" (2004) 171 CMAJ 845.

<sup>20</sup> A. Gabrielson *et al.*, "Assisted hatching improves implantation rates on cryopreserved- thawed embryos. A randomized prospective study" (2004) 19:10 Human Reproduction 2258; Practice Committee of the American Society for Reproductive Medicine, "The role of assisted hatching in in vitro fertilization: A review of the literature" (2004) 82: Suppl.1 Fertility and Sterility S164.

<sup>21</sup> IVF-infertility.com, online: <<http://www.ivf-infertility.com/ivf/hatching.php>>.

<sup>22</sup> *Supra* note 19.

<sup>23</sup> Tracy Hampton, "Panel Reviews Health Effects Data for Assisted Reproductive Technologies" (2004) 292:24 JAMA 2961.

<sup>24</sup> Eammon R. Maher, Masoud Afnan & Christopher L. Barratt, "Epigenetic risks related to assisted reproductive technologies: Epigenetics, imprinting, ART and icebergs?" (2003) 18 Human Reproduction 2508 [Maher, Afnan & Barratt]; David Secko, "How an imprint can lead to cancer" (2005) 172 CMAJ 1286; *supra* note 23; De Rycke, Liebaers & Van Steirteghem, *supra* note 14.

<sup>25</sup> Matthew G. Retzliff & Mark D. Hornstein, "Is intracytoplasmic sperm injection safe?" (2003) 80

the pressing need for further research.<sup>26</sup> In particular, there have been calls for longitudinal studies in ART-conceived children in order to determine whether these reported risks are “rare events without wider implications” or whether they represent the ‘tip of the iceberg.’<sup>27</sup>

As a number of commentators have noted, the data to be acquired from ART outcomes research will have significant implications for ART practice,<sup>28</sup> as well as for legal and policy decisions around acceptable and appropriate uses of the technologies.

### III. Consent to Participation in Research

Research into the long-term safety of ARTs is essential, but the suggestion that it should be carried out raises questions about the feasibility of such studies in light of relevant legal issues, which focus primarily on consent to participation in research, and related issues of risk and harm. The legal and ethical uncertainty surrounding research of the type contemplated here is compounded by a number of factors, including who the participants are, where the law is found, and the challenges posed by the nature of longitudinal research for legal rules around consent.<sup>29</sup> Legal regulation of health research in Canada is, to say the least, not well integrated. Québec has explicitly enshrined a number of general principles relating to research participation in its *Civil Code*.<sup>30</sup> In the remainder of Canada, legal rules respecting consent vary slightly according to jurisdiction, and are found in both

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Fertility and Sterility 851 [Retzliff]; Marcia A. Ellison *et al.*, “Psychosocial risks associated with multiple births resulting from assisted reproduction” (2005) 83 Fertility and Sterility 1422; Lisa Kelly-Vance, Kristine Anthis & Howard Needleman, “Assisted reproduction versus spontaneous conception: a comparison of the developmental outcomes in twins” (2004) 156 Journal of Genetic Psychology 157.

<sup>26</sup> *Supra* note 23; De Rycke, Liebaers & Van Steirteghem, *supra* note 14; U.S., President’s Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (Washington, D.C.: President’s Council on Bioethics, 2004); Emily L. Niemitz & Andrew P. Feinberg, “Epigenetics and Assisted Reproductive Technology: A Call for Investigation” (2004) 74 Am. J. Hum. Genet. 599; Michèle Hansen *et al.*, *supra* note 16, Klemetti *et al.*, “Children born after assisted fertilization have an increased rate of major congenital anomalies,” *supra* note 16; Klemetti *et al.*, “Increasing evidence of major congenital anomalies in children born with assisted reproduction technology: what should be done?,” *supra* note 1; Olson *et al.*, *supra* note 1; Francois Olivennes, “Do children born after assisted reproductive technology have a higher incidence of birth defects” (2005) 84:5 Fertility & Sterility 1325 [Olivennes]; and *supra* note 3.

<sup>27</sup> Maher, Afnan & Barratt, *supra* note 24.

<sup>28</sup> Olson *et al.*, *supra* note 1; Alastair G. Sutcliffe, “Congenital anomalies and assisted reproductive technology: more of the same” (2005) 84:5 Fertility and Sterility 1316; *supra* note 16; Olivennes, *supra* note 26.

<sup>29</sup> For an interesting discussion of issues raised by longitudinal research involving pregnancy and childhood, see S. E. Mumford, “Children of the 90s: ethical guidance for a longitudinal study” (1999) 81 Arch. Dis. Child Fetal Neonatal Ed. F146-F151; S.E. Mumford, “Children of the 90s II: challenges for the ethics and law committee” (1999) 81:3 Arch. Dis. Child Fetal Neonatal Ed. F228-F231.

<sup>30</sup> Art. 21 C.C.Q.; see also Kathleen Cranley Glass & Trudo Lemmens, “Research Involving Humans” in *supra* note 8, 459 at 477-79 [Glass & Lemmens]. As Glass & Lemmens note, the Quebec Civil Code does not comprehensively regulate research, but “articulates some legal principles that are to govern research.” at 478.

common law and legislation. Health research is also subject to ethical “regulation” and while this is more uniform across the country, jurisdictional<sup>31</sup> variations do exist. Canadian ethical guidelines arise out of the 1998 *Tri-Council Policy Statement*;<sup>32</sup> accordingly, the ethical principles and guidelines discussed herein will be based upon the *Tri-Council Policy Statement*.

Consent, or more particularly, informed consent, is a cornerstone of legal and ethical governance of health research.<sup>33</sup> In order to satisfy legal and ethical requirements, researchers must obtain the “free and informed consent”<sup>34</sup> of each participant. Legally and ethically valid consent to participation in research must be voluntary (given without undue influence, manipulation or coercion<sup>35</sup>), it must be given by a person competent to provide it,<sup>36</sup> and it must be “informed.” In the clinical practice context, the law holds that an informed patient is one who has been

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<sup>31</sup> Not only along provincial or territorial lines, but also depending on the setting of the research – does it take place in a publicly funded University? (While most University policies are modelled on the *Tri-Council Policy Statement*, there may be variations.) In a privately funded research corporation? In physician’s practices in the community? All of these various jurisdictions have governance mechanisms in place with respect to research ethics, and there may be slight variations among applicable guidelines. For example, the College of Physicians and Surgeons of Alberta has in place a Research Ethics Review Program to review research studies that will take place in the community setting where, for example, the researcher is not associated with a University department or other institution that has a research ethics committee. See College of Physicians and Surgeons of Alberta, online: <[http://www.cpsa.ab.ca/collegeprograms/research\\_ethics.asp](http://www.cpsa.ab.ca/collegeprograms/research_ethics.asp)>.

<sup>32</sup> *Supra* note 5.

<sup>33</sup> Indeed, many commentators have argued that this narrow focus on consent has strained the regulatory process; see e.g. Rhodes, *supra* note 5; and Ezekiel J. Emanuel, David Wendler & Christine Grady, “What makes clinical research ethical?” (2000) 283:20 JAMA 2701. The legal and ethical issues around the basic requirement of consent to participation in research have been canvassed elsewhere and will not be revisited in detail here. See, e.g., Glass & Lemmens, *supra* note 30.

<sup>34</sup> In limited circumstances, research may be carried out without individualized consent where the research ethics board reviewing the research proposal

finds and documents that: i. The research involves no more than minimal risk to the subjects; ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects; iii. The research could not practicably be carried out without the waiver alteration; iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and v. The waived or altered consent does not involve a therapeutic intervention.

(*Tri-Council Policy Statement*, *supra* note 5, Art. 2.1(c)). This most commonly applies in situations in which providing full disclosure of the purposes of the research would “colour the responses of the subjects and thus invalidate the research” (*Ibid.* at explanatory notes).

<sup>35</sup> *Tri-Council Policy Statement*, *ibid* at Art. 2.2 (explanatory notes) (explains that a determination as to the voluntariness of consent involves consideration of the existence of: inducements to participation, of an exercise of authority over the subject by another, of the context in which consent is given with a view to whether a relationship of trust and/ or dependency is at play. Similarly, in the legal context, consent is voluntary where not obtained by undue influence, coercion or fraudulent misrepresentation as to the nature of the procedures involved in the research. For elaboration of issues related to voluntariness, see *ibid.*; Erin Nelson, “The Fundamentals of Consent”, in *supra* note 8 at 120-22 [Nelson, “The Fundamentals of Consent”]; Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Toronto: Carswell, 1996) at 55-60 [Picard & Robertson].

<sup>36</sup> As will be discussed in more detail below, consent may be obtained from an authorized third party in situations where the individual him or herself is unable to provide valid consent (see *Tri-Council Policy Statement*, *ibid.*, Articles 2.5, 2.6, 2.7).

apprised of all “material, special or unusual risks” related to the proposed therapeutic intervention.<sup>37</sup> In the health research context, particularly where the research is not of intended benefit to the participants, the courts have held researchers to a higher standard of disclosure, that of “full disclosure” of all risks: rare, remote or potential.<sup>38</sup> Canadian ethics policy also demands that the researcher provide prospective subjects (or authorized third parties) with “full and frank disclosure of all information relevant to free and informed consent.”<sup>39</sup>

In the context of a longitudinal study of health outcomes for children conceived using ARTs, there are a number of points during the study at which consent issues will arise: during pregnancy, in early and late childhood, and adolescence. Each of these points will be considered in turn.

### i. During pregnancy

Recruitment of research subjects to longitudinal studies related to ARTs will take place immediately prior to or during pregnancy. Thus, consent to participation will initially be sought from the pregnant (or prospectively pregnant) woman. This, in turn, introduces concerns about potential risks that might flow from research-related procedures, such as amniocentesis<sup>40</sup> and chorionic villus sampling,<sup>41</sup> aimed at gathering genetic or environmental information about the fetus, and raises questions

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<sup>37</sup> Bernard M. Dickens, “Informed Consent” in *supra* note 8 at 131; see also *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1.

<sup>38</sup> Glass & Lemmens, *supra* note 30 at 484-86; *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608 (Sask. C.A.) (holding that the duty of disclosure to research subjects is “at least as great, if not greater than, the duty owed by the ordinary physician or surgeon to his patient” at 444); *Weiss v. Solomon* (1989), 48 C.C.L.T. 280, [1989] A.Q. No. 312 (Que. Sup. Ct.) (QL) (holding that the duty to disclose information to subjects participating in research from which they do not derive any benefit is more demanding than that required in the treatment context: “La Cour doit donc conclure qu’en matière de recherche purement expérimentale, le médecin doit révéler tous les risques connus même rares ou éloignés et à plus forte raison si ceux-ci sont d’une conséquence grave” at para. 109 (cited to QL)). As Glass & Lemmens note, Canadian courts have not yet articulated a specific standard of disclosure vis-a-vis research with intended benefit for participants, or indicated whether it would be different from that outlined in *Weiss v. Solomon*.

<sup>39</sup> *Tri-Council Policy Statement*, *supra* note 5 at Art.2.4 (explanatory notes).

<sup>40</sup> Amniocentesis involves the extraction and chromosomal analysis of amniotic fluid (the fluid that surrounds the fetus in utero) via the insertion of a hollow needle through the pregnant woman’s abdominal wall and into her uterus. See Rayna Rapp, *Testing Women, Testing the Fetus: The Social Impact of Amniocentesis in America* (New York: Routledge, 2000) at 27 [*Testing Women, Testing the Fetus*]. It involves a risk of miscarriage of 0.5 to one per cent, and a minor risk of fetal harm (serious fetal injury is rare). See Society of Obstetricians and Gynaecologists of Canada., “Amended Canadian Guidelines for Prenatal Diagnosis (2005) Change to 2005” “Techniques for Prenatal Diagnosis” (2005) 27: 11 *Journal of Obstetrics and Gynaecology Canada* 1048 online: <[www.sogc.org/guidelines/pdf/jogc%2Dnov05%2Dcpd%2D168%2Ddabs%5Fe.pdf](http://www.sogc.org/guidelines/pdf/jogc%2Dnov05%2Dcpd%2D168%2Ddabs%5Fe.pdf)> [SOGC].

<sup>41</sup> Chorionic villus sampling (CVS) is a biopsy of the chorion, which is the tissue that will ultimately become the placenta. The biopsy can be taken either transabdominally or through the woman’s cervix. It carries a risk of miscarriage of one to six per cent, depending on the method used. In addition, there is a small risk of limb or facial anomalies. See SOGC, *ibid*.

about whether a pregnant woman can consent to research, particularly genetic research, being conducted on the fetus she carries.

Although I am not keen to engage the debate around the moral and legal status of the fetus,<sup>42</sup> the question of the adequacy and legitimacy of maternal consent for research on the fetus demands attention.<sup>43</sup> As I have argued elsewhere, law and society must be prepared to respect the autonomy of pregnant women who refuse medical treatment that is recommended in the “best interests” of their fetus.<sup>44</sup> The ability to reject unwanted medical treatment, however, does not necessarily translate into an ability to consent to potentially harmful interventions undertaken for research purposes. A woman’s right to forego medical treatment can be defended on the basis of her interest in her bodily integrity and her right to self-determination, even if the decision might have negative consequences for the fetus.<sup>45</sup> But whether a woman can consent to an unnecessary procedure that poses some risks to the fetus remains an open question.<sup>46</sup>

It is uncontroversial that treatment can be given where it is both needed by the fetus and consented to by the pregnant woman. Similarly, research into treatment methods applied to the fetus may be consented to by the pregnant woman.<sup>47</sup> Article 9 of the *Tri-Council Policy Statement* states only that fetal

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<sup>42</sup> I agree with Emily Jackson, that the debate as to the moral status of fetal life is simply not amenable to consensus. Emily Jackson, *Regulating Reproduction: Law, Technology and Autonomy* (Oxford: Hart Publishing, 2001) at 1 [Jackson]. The legal status of the fetus is settled – the fetus is not a legal person. See *Tremblay v. Daigle* [1989] 2 S.C.R. 530, 62 D.L.R. (4th) 634. See also *Diamond v. Hirsch*, [1989] M.J. No. 377 (Q.B.)(QL) (wherein the Manitoba Court of Queen’s Bench refused to issue an order prohibiting Ms. Hirsch from obtaining an abortion), and *Murphy v. Dodd* (1989), 70 O.R. (2d) 681, 63 D.L.R. (4th) 515 (H.C.J.) (wherein an injunction was granted and later set aside, on the basis of a dispute about paternity).

<sup>43</sup> For the purposes of this discussion, the assumption is that the fetus will be carried to term. While I am not persuaded by the argument that the conduct of a pregnant woman could be constrained in part on the basis that she has decided to carry the fetus to term (see Justice Major’s dissent in *Winnipeg Child and Family Services (Northwest Area) v. D.F.G.*, [1997] 3 S.C.R. 925, 152 D.L.R. (4th) 193) there is a different balancing exercise required where a woman seeks a procedure that is unnecessary and that poses a potential risk to the fetus. See Charo, *supra* note 4 at 161.

<sup>44</sup> Erin Nelson, “Reconceiving Pregnancy: Expressive Choice and Legal Reasoning” (2004) 49 McGill L. J. 593. See also George J. Annas, “Forced Caesareans: The Most Unkindest Cut of All” (1982) 12 Hastings Center Rep. 17; Nancy K. Rhoden, “The Judge in the Delivery Room: The Emergence of Court-Ordered Cesareans” (1986) 74 Cal. L. Rev. 1951; Nancy Ehrenreich, “The Colonization of the Womb” (1993) 43 Duke L.J. 492; Janet Gallagher, “Collective Bad Faith: ”Protecting” the Fetus” in Joan C. Callahan, ed., *Reproduction, Ethics, and the Law: Feminist Perspectives* (Bloomington: Indiana University Press, 1995) 343; Sanda Rodgers, “State Intervention in the Lives of Pregnant Women” in *supra* note 8 at 331; Jackson *supra* note 42 at 115, 130-140.

<sup>45</sup> *Ibid.*

<sup>46</sup> See, e.g. Martin G.F. Lupton & David J. Williams, “The ethics of research on pregnant women: is maternal consent sufficient?” (2004) 111 BJOG: An International Journal of Obstetrics and Gynaecology 1307.

<sup>47</sup> *Tri-Council Policy Statement*, *supra* note 5, Section 9.C states that  
[r]esearch may be undertaken on methods to treat, in utero, a foetus that is suffering from genetic or

research (including the use of fetal tissue<sup>48</sup>) requires the free and informed consent of the pregnant woman. It is unclear whether placental tissue, the umbilical cord and cord blood would be considered fetal tissue, body parts of the pregnant woman, or some combination thereof.<sup>49</sup> Article 9 does not contemplate the situation of non-therapeutic research involving a fetus, nor does any other section of the *Tri-Council Policy Statement*. And, where research is the sole reason for subjecting a fetus to a risky procedure such as chorionic villus sampling (small though the risk may be), different issues arise. Ultimately, the question of whether a woman may consent to invasive procedures required solely for research purposes may prove to be unimportant, given that pregnant women are often reluctant to consent to such procedures even when they are clinically indicated,<sup>50</sup> but it bears mention that the contours of these legal and ethical issues remain to be mapped out.

Research investigating ART-outcomes will certainly involve collection of genetic information. Significant concerns have been raised around the question of whether parents may consent to (or, indeed, demand) genetic testing on behalf of their children where the genetic information sought is related to susceptibility or late onset disorders.<sup>51</sup> The concerns relate primarily to the notion that the autonomy of the child to choose to learn his or her genetic status might be foreclosed should

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congenital disorders. Because the fetus cannot be treated separately, any intervention on one involves an intervention the another. Accordingly, and consistent with the requirements of Section 2, research involving a human foetus requires the free and informed consent of the woman.

This of course does not contemplate the situation of "non-therapeutic" research, and no other section of the *Tri-Council Policy Statement* addresses non-therapeutic research on a fetus.

<sup>48</sup>The Article also states that a fetus is not to be used simply as a source of tissue, but should be recognized as a potential person deserving of respect (this of course applies to fetal tissue following miscarriage or abortion, not a fetus that is continuing to develop). *Ibid.*

<sup>49</sup>The *Tri-Council Policy Statement* (Section 10) mentions the "placenta" as a part of the body; presumably this means part of the woman's body, but it is unclear. *Ibid.* at Section 10.

<sup>50</sup>As Rayna Rapp notes, "...according to a leading epidemiologist of prenatal screening and birth defects, even the most perfectly accessible services are unlikely to yield higher than 70 percent utilization rates in this country." *Testing Women, Testing the Fetus*, *supra* note 40 at 167. See also Claire Julian-Reynier *et al.*, "Reasons for women's non-uptake of amniocentesis" (1994) 14:9 *Prenatal Diagnosis* 859; Jane Halliday, Judith Lumley & Lyndsey Watson "Comparison of women who do and do not have amniocentesis or chorionic villus sampling." (1995) 345:8951 *Lancet* 704; and Carron Sher *et al.*, "Factors affecting performance of prenatal genetic testing by Israeli Jewish women" (2003) 120A:3 *Am. J. Med. Genetics* 418, online:

<<http://www3.interscience.wiley.com/cgi-bin/fulltext/103524106/PDFSTART>>.

<sup>51</sup>See e.g. Bioethics Committee, Canadian Pediatrics Society, "Guidelines for genetic testing of healthy children" (2003) 8:1 *Pediatrics & Child Health* 42, online: <<http://www.cps.ca/english/statements/B/b03-01.htm>>; American Society of Human Genetics & American College of Medical Genetics, Board of Directors, "Points to consider: Ethical, legal, and psychosocial implications of genetic testing in children and adolescents" (1995) 57 *Am J Hum Genet* 1233; American Academy of Pediatrics, Committee on Bioethics, "Ethical issues with genetic testing" (2001) 107 *Pediatrics* 1451; L. Went, "Ethical Issues Policy Statement on Huntington Disease Molecular Genetics Predictive Test" (1990) 27 *J. Med. Genetics* 34; Peter S. Harper & Angus Clarke, "Should we Test Children for 'Adult' Genetic Diseases?" (1990) 335 *Lancet* 1205; Bartha Maria Knoppers & Geneviève Cardinal, "Genetics and the Law" in *supra* note 8 at 452; Ellen Wright Clayton, "Genetic testing in children" (1997) 22 *J. Med. Philos.* 233; Stephen Robertson & Julian Savulescu, "Is there a case in favour of predictive genetic testing in young children?" (2001) 15 *Bioethics* 26 [Robertson & Savulescu].

his or her parents insist on early testing.<sup>52</sup> The *Tri-Council Policy Statement* sets out a number of considerations relevant to genetic research, and has raised ethical concerns around the familial nature of genetic information, and around the unique, shared nature of genetic information. Indeed, the *Tri-Council Policy Statement* explicitly notes the “potential tension [that] exists between the individuals in the study and the families who are thereby implicated.”<sup>53</sup>

In Article 8.3, the potential harms of genetic research are described as potentially involving “moral, physical, psychological and social harms... For example, receiving information regarding susceptibility to genetic disease or even carrier status may provoke anxiety, disrupt relationships or undermine an individual’s sense of life opportunities.” The explanatory notes also observe that as with any health research, the involvement of children entails special ethical obligations and protections, and cautions that “genetic research involving children should not be done unless an effective intervention is available and the information to be gained outweighs the risk of harm.”<sup>54</sup>

Do these same concerns apply in the context of a pregnant woman consenting to the collection of fetal genetic information? And why (or why not)? There are distinct considerations related to genetic testing of a fetus compared with testing a child – parents are quite clearly entitled to obtain genetic information about their potential children (via PGD, amniocentesis or CVS) and indeed can sue their physicians for failure to inform them of the availability of such testing.<sup>55</sup> Currently, the ART regulator in the United Kingdom (the Human Fertilisation and Embryology Authority, or HFEA<sup>56</sup>) and the Canadian government are contemplating the legal and ethical issues related to permitting PGD for late-onset

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<sup>52</sup> Robertson & Savulescu, *ibid.* at 38-43, where the authors argue that the objections to childhood testing based on limiting the child’s future autonomy are mistaken. The predominant view, however, is that such testing should be deferred until the child is capable of deciding for him or herself.

<sup>53</sup> Further, it is suggested that, where possible, the informed consent process also involve relevant social structures. *Tri-Council Policy Statement*, *supra* note 5 at Article 8.1, explanatory notes.

<sup>54</sup> In addition, Article 8.5 considers ethical concerns related to the banking of genetic information for use in current and future research. *Ibid.* at Article 8.5.

<sup>55</sup> See, e.g., *Krangle (Guardian ad litem of) v. Brisco*, [2002] 1 S.C.R. 205 2002 SCC 9; Timothy Caulfield, “Gene testing in the biotech century: Are physicians ready?” (1999) 161:9 CMAJ 1122; and Erin Nelson & Gerald Robertson, “Liability for Wrongful Birth and Wrongful Life” (2001) 2:3 ISUMA 102. It should be noted that the limitations on precisely what genetic information parents are entitled to obtain via PGD or prenatal diagnosis remain somewhat unsettled. A recent example of policy making on this matter is the “saviour siblings” cases in the United Kingdom. For further discussion, see Erin L. Nelson, “Comparative Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada” *Alta. L. Rev.* [forthcoming in 2006].

<sup>56</sup> See U.K. Human Fertilisation and Embryology Authority, Meeting of the HFEA Ethics and Law Committee, *Emerging Issues in PGD: Project Initiation Document* ELC(04/05)01AnnexA (London: 14 April 2005), online: Human Fertilisation and Embryology Authority <<http://www.hfea.gov.uk/AboutHFEA/Committees/EthicsandLawCommittee/2005April/2005-04-14%20Committee%20ELC%20paper%20%2804-05%29%2001%20-%20Annex%20A.pdf>>.

disorders.<sup>57</sup> The rationale for preimplantation or prenatal genetic testing is to permit parents to make a decision about whether to terminate the pregnancy, or at least to allow them to prepare themselves for the birth of a disabled child. It is questionable whether the latter is legitimate in the case of late-onset disorders, but even if the only rationale is to allow the parents to make an informed decision about pregnancy termination, there is no requirement that fetuses affected by late-onset (or any other) disorders actually be aborted.<sup>58</sup> But what about the case of a fetus who will be carried to term, and where the only reason for the collection of genetic information is for purposes of research?

Another question that arises in the context of maternal consent to research on the fetus is whether the consent of the pregnant woman would shield the researcher from liability in the event that the fetus is harmed (negligently or otherwise) as a result of a research procedure, and, once born, the child suffers ill effects as a result of that harm.<sup>59</sup> In general, Canadian law takes the view that the decision of a pregnant woman to engage in risky behaviour is not legally relevant, or at least that it does not translate into a legal claim against her by her child born with injuries.<sup>60</sup> It is arguable that the decision of the woman to participate in research, after having been appropriately informed of the risks to herself and the fetus, would not insulate researchers against liability for injuries incurred by the fetus.<sup>61</sup>

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<sup>57</sup> Canada, Health Canada, *Request for comments on an issues paper regarding pre-implantation genetic diagnosis (PGD)*, online: Health Canada

<[http://www.hc-sc.gc.ca/ahec-asc/public-consult/col/pgd-dgp/pgd-dgp\\_e.html](http://www.hc-sc.gc.ca/ahec-asc/public-consult/col/pgd-dgp/pgd-dgp_e.html)>.

<sup>58</sup> Although this is what happens in the majority of cases. See e.g. Caroline Mansfield, Suellen Hopfer & Theresa M. Marteau, “Termination Rates After Prenatal Diagnosis of Down Syndrome, Spina Bifida, Anencephaly, and Turner and Klinefelter Syndromes: A Systematic Literature Review” (1999) 19:9 *Prenatal Diagnosis* 808.

<sup>59</sup> As the fetus is not a legal person and cannot advance a legal claim, such a claim cannot be brought until after the child is born alive. See *Dobson (Litigation Guardian of) v. Dobson*, [1999] 2 S.C.R. 753, 174 D.L.R. (4<sup>th</sup>) 1.

<sup>60</sup> See *Dobson (Litigation Guardian of) v. Dobson*, *ibid.*; *Preston (Guardian of) v. Chow* (2002), 211 D.L.R. (4<sup>th</sup>) 758, 163 Man. R. (2d) 134 (C.A.) (holding that by virtue of the decision in *Dobson*, contributory “negligence” of the mother is not relevant and other defendants cannot claim contribution or indemnity, because the mother cannot be found ‘liable’ to her later born child in the first place). It should be noted, however, that the Alberta Legislature has recently passed legislation that creates a limited exception to the holding in *Dobson*, in order to permit a child to sue his or her mother for injuries caused by “the mother’s use or operation of an automobile during her pregnancy if, at the time of that use or operation, the mother was insured under a contract of automobile insurance...” *Maternal Tort Liability Act*, S.A. 2005, c. M-7.5.

<sup>61</sup> This question has arisen in the context of drug trials, where pharmaceutical companies sponsoring research have traditionally been reluctant to include women of childbearing potential as research participants due to concerns about potential liability. In that context, Alta Charo has noted that while parents cannot waive a cause of action on behalf of their child, a manufacturer may be able to avoid liability if they recommend precautions to avoid pregnancy, and the woman herself fails to take precautions and becomes pregnant (and the child suffers harm as a result), because the woman’s conduct would break the “chain of causation” between the drug manufacturer and the child. This would not be the case in Canada, given the SCC’s decision in *Dobson*, *supra* note 59. See Charo, *supra* note 4 at 146; see also Mastroianni, *supra* note 4 at 186-91, suggesting ways in which liability can be mitigated.

## ii. Childhood

Once the child is born, new questions about consent will arise: to what extent are parents permitted to consent to research on behalf of their children? As noted earlier, there is a tension between legal (and ethical) constraints upon children's participation in research, and the recognition that children deserve the benefits of health research, which necessarily entails some exposure to the risks of participation.<sup>62</sup> The *Tri-Council Policy Statement* explicitly recognizes concerns that have been raised in relation to distributive justice in stating that "those who are not competent to consent for themselves shall not automatically be excluded from research which is potentially beneficial to them, or to the group that they represent."<sup>63</sup>

The common law protects unwilling recipients of medical intervention by requiring consent to treatment or diagnostic procedures. Unless consented to, even life-saving unwanted touching runs afoul of the law.<sup>64</sup> As has been explained, in order to be valid, consent must be provided by one with the capacity to give it. Where no such capacity exists on the part of the individual to be treated, a surrogate decision-maker may provide consent. In the case of children, the surrogate decision-makers are ordinarily the child's parents,<sup>65</sup> and parents are therefore permitted to consent to or refuse<sup>66</sup> recommended treatment.

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<sup>62</sup> See e.g., Miller & Kenny, *supra* note 4 at 218; Emanuel, Wendler & Grady, *supra* note 33 at 2705; Rhodes, *supra* note 5 at 21.

<sup>63</sup> *Tri-Council Policy Statement*, *supra* note 5 at Art. 5.3. In addition, Art. 5.1 provides that

Where research is designed to survey a number of living research subjects because of their involvement in generic activities ... that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so.

In Article 2.5, which deals with participation in research by incompetent individuals, the *Tri-Council Policy Statement* provides as follows:

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- The research question can only be addressed using individuals within the identified group(s); and
- Free and informed consent will be sought from their authorized representative(s); and
- The research does not expose them to more than minimal risks without the potential for direct benefits for them.

(*ibid.* at Art. 5.1, 2.5)

<sup>64</sup> There are of course exceptions to the consent requirement, including situations of emergency and circumstances in which legislation has been implemented in order to dispense with consent (generally public health legislation). See, e.g., Picard & Robertson, *supra* note 35 at 49-54; Nelson, "The Fundamentals of Consent", *supra* note 35 at 116-20; *Marshall v. Curry*, [1933] 3 DLR 260 (N.S.S.C.); *Malette v. Shulman* (1990), 72 O.R. (2d) 417, 67 D.L.R. (4<sup>th</sup>) 321 (C.A.); *Public Health Act*, R.S.A. 2000, c. P-37, ss. 39, 40.

<sup>65</sup> See Joan Gilmour, "Children, Adolescents and Health Care" in *supra* note 8, 205 [Gilmour]; Erin Nelson, Katrina Haymond & Mona Sidarous, "Selected Legal and Ethical Issues Relevant to Pediatric Genetics" (1998) 6 Health L. J. 83; and *B.(R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315, 122 D.L.R. (4<sup>th</sup>) 1 [Nelson, Haymond & Sidarous].

<sup>66</sup> It must be noted that parents' authority to refuse recommended medical treatment on behalf of their children is not absolute, and the court may intervene where a parental treatment refusal does not accord with the best interests of the child. See *ibid.*

While it is settled law that parents may provide consent to their child’s participation in research of potential benefit,<sup>67</sup> there exists real doubt about parental authority to consent to their child’s participation in ‘non-beneficial’ research,<sup>68</sup> and particular concerns have been raised in the context of genetic research.<sup>69</sup> Parents’ authority to consent to their child’s participation in research stems from their authority to consent to their child’s medical care, but here (as in the treatment context), the parents’ decision must be consistent with the child’s best interests.<sup>70</sup> The clear implication, in the clinical setting, of a particular intervention being recommended, is that it is in the best interests of the child to undergo the procedure or treatment in question. In the case of participation in health research, the picture becomes clouded.

With respect to the legal authority of parents to consent to their child’s participation in non-therapeutic research, there are two streams of opinion. The first is that, based on the decision of the Supreme Court of Canada in *E (Mrs.) v. Eve*,<sup>71</sup> the obligation of parents to act in the best interests of their child means that they have no authority to consent to the child’s participation in research with no intended benefit to the child.<sup>72</sup> The counter-argument is that because this position would leave children “therapeutic orphans” and impede important benefits that can accrue to children in general through research into conditions or treatments specific to children, parents can consent to non-beneficial research if it poses no more than minimal risk.<sup>73</sup>

In *Eve*, the Court confronted the difficult legal question of whether a substitute decision-maker may ever consent to sexual sterilization – an invasive procedure that completely and permanently removes one’s reproductive capacity – where

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<sup>67</sup> Glass & Lemmens, *supra* note 30; Bernard M. Dickens, “The Legal Challenge to Health Research Involving Children” (1998) 6 Health L. J. 131 [Dickens, “Legal Challenge”]; Baylis & Downie, *supra* note 4.

<sup>68</sup> *Ibid.*; Canada, Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects (Working Paper No. 4)* (Ottawa: Law Reform Commission, 1988) [*Biomedical Experimentation Involving Human Subjects*]; U.S., National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: Supt. of Government Documents, 1979) [*Belmont Report*].

<sup>69</sup> Marie Hirtle, “Children and Genetics: Comparative Study of International Policy Positions” (1998) 6 Health L.J. 43 [Hirtle]; Timothy Caulfield & Bartha Maria Knoppers, “Genetic Testing, Legal Capacity and Adolescents” (1998) 6 Health L.J. 115 [Caulfield & Knoppers]; Patrik S. Florencio, “Genetics, Parenting and Children’s Rights in the Twenty-First Century” (2000) 45:2 McGill L. J. 527.

<sup>70</sup> See Dickens, “Legal Challenge”, *supra* note 67.

<sup>71</sup> *E. (Mrs.) v. Eve*, [1986] 2 S.C.R. 388, 31 D.L.R. (4<sup>th</sup>) 1 (In *Eve*, the mother of a 24 year old woman with extreme expressive aphasia and mild to moderate intellectual disability sought to have her sterilized to prevent pregnancy. The rationale for the sterilization was that “Eve” herself would not be able to care for a child, and the mother was concerned that it would fall to her to look after the child. The Court held that non-therapeutic sterilization could never safely be authorized by parents or by the courts on behalf of an incompetent person).

<sup>72</sup> Dickens, “Legal Challenge”, *supra* note 67 at 133.

<sup>73</sup> Baylis & Downie, *supra* note 4.

there is no medical indication for the procedure. The Court was particularly concerned about the "negative psychological impact" of non-consensual sterilization, given the individual significance of reproductive capacity.<sup>74</sup> As Dickens acknowledges,<sup>75</sup> it may very well be the case that the Supreme Court of Canada would not apply the reasoning adopted in *Eve* to the case of non-therapeutic health research on children, but the Court has not addressed that issue, and the resulting uncertainty is what creates the "chilling effect" on parental consent to non-beneficial research involving minors.<sup>76</sup>

The only Canadian jurisdiction to have resolved the issue of parental consent to a child's participation in research is Québec. Article 21 of the *Civil Code* provides that minors may participate in non-beneficial research with the consent of their parents, as long as they do not object and there is no serious risk to their health as a result of participating.<sup>77</sup> In cases involving research on a group of minors, the *Code* requires that there be some potential benefit for others of the same age group or having the same disease or disability as the participants, and the research must be approved by an appropriate research ethics board (REB).<sup>78</sup>

The Law Reform Commission of Canada has recommended regulation permitting parents to consent to such research, provided: that it does not involve "any serious risks" for the child, that in addition to a parent, a third party (a judge, ombudsman or the child's lawyer) provides consent, and that the child's refusal to participate should always be respected, whatever his or her age.<sup>79</sup> This approach parallels that taken in the United States, based on the recommendations of the Belmont Report,<sup>80</sup> which states that pediatric research with no intended benefit for participants can be undertaken where: the experiment cannot be performed on other groups; consent is obtained from children over the age of seven; the risk is minimal and will be assessed by an independent ethics committee; and the research is of major scientific importance.

The very idea of beneficial, or non-beneficial, research is inextricably linked to notions of benefit, best interests, harm and risk, all of which merit further

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<sup>74</sup> See *supra* note 71 at para. 80.

<sup>75</sup> Dickens subscribes to the view that *Eve* does restrain parents from consenting to children's participation in non-therapeutic research, see Dickens, "Legal Challenge", *supra* note 67.

<sup>76</sup> Dickens, "Legal Challenge", *ibid.* at 132.

<sup>77</sup> Art. 21 C.C.Q.

<sup>78</sup> *Ibid.* at para. 2.

<sup>79</sup> *Biomedical Experimentation Involving Human Subjects*, *supra* note 68. Even if the law were clarified to reflect that parents may approve their child's participation in non-beneficial research with no more than minimal risk, whether consent to a particular research protocol is permissible may still depend on the procedures or interventions required for participation. In the Criminal Code of Canada, "wounding" constitutes an aggravated assault; parents of course cannot legally authorize this. And venepuncture, which is seen as minimal risk, would be currently classified as wounding within the Code definition. See e.g. Dickens, "Legal Challenge", *supra* note 67 at 135-36; Baylis & Downie, *supra* note 4 at 50-52.

<sup>80</sup> *Supra* note 68. Research in the U.S. is governed by United States Department of Health and Human Services, Protections of Research Subjects, 45 C.F.R. 46 (1991).

consideration in this context. Is it ever in the best interests of an individual child to participate in health research which promises no benefit to the child? The answer depends a great deal on how one characterizes benefit and "best interests," but an argument could be made that the close medical follow-up that would be a part of ART-outcomes research would be in the child's medical interests, in that it would permit early detection of developmental and other health problems which might lead to beneficial intervention. Further, in a longitudinal research study aimed at obtaining safety information about ARTs, the question of 'harm' is quite different from that envisaged in the context of a study requiring medical or other interventions.<sup>81</sup> There is likely significant consensus around the meaning of 'harm' and 'risk' in, for example, drug trials, whereas these notions are more slippery<sup>82</sup> when we conceive of collecting genetic data to be stored and reconsidered over a lengthy period of time.

In addition to the unsettled question of parental consent to children's involvement in health research, other complicating factors exist. Given that longitudinal prospective research into ART safety will extend beyond early childhood, assent (and, later, consent) will inevitably be sought from the child him or herself. The role of the child, as an individual with developing capacity, is therefore an essential consideration.<sup>83</sup> And, while the concept of assent is relatively well-developed from the perspective of ethical discourse,<sup>84</sup> the legal implications of the assent and, for that matter, dissent of the child participant demand consideration.<sup>85</sup> As Miller & Kenny note, the concepts of assent and dissent are "internally contradictory and difficult to apply in practice. The general tendency has been to conflate assent with consent and dissent with refusal."<sup>86</sup> In part, this is the result of the privileged

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<sup>81</sup> Mylène Deschênes *et al.*, "Human genetic research, DNA banking and consent: a question of form?" (2001) 59:4 *Clinical Genetics* 221 at 223-24 [Deschênes *et al.*]; Bartha Maria Knoppers *et al.*, "Children and incompetent adults in genetic research: consent and safeguards" (2002) 3:3 *Nature Reviews Genetics* 221 at 223 [Knoppers *et al.*]. For an interesting discussion of the distinctions between risks in population genetic research as opposed to family-based genetic research see Laura M. Beskow *et al.*, "Informed Consent for Population-Based Research Involving Genetics" (2001) 286:18 *JAMA* 2315. See also R.R. Sharp & M.W. Foster, "Involving Study Populations in the Review of Genetic Research" (2000) 28 *J. L. Med. & Ethics* 41; George J. Annas, "Reforming Informed Consent to Genetic Research (2001) 286:18 *JAMA* 2326.

<sup>82</sup> As Loretta Kopelman has pointed out, the notion of "minimal risk" is not clearly defined in research ethics guidelines, and is potentially subject to widely varying interpretations. See Kopelman, *supra* note 4 at 750-56.

<sup>83</sup> Timothy Caulfield & Nola Ries, "Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context" (2004) 12: Supp.1 *Health L. J.* 1 [Caulfield & Ries]; Knoppers *et al.*, *supra* note 81.

<sup>84</sup> Christine P. Harrison, *et al.*, "Bioethics for Clinicians: 9. Involving children in medical decisions" (1997) 156:6 *CMAJ* 825; Gilmour, *supra* note 65; Hirtle, *supra* note 69; Knoppers *et al.*, *supra* note 81; and *Tri-Council Policy Statement*, *supra* note 5.

<sup>85</sup> Glass & Lemmens, *supra* note 30; Francoise Baylis, "The Moral Weight of a Child's Dissent" (1993) 3 *Ethics & Medical Practice* 2; Claire Bernard & Bartha Maria Knoppers, "Legal Aspects of Research Involving Children in Canada" in Bartha Maria Knoppers, ed., *Canadian Child Health Law* (Toronto: Thompson Educational Publishing, 1992) at 259 [Bernard & Knoppers].

<sup>86</sup> Miller & Kenny, *supra* note 4 at 227.

position of informed consent in the health care ethics context,<sup>87</sup> and the need, from a legal perspective, for clarity around the question of the appropriate decision-maker. Although assent and dissent have specific meaning in the ethics literature, the law is unable to take account of their nuanced meanings in that context. And, indeed, the *Tri-Council Policy Statement's* instructions around assent and dissent only serve to compound the uncertainty about how these notions should be applied. Article 2.7 provides:

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. *The potential subject's dissent will preclude his or her participation.* [emphasis added]

First, the article seems internally contradictory. In law, in order to be decisionally capable, an individual must be able to “understand the information relevant to making a decision about the [research], and to appreciate the reasonably foreseeable consequences of a decision to” participate or not.<sup>88</sup> Describing a “legally incompetent individual” as one who is able to “understand the nature and consequences of the research” is confusing, to say the least. Moreover, the fact that a potential subject’s dissent is to be treated as a competent refusal to participate seems to blur the distinction between consent and refusal on the one hand, and assent and dissent on the other.<sup>89</sup> Clearly, these ethical and legal issues must be addressed in order to facilitate the conduct of research into health outcomes for children conceived using ARTs.

### iii. Adolescence

In acknowledgement of the developing autonomy of children and adolescents, the courts have articulated the “mature minor” doctrine.<sup>90</sup> A mature minor is

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<sup>87</sup> Rhodes, *supra* note 5; Miller & Kenny, *ibid.* at 226.

<sup>88</sup> Gilmour, *supra* note 65 at 206.

<sup>89</sup> As Baylis, Downie & Kenny note:

if a parent’s legally and morally valid authorization can be overridden by a child’s dissent, then it appears that a dissent by a person with developing decision-making capacities has the same moral force as a refusal by a person with decision-making capacities. This is perplexing, for while it is undeniably important to heed a child’s objections, it is not clear that these objections should be authoritative in the same way and for the same reasons that a refusal by a person with decision-making capacity is generally regarded as authoritative.

Francoise Baylis, Jocelyn Downie & Nuala Kenny, “Children and decision-making in health research” (1999) 21:4 IRB: *A Review of Human Subjects Research* 5 at 6.

<sup>90</sup> (*C.*) *J.S. v. Wren*, [1987] 2 W.W.R. 669, (1986), 49 Alta. L.R. (2d) 289 (C.A.); *Gillick v. West Norfolk and Wisbech Area Health Authority*, [1986] 1 A.C. 112 (H.L.); *Ney v. Canada (Attorney-General)*, [1993] 6 W.W.R. 135, 79 B.C.L.R. (2d) 47 (S.C.); *Walker v. Region 2 Hospital Corp.* (1994), 116 D.L.R. (4th) 477, 150 N.B.R. (2d) 366 (C.A.); Bernard & Knoppers, *supra* note 85; Gilmour, *supra* note 65; and Nelson, Haymond & Sidarous, *supra* note 65. A few Canadian jurisdictions have (at least partially) dealt with the question of age of consent to treatment by way of legislation: *Medical Consent of Minors Act*,

a person who has not yet reached the age of majority, but who is found to have the capacity to consent to the treatment in question, on the basis of an assessment of his or her ability to understand the nature and consequences of the treatment and of accepting or refusing it.<sup>91</sup> Where a minor is considered mature, the minor’s consent is necessary and sufficient with respect to medical treatment.<sup>92</sup>

Questions remain, however, about the contours of the doctrine, even in the clinical treatment context, out of which it emerged.<sup>93</sup> In particular, there have been a number of cases decided in the last several years that raise some uncertainty about the scope and application of the common law mature minor doctrine in the situation of a refusal of life-saving treatment by a mature minor. The three most recent cases, *C.U. (Next Friend of) v. McGonigle*, *B.H. (Next Friend of) v. Alberta (Director of Child Welfare)* and *S.J.B. (Litigation Guardian of) v. British Columbia (Director of Child, Family and Community Services)* have held that, in situations of refusal of life-saving medical treatment, child welfare legislation allows for the refusal of a mature minor to be overridden.<sup>94</sup> All three cases have involved refusals of blood transfusions by adolescents who subscribe to the tenets of the Jehovah’s Witness faith.

Clearly, the cases cited above involve issues that differ significantly from decisions about participation in (most) health care research. But even though they are not directly on point, the cases demonstrate that the boundaries of the mature minor doctrine remain to be fully articulated and that the courts seem to be prepared to take different approaches to different health care decisions made by mature

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S.N.B. 1976, c.M-6.1, s.2; *Infants Act*, R.S.B.C. 1996, c. 223, s.17, *Substitute Decisions Act*, 1992, S.O. 1992, c.30, s.2(2). Arts. 14, 16 and 17 of the C.C.Q provide that minors aged 14 and older can consent to required health care. In Manitoba, *The Child and Family Services Act*, S.M. 1985-86, c.8, C.C.S.M., c. C80, s.25 provides that those medical and / or dental evaluation and treatment of those aged 16 and older who have been apprehended by child welfare authorities requires either the consent of the minor or a court order.

<sup>91</sup> Timothy Caulfield, “Testing Adolescents for the Alzheimer Gene: Tensions in Law and Policy” (1997) 25 *Man. L. J.* 31; Rebecca J. Cook & Bernard M. Dickens, “Recognizing adolescents’ ‘evolving capacities’ to exercise choice in reproductive healthcare” (2000) 70:1 *International Journal of Gynecology and Obstetrics* 13; Caulfield & Knoppers, *supra* note 69; Gilmour, *supra* note 65.

<sup>92</sup> See Gilmour, *ibid.* at 212; Picard & Robertson, *supra* note 35 at 73.

<sup>93</sup> *S.J.B. (Litigation Guardian of) v. British Columbia (Director of Child, Family and Community Services)* (2005), 42 B.C.L.R. (4<sup>th</sup>) 321, 2005 BCSC 573; *B.H. (Next Friend of) v. Alberta (Director of Child Welfare)*, [2002] A.J. No. 568 (QL), 2002 ABCA 109; *B.H. (Next friend of) v. Alberta (Director of Child Welfare)* (2002), 302 A.R. 201, 2002 ABQB 371; *C.U. (Next friend of) v. McGonigle* (2000), 273 A.R. 106, 2000 ABQB 626; *C.U. v. McGonigle* (2003), 327 A.R. 25, 2003 ABCA 66.

<sup>94</sup> In *B.H. v. Alberta (Director of Child Welfare)* (2002), 303 A.R. 115, 2002 ABCA 109, the Court of Appeal held that the decision of Kent J. in the Court of Queen’s Bench “found that at and around the particular time when she held her hearing, the appellant B.H. was not a mature minor because she could not then give a true informed refusal of medical treatment. (She held that there had been such ability earlier, contrary to what the trial judge had held, but that such ability had ended.)” As a result, the Court of Appeal found it unnecessary to determine whether the *Child Welfare Act*, S.A. 1984, c.C-.8.1 (now the *Child, Youth and Family Enhancement Act*, R.S.A. 2000, c. C-12) permits the decision of a mature minor to be overruled and whether, if it does, the Act is inconsistent with the *Charter*. In the other two cases the judges found that the *Child Welfare Act* can override the health care decision of a mature minor.

minors. And, as yet, no court has been called upon to determine whether and to what extent the mature minor doctrine applies in the research context. Courts may well be prepared to concede that a mature minor may consent to research with potential therapeutic benefit, but might hesitate to go so far as to conclude that participation in long-term research that might reveal significant future health risks is something to which a mature minor could provide valid consent. In spite of arguments about the erroneous, deterministic thinking that informs many of the concerns related to the disclosure of genetic information,<sup>95</sup> concerns about obtaining insurance and employment, and possible stigmatisation after disclosure persist.<sup>96</sup> Those concerns, together with the immutability of genetic information, have led to reluctance to test children unnecessarily (i.e. for late onset disorders, or susceptibility information).<sup>97</sup> Given the emergence of new information about the relationship between epigenetic and imprinting errors and, for example, cancer risk, and given the difficulty that adults have in understanding risk analysis and genetic information,<sup>98</sup> it may not be safe to accept the consent of one who appears to be a mature minor, even if based on the procedures it requires, the protocol appears to pose minimal risk.

As if the above-noted issues and questions around potential legal and ethical barriers to consent are not complicated enough, it must also be borne in mind that there is significant variation among Canadian jurisdictions in terms of consent law generally, and consent by adolescents specifically.<sup>99</sup> Given the large numbers of participants required for longitudinal ART studies to be effective,<sup>100</sup> it is extremely unlikely that research of this nature could be accomplished with subjects drawn from only one Canadian jurisdiction; it is therefore essential to address this variation among Canadian jurisdictions, both to examine the relevance of the differences and to attempt, where possible, to harmonize the rules.

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<sup>95</sup> See e.g. Timothy Caulfield, "Cloning and genetic determinism – a call for consistency" (2001) 19:5 *Nature biotechnology* 403; Peter McGuffin, Brien Riley & Robert Plomin, "Genomics and Behavior: Toward Behavioral Genomics" (2001) 291 *Science* 1232; U.S., National Bioethics Advisory Commission, *Cloning human beings: report and recommendations of the National Bioethics Advisory Commission* (Rockland, MA.: NBAC, June 1997).

<sup>96</sup> Pamela Sankar, "Genetic Privacy" (2003) 54 *Annual Rev. Med.* 393, esp. 398-99; Trudo Lemmens, "Genetics and Insurance Discrimination: Comparative Legislative, Regulatory and Policy Developments and Canadian Options" (2003) 11 *Health L. J.* 41.

<sup>97</sup> See *supra* note 51.

<sup>98</sup> See e.g. Jill K. Frizzley, "Ethical Issues in Breast Cancer Susceptibility Testing" (1998) 6 *Health L. Rev.* 14 at para. 26 (QL); Dorothy C. Wertz *et al.*, "Attitudes Towards the Prenatal Diagnosis of Cystic Fibrosis: Factors Affecting Decision-Making Among Affected Families" (1992) 50 *Am. J. Hum. Genet.* 1077; M. Richards & M. Ponder, "Lay Understanding of Genetics: A Test of a Hypothesis" (1996) 33 *J. Med. Genet.* 1032.

<sup>99</sup> Nelson, "The Fundamentals of Consent," *supra* note 35; Angela Campbell, "Children Living with HIV: Reshaping Law and Policy in Quebec to Preserve and Promote Their Rights" (2000) 8 *Health L. J.* 143; Caulfield & Ries, *supra* note 83.

<sup>100</sup> Retzlloff, *supra* note 25; De Rycke, Liebaers & Van Steirteghem, *supra* note 14.

#### IV. Regulation of ART-related Research

The recent enactment of the *Assisted Human Reproduction Act*<sup>101</sup> holds some promise of comprehensive governance specifically in relation to ART research, but review of the legislation reveals that whether such promise will be attained remains an open question. In terms of research procedures, the *AHR Act* is concerned specifically with embryo research; its ambit extends only up to the point of implantation of the embryo into a woman’s uterus. Thus, at least as far as procedures are concerned, the type of research required to assess health and safety outcomes for children conceived using ARTs is not comprehended by the *Act*.

The main role that the *AHR Act* will play in connection with longitudinal ART-outcomes research is in relation to its information registry. The creation of an information registry by the Assisted Human Reproduction Agency of Canada (AHRA) is viewed as an integral component of the regulation of ARTs, and has a number of purposes, including:

- (i) assessment of short and long-term health outcomes for the children resulting from the procedures;
- (ii) assessment of health effects for the women who undergo the procedures;
- (iii) ongoing information on assisted human reproduction services, drugs and procedures including the outcomes and success rates;
- (iv) access by genetic offspring from sperm, egg or embryo donation to non-identifying donor information; and

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<sup>101</sup> *Assisted Human Reproduction Act*, S.C. 2004, c.2 [*AHR Act*]. The enactment of this legislation follows a long and tortured path commencing in 1989 with the creation of the Royal Commission on New Reproductive Technologies (for a more complete discussion, see Erin Nelson, “Comparative Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada,” supra note 55). The Canadian legislation is most similar in approach to that adopted in the U.K. with the *Human Fertilisation and Embryology Act*, (U.K.) 1990, c.37 (*HFE Act*), in that it adopts the model of a single national regulator for research and clinical applications of ARTs. It is worth noting that research on ART outcomes has not been facilitated in the U.K., given strict confidentiality provisions in the legislation. See U.K., H.C., Science and Technology Committee, *Human Reproductive Technologies and the Law – Fifth Report of Session 2004-05* (London: The Stationary Office, 2005) at 115-16. The *HFE Act* is currently under review by the U.K. Department of Health, see Department of Health, News Release, “Review of the Human Fertilisation and Embryology Act 1990” (20 January 2004), online: Department of Health <[http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/AssistedConception/AssistedConceptionGeneralInformation/AssistedConceptionGeneralArticle/fs/en?CONTENT\\_ID=4069149&chk=MSMizC](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/AssistedConception/AssistedConceptionGeneralInformation/AssistedConceptionGeneralArticle/fs/en?CONTENT_ID=4069149&chk=MSMizC)>.

(v) provision of research data for understanding the physical and emotional outcomes on persons involved with or resulting from assisted human reproduction processes.<sup>102</sup>

Section 17 of the *AHR Act* requires the AHRA to “maintain a personal health information registry containing health reporting information” about gamete and embryo donors, persons who undergo ART procedures and persons conceived by means of ARTs. In turn, “health reporting information” is defined as information provided pursuant to the Act with respect to “the identity, personal characteristics, genetic information and medical history” of the persons referred to in section 17.<sup>103</sup>

The Act specifies that the health reporting information within the registry is confidential and “shall be disclosed only with the written consent of the donor or [the person undergoing or conceived using ART procedures], as the case may be.”<sup>104</sup> Section 18(8), however, provides that health reporting information may be disclosed for “scientific research or statistical purposes, other than the identity of any person – or information that can reasonably be expected to be used in the identification of any person.”

To the extent that the information required by researchers is individually identifying, consent will have to be obtained from the individual to whom the information refers before the AHRA can disclose it. Conversely, to the extent that the information required by researchers cannot “reasonably be expected to be used in the identification of any person,” such information can be disclosed by the AHRA without consent. This likely refers to anonymized or identifiable (as opposed to identifying) information. It is possible to anonymize genetic information by stripping it of personal identifiers, and it is also possible to render information identifiable by coding or encrypting personal identifiers. Anonymized information cannot be linked to the individual(s) it relates to, while identifiable information can be linked to the individual by a person with access to the key.<sup>105</sup> Although anonymization of data would provide the best protection against the possibility of identifying a specific individual, as Deschênes *et al.* note, “[t]he International Ethics Committee of the Human Genome Organization points out, however, that ... anonymization may compromise the development of future research since once anonymized, the sample cannot be identified and so no future clinical data can be added or studied.”<sup>106</sup>

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<sup>102</sup>See Canada, House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (Ottawa: Standing Committee on Health, December 2001), online: Parliament <<http://www.parl.gc.ca/InfoComDoc/37/1/HEAL/Studies/Reports/healrp01/03-cov-e.htm>>.

<sup>103</sup>Health reporting information also includes information respecting “the custody of donated human reproductive materials and in vitro embryos and the uses that are made of them.” *AHR Act*, *supra* note 101 at s.3.

<sup>104</sup>*AHR Act*, *ibid.* at s.18(2).

<sup>105</sup>See Caulfield & Ries, *supra* note 83 at 36.

<sup>106</sup>Deschênes *et al.*, *supra* note 81 at 222. A concern that may arise uniquely in the ART research context (as compared to general population-based genetic research) is the small size of the population of potential

While it may be possible for researchers to obtain health reporting information without obtaining individual consent, because new genetic tests will continually emerge, it is unlikely that the information registry will contain all of the information needed by researchers. Moreover, it is still uncertain precisely what data about any given individual is (and will be) needed to answer questions about long-term health outcomes. Even assuming, however, that the information registry contains all of the information required for longitudinal prospective research on outcomes, and that this information is useful even if potentially identifying information is not provided, it will be some time before the information registry serves a useful function for long-term follow-up of children conceived using ARTs.

The Canadian government is now in the process of recruiting for the Agency's Board of Directors, and had planned to announce the appointees in early 2006,<sup>107</sup> but this may change given the dissolution of government and election call in late November 2005. And, currently, the *AHR Act* itself is only partly in force. The regulatory process began in the Fall of 2004, and will continue over the next three years, after which the entire *Act* will be proclaimed in force.<sup>108</sup> Data collection presumably cannot commence until the relevant sections of the *Act* are in force and the regulatory details have been sorted out; this means that data collection will in all likelihood not even begin until 2008. Further, the data collected initially will relate to donors, those undergoing ARTs and those conceived via ARTs from the point at which collection begins. Thus, it seems that data relevant to longitudinal prospective research will likely only become available several years after the Agency's information registry is established. An additional problem, which may also add to the time lag, is the very question of what kind of data are required in order for such research to be effectively pursued. As noted earlier, questions remain about the causes of the ART-related health concerns that have been identified to date. Until there is more clarity around what types of data are required for study into ART outcomes, the Agency's information registry may be of limited utility.<sup>109</sup>

In light of these uncertainties, it remains to be seen whether and to what extent the *Act* will in fact help to clarify the fragmented nature of current law and policy around consent to participation in ART-related health research in Canada.<sup>110</sup>

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research subjects. The question of whether information is truly non-identifying may require further consideration in a context where the pool of potential participants is quite small.

<sup>107</sup> See Health Canada, online:

<[http://www.hc-sc.gc.ca/english/lifestyles/reproduction/ahrac\\_bod\\_recruitment\\_e.html](http://www.hc-sc.gc.ca/english/lifestyles/reproduction/ahrac_bod_recruitment_e.html)>.

<sup>108</sup> See Health Canada, online: <[http://www.hc-sc.gc.ca/english/lifestyles/reproduction/noi\\_e.html](http://www.hc-sc.gc.ca/english/lifestyles/reproduction/noi_e.html)>.

<sup>109</sup> And, as my colleague Jane Steblecki has pointed out, the onerous administrative burden on the AHRA, of transforming potentially identifying information to non-identifying (or anonymised) information, and managing the same, in the context of requests for information for use in longitudinal studies raises yet another issue.

<sup>110</sup> The use of health information for research purposes itself gives rise to a number of considerations relevant to ART-outcomes research. Researchers who intend to do such work will face a web of overlapping legislation dealing with health information in addition to provisions found in the *AHR Act* (*supra* note 101), including federal private sector privacy legislation (*Personal Information Protection and Electronic Documents Act*, S.C. 2000, c.5 (PIPEDA)); provincial health information legislation

## V. Conclusion

As they now stand, legal rules and ethical guidelines around consent to health research involving children will frustrate the creation of research protocols that investigate health and safety issues related to the use of ARTs. In order for such research to proceed, it is essential that these issues and uncertainties be addressed. The intent of this paper has been to signal the consent-related issues that require consideration and clarification to facilitate the conduct of longitudinal prospective research into ART outcomes without which, as one group of authors has noted, "human ART procedures remain a series of experiments-in-progress."<sup>111</sup>

Consideration of these consent and risk-related issues is clearly needed in order to create some certainty around law and consent in this specific research context. In addition to the legal complexities around consent involved in studies of this nature, however, there are larger issues to consider. Further research is needed into how consent law treats different groups (competent adults, incompetent adults, pregnant women, adolescents and children) who are making critical decisions about participation in health research, in order to elucidate some of these more subtle issues, such as: who the law considers vulnerable and why; the tension between autonomy and vulnerability; and how law attempts to justify decisions about which parties are recognized as decision-makers in the health research context.

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(*Health Information Act*, R.S.A. 2000, c.H-5; *Health Information Protection Act*, S.S. 1999, c.H-0.021; *Personal Health Information Act*, C.C.S.M. c.P33.5; *Act respecting health services and social services*, R.S.Q. S-4.2 (the Québec legislation does not deal with health information generally but regulates disclosure of health information for research purposes)) and provincial and federal freedom of information and privacy legislation (*Privacy Act*, R.S.C. 1985, c. P-21; *Freedom of Information and Protection of Privacy Act*, R.S.B.C. 1996, C.165; R.S.A. 2000, c. F-25; S.S. 1990-91, c. F-22.01; C.C.S.M., c. F175; R.S.O. 1990, c. F-31; S.N.S. 1993, c. 5; R.S/P.E.I. 2002, c. F-15.01; *Protection of Personal Information Act*, S.N.B. 1998, c.P-19.1; and *Access to Information and Protection of Privacy Act*, S.N.L. 2002, c.A-1.1 (Part IV, which deals with protection of privacy, is not yet in force); R.S.Y. 2002, c.1; S.N.W.T. 1994, c.20; and R.S.N.W.T. 1994, c.20 (Nunavut)).

<sup>111</sup>Jeremy G. Thompson *et al.*, "Epigenetic risks related to assisted reproductive technologies: Short- and long-term consequences for the health of children conceived through assisted reproduction technology: more reason for caution?" (2002) 17 *Human Reproduction* 2783 at 2786.