

# Adequate Protection for the Autonomous Research Subject? The Disclosure of Sources of Funding and Commercialisation in Genetic Research Trials

---

ANNE CÔTÉ\*

It is ... naïve to view the scientific activity as purely objective and disinterested, operating simply for the good of others and sharing the same goals, attitudes and values as others in society.

Paul M. McNeill, *The Ethics and Politics of Human Experimentation*

As new risks evolve, often as a consequence of new scientific tools that provide new levels and types of knowledge, it is the obligation of the academic and commercial research communities to alter their disclosure practices.

Philip R. Reilly, *et al.*, *Ethical Issues in Genetic Research: Disclosure and Informed Consent*

## I. INTRODUCTION

THE REALM OF RESEARCH ETHICS HAS ARISEN out of the horrors of past abuses perpetrated against unwitting subjects of so-called scientific experimentation. Incidents such as the Nuremburg trials and the Tuskegee syphilis experiments have led to public outcry and to a deeper understanding of the importance of protecting the rights of those involved in human experimentation. To add to the darkened cloud that has, at least for many bioethicists, hung over the enterprise of medical research, a new cloud has appeared: the commercialisation of research in general, and genetic research in particular. While the importance of informed consent has continued its ascendancy in the medical context at large, it lingers more tellingly over the genetic enterprise, due in large part to the complexity of the issues raised by new genetic technologies. The

---

\* Student-at-law, Court of Appeal and Court of Queen's Bench of Alberta. The author would like to thank Professor Timothy Caulfield, Faculty of Law, University of Alberta, for his helpful comments on an earlier draft of this article.

commercialisation of this type of research has only added to this complexity.

What is the individual research subject to make of the complexities of these issues, and of the commercialisation of the genetic enterprise? While some may feel that the commercialisation of research is inevitable or inconsequential, others may well question the impact of commercialisation. A well informed potential subject may ask questions of a researcher involved in this area, but this does not describe the majority of subjects likely to be involved. There is increasing support for the idea that potential research subjects ought not to have to ask specific questions of researchers, but that this information ought to be disclosed as a matter of course. In fact, the new research guidelines put out by the agencies responsible for its oversight in Canada<sup>1</sup> seems to suggest that this type of funding and commercialisation information ought to be disclosed. The various bases for the obligation to disclose will be discussed below, as will the limitations of the various approaches. First, the discussion will turn to an analysis of the scope of the problem.

## II. THE COMMERCIALISATION OF GENETIC RESEARCH:<sup>2</sup> A NEED TO DISCLOSE OR A TEMPEST IN A TEAPOT?

ARGUABLY, IN THE BIOTECHNOLOGY FIELD, the days of the lone university-funded or government-funded scientist toiling sedulously away at a project intended solely for the betterment of science and society is fast becoming the exception and not the rule (if this "Golden Age" ever truly existed<sup>3</sup>). The scien-

---

<sup>1</sup> Tri-Council Policy Statement, *Ethical Conduct for Research Involving Humans*, 1998 [hereinafter Tri-Council Statement]. This statement was drafted by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

<sup>2</sup> Although many commentators distinguish between therapeutic and non-therapeutic research and/or research performed by a subject's doctor or by a researcher who is otherwise a stranger to the subject, all types of research will be addressed in this paper unless otherwise distinguished where applicable, such as in discussing causation in the tort analysis or in discussing fiduciary obligations. However, the blurring of the line between research and therapy does not lessen the duty to the subject-patient and may in fact strengthen it. The use of the term "gene therapy" encourages the blurring of this line, perhaps to the benefit of both the researcher hoping for subjects and the potential subject hoping for therapy. See L.R. Churchill *et al.*, "Genetic Research as Therapy: Implications of 'Gene Therapy' for Informed Consent" (1998) 26 *J. L. Med. & Ethics* 38 at 41.

<sup>3</sup> Gibbons suggests that the beginning of the commercialisation of science truly began in the 16th century: M. Gibbons, "The Changing Role of the Academic Research System" in M. Gibbons and B. Wittrock, eds., *Science as a Commodity—Threats to the Open Community of Scholars* (Harlow, Essex: Longman Group, 1985) 2 at 17. See also P. Werhane & J. Doering, "Conflicts of Interest and Conflicts of Commitment" in D. Elliott and J.E. Sterne, eds., *Research Ethics—A Reader* (Hanover: University Press of New England, 1997) 165 at 167;

tific empire itself increasingly involves the funding resources of commercial corporations. For instance, in a 1996 study of American life sciences research, Blumenthal *et al.* found these commercial partnerships to be increasing.<sup>4</sup> Over 70% of the firms surveyed had funded university research,<sup>5</sup> and more than 60% of those companies investing in academic research had realized patents, products, or sales therefrom.<sup>6</sup> In another recent survey of Canadian academic-industry relationships,<sup>7</sup> the amount of research funded by for-profit corporations rose from 2% in 1976 to 12% in 1996.<sup>8</sup> As well, the pharmaceutical industry's funding of research rose from 15% in the 1980s to over 30% in 1996, while 29% of health research was performed in a private setting, up from 9% in 1976.<sup>9</sup> By 1999, the pharmaceutical industry spent \$19 billion on research and development compared to Canada's Medical Research Council, now the Canadian Institutes of Health Research, which spent only \$19 million.<sup>10</sup> The genetic research enterprise is by no means untouched by this trend. Commentators point tellingly to the fact that "[n]early every major geneticist is associated with a biotechnology firm; some as directors, others as consultants. And scientists, hospitals, and universities are patenting genes."<sup>11</sup> Gene therapy sales are expected by some to reach \$3.5 billion by 2005.<sup>12</sup> The fear is also expressed that increased commercialisation has led to pressure on the Research Ethics Boards ("REBs") to ensure the overly speedy approval of research projects, presumably in order to maintain the cutting-edge nature—and hence the commercial potential—of

---

A.M. Hedgecoe, "Reconstructing Geneticization: a Research Manifesto" (1999) 7 Health L.J. 5.

<sup>4</sup> D. Blumenthal, *et al.*, "Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey" (1996) 334: 6 NEJM 368.

<sup>5</sup> *Ibid.* at 369.

<sup>6</sup> *Ibid.* at 369–70.

<sup>7</sup> A. Silversides, "Private Sector Becoming the Key to Research Funding in Canada" (1998) 159 CMAJ 397.

<sup>8</sup> *Ibid.* at 397.

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

<sup>10</sup> D. Hailey, "Scientific Harassment by Pharmaceutical Companies—Time to Stop" (2000) 162 CMAJ 212 at 212.

<sup>11</sup> D. Nelkin & L. Andrews, "Homo Economicus—Commercialization of Body Tissue in the Age of Biotechnology" (1998) Sep-Oct. Hastings Ctr. Report 30 at 31.

<sup>12</sup> E. Marden & D. Nelkin, "Displaced Agendas: Current Regulatory Strategies for Germline Gene Therapy" (2000) 45 McGill L.J. 461 at para. 16.

these projects.<sup>13</sup>

There are financial aspects of research that caused concern long before any furor arose regarding increased commercialisation. Some commentators fear that finder's fees given to doctors and residents may encourage the recruitment of unsuitable subjects.<sup>14</sup> Concerns have been raised about the gifts given to researchers which, some fear, are used in order to circumvent existing university policies about external funding.<sup>15</sup> These gifts may come with problematic restrictions: for example, one study found that 32% of researchers receiving bio-materials thought that this entailed the corporation's ownership of all ensuing patentable materials.<sup>16</sup> Others are concerned that the per-patient fees, that some doctors are paid for their research, will influence the decision-making of researchers. However, one study indicated that the views of doctors and patients regarding this issue appear to diverge: while 64% of doctors found it acceptable to be paid a per-patient fee, 56% of patients found this to be unacceptable.<sup>17</sup> Interestingly, the majority of both doctors and patients—67% and 69%, respectively—feel that some doctors might be influenced to enroll patients merely for the fee.<sup>18</sup>

Has the academic concern translated into a general concern for these issues among possible subjects of research? It seems likely that the general public remains blissfully unaware of the specifics of research commercialisation and its sources of funding. The practice thus far seems to be that disclosure of funding and commercialisation issues is not generally included in consent forms for ge-

---

<sup>13</sup> R. Dresser, "Time for New Rules on Human Subjects Research?" (1998) Nov-Dec. *Hastings Ctr. Report* 23 at 23; P.M. McNeill, *The Ethics and Politics of Human Experimentation* (NY: Cambridge University Press, 1993).

<sup>14</sup> E.A. Maher, in "An Analysis of Finder's Fees in Clinical Research" (1994) 150 *CMAJ* 252, persuasively argues in fact that finder's fees actually do not address the causes leading to low recruitment, and therefore cannot be defended based on need or on ethics.

<sup>15</sup> E.G. Campbell *et al.*, "Looking a Gift Horse in the Mouth—Corporate Gifts Supporting Life Sciences Research" (1998) 279 *JAMA* 995.

<sup>16</sup> *Ibid.* at 998. The authors do acknowledge, however, that they did not check the researcher's assumptions against those of the corporations, although this would hardly seem to matter if the researchers *do* hand over the expected ownership and/or otherwise abide by the assumed restrictions.

<sup>17</sup> J. LaPuma *et al.*, "Financial Ties as Part of Informed Consent for Postmarketing Research—Attitudes of American Doctors and Patients" (1995) 310 *BMJ* 1660. As well, doctors and patients differed in the amount that they considered appropriate for this purpose: patients chose a median of \$15 (range \$10–100), while doctors chose a median of \$100 (range \$10–2500). In reality, these fees may be thousands of dollars per patient: J.A. Goldner, "Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach" (2000) 28 *J.L. Med. & Ethics* 379 at 382.

<sup>18</sup> LaPuma, *Ibid.*

netic research.<sup>19</sup> Subjects of research may not be aware that their tissues may be used for purposes other than that of the original research—such as for the patenting of genetic material. Subjects may assume that if they were not made aware of this fact in the consent process, no further uses are planned, or possible, in the future.<sup>20</sup> When given the choice, patients as well as doctors favour the disclosure of per-patient fees for research, as well as disclosure of commercial interests, such as stock options, in proposed research.<sup>21</sup>

It certainly seems likely, therefore, that many potential research subjects would be interested in funding and commercial information surrounding the proposed research.<sup>22</sup> Not only does the concern about the application of genetic technology—for example, the patenting of genes, or eugenic concerns—already percolate around discussions of the social ramifications of genetic discoveries,<sup>23</sup> there is further concern that research may not be undertaken solely for the good of society. It may be felt that “[a] participant’s altruistic feelings might well change depending on the extent to which someone else stands to profit from the research.”<sup>24</sup> There exists the

... perception that the physician [being] well-intentioned is being altered by the entrepreneurial activities that lead to a conflict of interest between the economic interests of physicians and the best interests of the patients.<sup>25</sup>

This is at least as applicable in the case of research where there is no previous relationship between the researcher and the subject. As Nelkin and Andrews,

[m]edical research and clinical practice are ideally considered distinct from the motives of the market. We are leery of scientists who have profit motives in the outcomes

---

<sup>19</sup> T. Caulfield & C. Feasby, “The Commercialization of Human Genetics in Canada: An Overview of Policy and Legal Issues” in B.M. Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Cowansville, Que.: Les Editions Yvon Blais, 1998) at 375.

<sup>20</sup> E. Wright Clayton, et al., “Informed Consent for Genetic Research on Stored Tissue Samples” (1995) 274(22) *JAMA* 1786 at 1787.

<sup>21</sup> La Puma, *supra* note 17 at 1660.

<sup>22</sup> Although R.F. Weir, “Differing Perspectives on Consent, Choice and Control” in B.M. Knoppers, ed., *Human DNA: Law and Policy—International and Comparative Perspectives* (Boston: Kluwer Law International, 1996) 91 at 105, discusses one study to the contrary, given the information available elsewhere, especially in light of the particular concerns of genetic technologies, this seems an anomaly.

<sup>23</sup> Caulfield & Feasby, *supra* note 19 at 352 ff.

<sup>24</sup> H.T. Greely, “Genomics Research and Human Subjects” (1998) 282:23 *Science* 625.

<sup>25</sup> A. Goldworth, “Informed Consent in the Human Genome Enterprise” (1995) 4 *Cambridge Q. Healthcare Ethics* 296 at 302.

of their research...<sup>26</sup>

#### And further

... as biomedical research becomes more closely tied to commercial goals, the encroachment of the market is triggering a growing sense of disillusionment and mistrust. For the encroachment of commercial practices on the human body is increasingly challenging individual and cultural values, encouraging exploitation through the collection and use of tissue, and turning tissue (and potentially people) into marketable products.<sup>27</sup>

In an infamous case where researchers secretly exploited the tissues of a patient who described the experience as being "harvested,"<sup>28</sup> the Supreme Court of California determined that patients would find it material to know of researchers' commercial interests.<sup>29</sup> This echoes the findings of LaPuma.<sup>30</sup> Given the fears regarding the influence of commercial gifts, per-patient fees, and other commercial funding of research, and given the specific social and ethical ramifications of the commercial exploitation of genetic information, it seems clear that many potential subjects would be interested in the financial background of proposed research. Continued public confidence in genetic research may require it. While some feel that disclosing a conflict of interest may be a "bit like bolting the barn door after the horse has fled,"<sup>31</sup> at the very least it may allow a freer choice to the potential research subject.

### III. ETHICAL AND LEGAL BASES FOR REQUIRING DISCLOSURE

#### A. The Tri-Council Policy Statement

This latest Canadian research policy statement is in good company. It follows upon the tradition of the ethical regulation of research first proposed by the

---

<sup>26</sup> Nelkin & Andrews, *supra* note 11 at 36.

<sup>27</sup> *Ibid.* at 38.

<sup>28</sup> *Ibid.* at 32.

<sup>29</sup> *Moore v. Regents of the University of California*, 51 Cal.3d 120 (1990) [hereinafter *Moore*]. This case will be discussed further below in the analysis of fiduciary obligations.

<sup>30</sup> *Supra* note 17.

<sup>31</sup> T.R. Cech & J.S. Leonard, "Conflicts of Interest: Moving Beyond Disclosure" (2001) 291 *Science* 989 at 989. See also R. Horton, "Conflicts of Interest in Clinical Research: Opprobrium or Obsession?" (1997) 349 *The Lancet* 1112.

Nuremberg Code of 1948.<sup>32</sup> Making up a part of the judgment against Nazi doctors “experimenting” on hapless patients, this code has as its primary tenet that research ought only to be performed on subjects who are voluntarily consenting. Following in this vein, the World Medical Association’s original Declaration of Helsinki elaborated that, in order to consent, the potential subject must be informed of the “aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.”<sup>33</sup> This code has recently been updated<sup>34</sup> and Article 22 now reads:

In any research on human beings, 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.

The Tri-Council statement, in its earlier versions, and certainly in its latest incarnation, provides specific protections for the subjects of research. In fact, the statement adopts a subject-centred approach which will

...recognize that researchers and research subjects may not always see the harms and benefits of a research project in the same way. Indeed, individual subjects within the same study may respond very differently to the information provided in the free and informed consent process. Hence, researchers and REBs must strive to understand the views of the potential or actual research subjects.<sup>35</sup>

Therefore, it appears that the protection of the subject’s interest ought to be given greater weight than that of the interests of the researcher.

Article 2.4 states that researchers are to provide “full and frank disclosure of all information relevant to free and informed consent.” This is to include

(c) A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm; and

(e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of the researchers, their institutions or sponsors.

---

<sup>32</sup> Germany Military Tribunals, *Trials of War Criminals Before the Military Tribunals: The Medical Cases*, vols. I and II (Washington, D.C.: U.S. Government Printing Office, 1948). For a discussion of this code, see, e.g., McNeill, *supra* note 13 at 42.

<sup>33</sup> Basic Principle 9. First adopted by the 18<sup>th</sup> World Medical Assembly, Helsinki, Finland, June 1964.

<sup>34</sup> 52<sup>nd</sup> World Medical Association General Assembly, Edinburgh, October 2000.

<sup>35</sup> Tri-Council Statement, *supra* note 1 at 1.7.

Table 1 provides additional information that may be required for some projects, such as “[a]n indication as to who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of data.” It seems clear that anticipated commercial uses of research and research data will most likely need to be disclosed to potential subjects.

This protection is further strengthened in the context of genetic research. The statement warns that

[n]ew technologies to analyze genetic material are being developed at an unprecedented rate. Indeed, new discoveries may be quickly incorporated into health care practices without sufficient research into their effectiveness or means of delivery. Given the present inability to know the limits or effects of such research, or the context in which genetic information is interpreted and used, caution should be exercised. These rapid changes and the potential for financial gain from marketing the technologies drive the need to be sensitive to ethical issues in genetic research.<sup>36</sup>

Article 8.2 states that “[t]he researcher and the REB shall ensure that the results of genetic testing and genetic counseling records are protected from access by third parties, unless free and informed consent is given by the subject.” As well, Article 8.6 ensures that the ethical concerns of subjects and REBs regarding confidentiality must be addressed. While the ethical concerns are not strictly defined, methods for dealing with secondary uses are suggested: comprehensive consent forms allowing choice from a number of options,<sup>37</sup> use restricted to the condition in question, or permission for recontact of the subject in the future. Therefore, these and the general provisions regarding confidentiality seem to preclude secondary uses unknown to the subject. However, the anonymizing of data is mentioned as though this may resolve concerns about future uses. Even if this were so, Article 8.7 reiterates the need to disclose commercial uses:

At the outset of a research project, the researcher shall discuss with the REB and the research subject the possibility and / or probability that the genetic material and the information derived from its use may have potential commercial uses.

This is further explained:

The fact of commercial sponsorship of genetic research should be revealed to the subject at the beginning of the project. Similarly, possible commercialization occurring after involvement in research should also be revealed at the outset if possible.

It is unclear what is meant by the words “if possible.” It may mean any fu-

---

<sup>36</sup> *Ibid.* at 8.1

<sup>37</sup> This option is also suggested for research performed in the United States. The National Bioethics Commission suggests that consent forms include sufficient options for subjects to understand the nature of their consent: NBAC, *Research Involving Human Biological Materials*, online: NBAC <[www.bioethics.gov](http://www.bioethics.gov)> (date accessed: 02 September 2001).



ture use that is planned at the time of consent, or it may refer to commercial products technologically foreseeable but about which no particular plans have been made. A logical reading of the statement is that it is meant to prevent the foreseeable commercial exploitation of genetic material without consent, but that it does not refer to commercial applications not yet dreamt up. Arguably, even the unforeseen could be included in the informed consent process, much as provision is made for newly discovered medical information to be disclosed to those participants who request this. Consent forms could require the re-contacting of subjects or the refusal of unforeseen commercial uses. As well, the statement provides that it is “inappropriate to seek a blanket permission for ‘research in general,’”<sup>38</sup> although the statement appears to suggest that secondary uses are acceptable if data is anonymized, unless the REB especially requires informed consent. It seems likely that the special nature of genetic information recognised throughout the statement would point to informed consent always being necessary in genetic research. What is clear is that planned commercial applications—and perhaps commercial sponsorship and funding—need to be disclosed to potential subjects.

Potential subjects are further protected in that researchers are required, under Article 4.1, to “disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest.” This is necessary because “[r]esearchers hold trust relationships with research subjects, research sponsors, institutions, their professional bodies and society.”<sup>39</sup> Although the definition of the term “conflict of interest” is not always agreed upon,<sup>40</sup> it is most easily understood in this context as a conflict between the researcher’s role in protecting the subject and his/her own profit motives—or that of the industry sponsor. Some commentators mention that it is uncertain whether conflicts of interest are illegal or unethical *per se*, or whether it is the sacrifice of the vulnerable party’s interest that runs afoul of law and ethics.<sup>41</sup> Most likely, a conflict need not actually be proven. Mere perception of conflict is enough to raise the issue; it does not require proof of actual influence on the actions of the researcher any more than it requires a proof of benefit directly accrued to the researcher.<sup>42</sup> Therefore, the Tri-Council statement notes

---

<sup>38</sup> Tri-Council Statement, *supra* note 1 at 8.8.

<sup>39</sup> *Ibid.* at 4.1. This issue will be further addressed below with regard to fiduciary obligations.

<sup>40</sup> D.S. Shimm & R.G. Spece, “Introduction” in R.G. Spece *et al.*, eds., *Conflicts of Interest in Clinical Practice and Research* (New York: Oxford University Press, 1996) 1 at 6 indicate that there may be a distinction between a completed act influenced by other motives and a mere risk of influence.

<sup>41</sup> B.M. Dickens, “Conflicts of Interest in Canadian Health Care Law” (1995) 21 *Amer. J. L. & Med.* 259 at 262.

<sup>42</sup> *Cox v. College of Optometrists of Ontario* (1988), 65 O.R. (2d) 461 (Div. Ct.).

that “[t]he appearance of a conflict may in some cases be as damaging as a real conflict”<sup>43</sup> and calls for

[r]esearchers, their institutions and REBs [to] identify and address conflicts of interest—real or apparent—to maintain the public confidence and trust, discharge professional obligations and ensure accountability.”<sup>44</sup>

The statement only expressly calls for the disclosure of a “significant real or apparent conflict of interest.”<sup>45</sup> What is meant by “significant” is not clarified. Perhaps the word is meant to distinguish conflicts of interest from what some have termed conflicts of commitment: the competing time conflicts that many researchers have—for example, the obligations to subjects competing for time with obligations to students or research assistants.<sup>46</sup> Another reading of the word is that it is meant to exempt the disclosure of conflicts common to almost all research situations, such as the fact that the researcher is being paid a salary. The statement also goes on to indicate that the

REB management of conflicts of interest requires a proportionate approach. Sometimes, the conflict of interest is so pervasive that it is not enough merely to disclose it to the research subjects, the sponsors of research, institutions, relevant professional bodies or the public at large. In such instances, the REB may require that the researcher abandon one of the interests in conflict. A conscientious researcher will, under such circumstances, either withdraw from the research or allow others to make research-related decisions without being directed to do so. However, in some cases, the REB might conclude that the identified conflict of interest does not warrant specific actions.<sup>47</sup>

This statement does not entirely clarify matters. This explanation appears on the one hand to imply that all conflicts need to be disclosed as it is not enough in some instances “merely to disclose” it to subjects. On the other hand, some conflicts may “not warrant specific actions,” indicating that disclosure to subjects will not always be necessary. This reading would appear to be contrary both to the specific provisions regarding the disclosure of the commercialisation of genetic research, and to the subject-centred approach of the document as a whole. Certainly, it is hard to imagine why the conflict would need to be disclosed to the REB—this is ensured both by this section of the statement and by

---

<sup>43</sup> Tri-Council Statement, *supra* note 1 at 4.1.

<sup>44</sup> *Ibid.*

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

<sup>46</sup> Werhane & Doering, *supra* note 3.

<sup>47</sup> Tri-Council Statement, *supra* note 1 at 4.1–4.2.

Article 7.3<sup>48</sup>—and not to the subjects themselves. Given the concerns expressed by the Tri-Council about commercialisation and conflicts of interest, it would be antithetical to assume that conflicts disclosed to REBs need not be disclosed to potential subjects.

Theoretically, even a conservative reading of the Tri-Council statement offers great protection for the interests of subjects, and great possibilities for the disclosure of financial and commercial background information. However, this statement is only as effective as its scope and application allow. The statement does contain the possibility of waiving the consent process.<sup>49</sup> However, the examples given in this section indicate that this process is meant for situations where deception is necessary for the completion of the research, such as social science and psychological research. This would not apply in the case of genetic research, especially given the emphasis placed on informed consent in the sections regarding genetic research. It seems likely that no exception would be granted regarding the disclosure of commercialisation of genetic research or regarding arrangements leading to questions of conflicts of interest (such as commercial sponsorship).

The Tri-Council statement is said to apply to all human subject research conducted in an “institution” which requires ethics review. The statement includes as an appendix, a comprehensive list of research requiring ethical review adapted from the University of Alberta’s *General Faculty Council Policy Manual*. This statement indicates that all applicable research with a connection to the institution requires ethical review.<sup>50</sup> Therefore the Tri-Council statement ap-

---

<sup>48</sup> *Ibid.* at 7.4. This provision ensures that the budgets for clinical trials (including mechanisms of payment) are disclosed to REBs. This section also expresses concern about the conflict inherent in per capita, or per-patient payments.

<sup>49</sup> Article 2.1(c) the REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB 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.

<sup>50</sup> This includes research performed by faculty and students, funded or not, inside or outside of Canada, etc.: *ibid.* at A.1. Institutional research would also have to follow any applicable institutional rules: for instance, a particular university may have conflict of interest guidelines, or a method of dealing with corporate funding and gifts. However, where these guide-

plies to the majority of research done in Canada. Any research performed by a physician outside of an institutional setting must also go through an ethical review process overseen by the appropriate Medical Association.<sup>51</sup> While the guidelines used in this review process are not as detailed nor as stringent as the Tri-Council statement, it is possible that the statement may have persuasive force over medical review boards. It is nonsensical for research performed in a private setting to have fewer controls than that performed in a regulated institutional setting. Nevertheless, if the Tri-Council statement is not adopted by non-institutional ethics boards, the possibility exists for differing standards and for lower levels of protection for potential research subjects.

Another possible concern regarding the effectiveness of this regulatory statement lies with the REBs themselves. The possibility exists that the REBs will not give this regulatory framework its due importance. It is left up to the REBs to oversee the implementation of the consent process that will ensure the disclosure of commercial and financial matters to potential research subjects.<sup>52</sup> If this supervision is not seriously undertaken, there is nothing to prevent a researcher from ignoring the duties proposed in the Tri-Council statement. While it is possible to obtain a judgment against an ethics board,<sup>53</sup> this after-the-fact judgment may not truly achieve the desired goal—*i.e.*, the protection of human subjects. As the statement points out, REBs themselves are not immune to conflicts of interest.<sup>54</sup> The pressures of commercialisation and industry-friendly policies within institutions conducting ethical reviews have only added to this concern.<sup>55</sup> It is therefore possible that, even with the clear duties of disclosure

---

lines may conflict with other regulation, this situation may be confusing for researchers: see, for instance, L.A. Bero, "Disclosure Policies for Gifts from Industry to Academic Faculty" (1998) 279(13) JAMA 1031 at 1032.

<sup>51</sup> For instance, the Alberta Medical Association uses European guidelines: The European Agency for the Evaluation of Medical Products—Human Medicines Evaluation Unit, *Note for Guidance on Good Clinical Practice, Consolidated Guidelines* (London: ICH, 1996). These guidelines do not require the disclosure of commercial interests, nor do they address secondary uses of research materials.

<sup>52</sup> While the REB can review the consent forms and the content of information to be given to subjects, this is done away from the actual conversations that take place between researchers and subjects. Financial data can easily be buried in technical or scientific terminology: Goldner, *supra* note 17 at 394. The importance and spirit of informed consent must therefore be stressed, rather than "routinized": Churchill *et al.*, *supra* note 2 at 42.

<sup>53</sup> *Weiss v. Solomon* (1989), 48 C.C.L.T. 280 (Que. C.S.) [hereinafter *Weiss*].

<sup>54</sup> *Supra* note 1 at 4.1–4.2.

<sup>55</sup> Caulfield & Feasby, *supra* note 19 at 382. McNeill has suggested that one possible solution is the inclusion of subject representatives on ethics boards: *supra* note 13 at 9. Globalization and "forum shopping" have also become concerns: see, *e.g.*, T. Caulfield, "Globalization,

laid out by the Tri-Council, there may be a need for further obligations leading to disclosure.

## **B. Informed Consent and a Remedy in Tort**

The world of medicine has undergone a shift in ideals from a system encouraging paternalistic care for the welfare of the patient, to an increased appreciation of the patient's autonomous being, embodying a transition from blind trust in physicians to mutual trust between the physician and the patient.<sup>56</sup> The law is less apt to trust in the integrity of the physician in order to determine the best interests of the patient, and more apt to look to the patient him/herself to make autonomous decisions about his/her body.<sup>57</sup> There is a "moral commitment to autonomy and respect for persons [which] finds a legal parallel in the commitment to self-determination."<sup>58</sup> This embrace of autonomy, of liberty over the "caring custody" of physicians, is not surprising in the Anglo-American legal tradition which is often seen to prefer liberty over control.<sup>59</sup> The idea of autonomy is often traced to Kant's notion that people must not be seen as means to an end, but rather as ends in and of themselves, and hence must be able to make their own choices.<sup>60</sup> The greater the personal consequences, the greater the attention paid to autonomy. Therefore, the effects on bodily integrity involved in medical decision-making are ideally suited to this autonomy analysis.<sup>61</sup> This is especially true in the research context, where competent subjects are viewed as being the only parties capable of assenting to research which may only benefit others and not the subjects themselves. Those who bear the risks of research ought to decide if they are willing to participate.<sup>62</sup>

Autonomy is "fundamental to the common law" and is the basis for disclo-

---

Conflicts of Interest and Clinical Research: An Overview of Trends and Issues" (2001) *Widener Law Symposium Journal* (forthcoming).

<sup>56</sup> J. Katz, *The Silent World of Doctor and Patient* (New York: The Free Press, 1984) at xvi.

<sup>57</sup> T. Smith, *Ethics in Medical Research—A Handbook of Good Clinical Practice* (Cambridge: Cambridge University Press, 1999) at 1.

<sup>58</sup> B.C. White & J. Zimelman, "Abandoning Informed Consent: An Idea Whose Time Has Not Yet Come" (1998) 23 *J. Med. & Philos.* 477 at 479.

<sup>59</sup> *Ibid.* at 2.

<sup>60</sup> Goldworth, *supra* note 25; McNeill, *supra* note 13 at 140 ff.

<sup>61</sup> M.M. Shultz, "From Informed Consent to Patient Choice: A New Protected Interest" (1985) 95 *Yale L.J.* 219 at 220.

<sup>62</sup> G.J. Annas, et al., *Informed Consent to Human Experimentation: The Subject's Dilemma* (Cambridge, Mass.: Ballinger Publishing, 1977) at 35.

sure of information in the informed consent process.<sup>63</sup> Meaningful consent to medical treatment or to research is not possible without sufficient information on which to base a decision.<sup>64</sup> The information must be sufficient to allow autonomous decision-making. Informed consent does not have as its purpose the automatic obtaining of consent as its name may imply,<sup>65</sup> but rather of an informed decision—in the negative or in the affirmative. Informed consent is not a “moment in time,”<sup>66</sup> it “is not simply a routine legal requirement or a lifeless piece of paper, but rather a vital process of communication between doctor and patient.”<sup>67</sup> The patient is not merely the passive recipient of information, but an active participant in the communication process.<sup>68</sup> The consent form is merely evidence of the negotiations.<sup>69</sup> Some commentators have therefore theorized that the process ought to be termed “informed choice” in order to reflect the ideal of the patient as locus for autonomous decision-making.<sup>70</sup>

In Canada, the preeminent cases in the area of informed consent that laid

---

<sup>63</sup> *Ciarlariello v. Schacter*, [1993] 2 S.C.R. 119 at 135 [hereinafter *Ciarlariello*].

<sup>64</sup> J.F. Merz, “On a Decision-Making Paradigm of Medical Informed Consent” (1993) 14 *J. Legal Med.* 231 at 240, claims that “[t]he law rests upon two somewhat inconsistent assumptions: that patients have the intellectual tools needed to make medical decisions that will promote their interests, but that they do not have the wherewithal to protect those interests by asking questions and seeking alternative opinions.” This is a specious argument. Patients cannot be expected to guess what information physicians possess. They must make decisions based upon the medical information that the doctor would base a decision upon, assessed in light of their autonomous decision-making. Another problem with Merz’s clever comment is that in practice, patients tend not to ask questions of their physicians: E.I. Picard & G.B. Robertson, *Legal Liability of Doctors and Hospitals in Canada* (Toronto: Carswell, 1996) at 140.

<sup>65</sup> N. Fontigny, “When Yes Really Means Yes: The Law of Informed Consent in Canada Revisited” (1996) 4(3) *Health L. Rev.* 17 at para. 14; B.M. Dickens, “Informed Consent” in J. Downie & T. Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) 117 at 118. For this reason, the Tri-Council Statement has adopted the term “free and informed consent” in order to emphasize the choice of the potential subject: Tri-Council Statement, *supra* note 1 at 1.10.

<sup>66</sup> *Ciarlariello*, *supra* note 63 at 620.

<sup>67</sup> Picard & Robertson, *supra* note 64 at 111.

<sup>68</sup> *Ibid.*

<sup>69</sup> R.J. Levine, *Ethics and Regulation of Clinical Research*, (Baltimore: Urban & Schwarzenberg, 1986) at 135.

<sup>70</sup> For example, R.C. Fraser & K.M. Avery, “What You Don’t Know Can Hurt You” (1994) 3(1) *Health L. Rev.* 3 at 4; Fontigny, *supra* note 65. Shultz, *supra* note 61 at 278 opines that there ought to be a separate protection of medical choice which might resemble tortious action for appropriation of name and image.

out the parameters of the doctrine are *Hopp v. Lepp*<sup>71</sup> and *Reibl v. Hughes*.<sup>72</sup> In *Hopp*, the Supreme Court of Canada reiterated the value of autonomy underlying the doctrine of informed consent: “[t]he underlying principle is the right of the patient to decide what, if anything, should be done with his body.”<sup>73</sup> Laskin C.J.C. (as he then was) stated that the scope of disclosure should be determined in light of the circumstances of each particular case but that

... in obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation.<sup>74</sup>

The Chief Justice quoted approvingly the statement in *Canterbury v. Spence*<sup>75</sup> that

... [a] risk is material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy.<sup>76</sup>

The Supreme Court of Canada further clarified the doctrine in *Reibl*. This decision stated that lack of disclosure will not ordinarily result in a cause of action in battery; rather if there was consent to the procedure itself but the disclosure was not fully informed, this action ought to be framed in negligence. The court again confirmed that “material risks” need to be disclosed and further states that the determination of what is material ought not to be put solely into the hands of the medical profession (an objective standard) because this would, in essence, allow doctors to determine the standard of care owed to the patient and what would entail its breach. However, a fear was expressed that allowing the patient-plaintiff to determine what the standard of disclosure ought to be (a subjective standard) would be a worse scenario:

The objective standard of what a reasonable person in the patient’s position would do would seem to put a premium on the surgeon’s assessment of the relative need for the surgery and on supporting medical evidence of that need.<sup>77</sup>

...

---

<sup>71</sup> (1980), 112 D.L.R. (3d) 67 (S.C.C.) [hereinafter *Hopp*].

<sup>72</sup> (1980), 114 D.L.R. (3d) 1 (S.C.C.) [hereinafter *Reibl*].

<sup>73</sup> *Hopp*, *supra* note 71 at 70.

<sup>74</sup> *Ibid.* at 81.

<sup>75</sup> 464 F. 2d 772 (D.C. Cir. 1972).

<sup>76</sup> *Hopp*, *supra* note 71 at 640.

<sup>77</sup> *Reibl*, *supra* note 72 at 15.

[But] to apply the subjective test to causation would, correlatively, put a premium on hindsight, even more of a premium than would be put on medical evidence in assessing causation by an objective standard.<sup>78</sup>

Therefore, the standard was said to be that of the “reasonable prudent person” in the patient’s position and circumstances.<sup>79</sup> However, the judgment clearly stated that the patient’s concerns must be reasonably based. They can be based on economic concerns—as they were in *Reibl*—but the plaintiff’s particular circumstances and concerns must be reasonably apparent or accessible to the physician.

This “modified objective test,” as it has been termed,<sup>80</sup> was confirmed by the majority of the Supreme Court of Canada in *Arndt v. Smith*.<sup>81</sup> Cory J. agreed that the subjective test is not reliable, further adding that the consent process may be “coloured by trauma” when recollected by the plaintiff.<sup>82</sup> An objective test of the concerns of the reasonable person would include his or her reasonable “beliefs, fears, desires and expectations.”<sup>83</sup> These would ordinarily be revealed by the type of questions asked by the plaintiff.<sup>84</sup> However, this would not include idiosyncratic concerns that do not relate directly to the risks of the procedure.<sup>85</sup> As illustration, Cory J. gave the example of a patient afraid that a rash indicated a supernatural cause.<sup>86</sup>

Academic discussion has pointed to the inconsistencies both in the approach of the modified objective test in general, and in the *Arndt* decision in particular. The Supreme Court of Canada in *Reibl* and in *Arndt* acknowledged that it would be unfair to ignore the particular circumstances of the patient entirely. However the Court did not readily define which circumstances would be

---

<sup>78</sup> *Ibid.* at 16.

<sup>79</sup> *Ibid.*

<sup>80</sup> T. Caulfield & E. Nelson, “You Can’t Get There From Here: A Case Comment on *Arndt v. Smith*” (1998) 32 U.B.C.L. Rev. 353 at para. 7.

<sup>81</sup> (1997), 148 D.L.R. (4<sup>th</sup>) 48 (S.C.C.) [hereinafter *Arndt*]. Sopinka and Iacobucci JJ., and McLachlin J. (as she then was) all felt that the test ought to be some form of subjective analysis. McLachlin J. at 71 even went so far as to suggest that this would be in keeping with the previous decision in *Reibl*.

<sup>82</sup> *Ibid.* at 53.

<sup>83</sup> *Ibid.* at 54.

<sup>84</sup> However, this certainly was not the result in *Videto v. Kennedy* (1981), 125 D.L.R. (3d) 127 (Ont. C.A.) [hereinafter *Videto*] where the fact that the plaintiff asked about scarring was not found to be sufficient to indicate a particular concern.

<sup>85</sup> *Supra* note 81 at 55.

<sup>86</sup> *Ibid.* at 56.



appropriately considered under the test, an omission which has garnered complaint.<sup>87</sup> This has led to the fear that, with the modified objective test, courts are left merely to insert their own subjective assessment of what is reasonable in the patient's position, rather than allowing the patient's subjective interests to prevail. While commentators may feel that this is an improvement over a purely objective test,<sup>88</sup> others point to the diversity of factors that courts are left to include or to exclude from the analysis,<sup>89</sup> pointing to the fact that the test really turns on the question of how much subjectivity is needed in the modified objective test. Although this question is not new to tort law,<sup>90</sup> it does add an element of confusion and unpredictability to the realm of informed consent.

The question may be seen to turn on the reasonableness of the patient's concern about the proposed procedure. The majority in *Arndt* felt that idiosyncratic fears which do not relate directly to risks—and which are often unknown to the physician—ought not to trigger a duty of disclosure.<sup>91</sup> This is echoed in *Videto*, where the physician was not held responsible because he was unaware of this patient's personal—and, it is implied, unreasonable—concern.<sup>92</sup> Rather than to focus on the doctor's knowledge, it may be more realistic to assume that all decision-making is highly subjective,<sup>93</sup> and to assume that doctors will inevitably be unable to completely assess the decision-making process of each patient. It is not sufficient to focus only on "reasonable" concerns, for this

... illustrates that the modified objective test is itself arbitrary and subjective. Either the test is dictating what the particular patient (and society as a whole) should consider to be reasonable fears and concerns (an incredibly paternalistic stance), or it is simply a subjective analysis that filters out unwanted evidence. The former explanation is an enormous step backward from the apparent affirmation of autonomy in *Reibl*, and the latter is arbitrary, unpredictable, and potentially unjust.<sup>94</sup>

Not only is the acceptance of solely reasonable concerns contrary to the

---

<sup>87</sup> Caulfield & Nelson, *supra* note 80; M. Gochnauer & D.J. Fleming, "Tort Law—Informed Consent—New Directions for Medical Disclosure" (1981) 15 U.B.C.L. Rev. 475.

<sup>88</sup> Merz, *supra* note 64 at 264; Gochnauer & Fleming, *ibid.*

<sup>89</sup> Caulfield & Nelson, *supra* note 80 at para. 9.

<sup>90</sup> For example, the question arises in assessing whether children are responsible for their tortious actions.

<sup>91</sup> *Arndt*, *supra* note 81 at 55. Interestingly, the plaintiff's desire for children and her suspicion of mainstream medicine were apparently taken into account, while the controversies of abortion were not.

<sup>92</sup> *Videto*, *supra* note 84.

<sup>93</sup> Merz, *supra* note 64 at 264.

<sup>94</sup> Caulfield & Nelson, *supra* note 80 at para. 13.

very spirit of autonomous decision making—which includes the right to make “good” as well as “bad” decisions<sup>95</sup>—it belies the reality of many modern medical situations. There are many instances in which there is no one decision that is any more “reasonable” than another. Nowhere is this more evident than in the *Arndt* case, involving the ever-contentious abortion issue.<sup>96</sup> While the modified objective test is not meant to consider the character, temperament, or philosophy of a particular patient,<sup>97</sup> these are often the only distinctions available where there is no one rational medical decision. Certainly, if health were the only value or the most important value in question, this could be objectively determined by a doctor, and the doctrine of informed consent would not be necessary.<sup>98</sup> Nevertheless, the doctrine of informed consent is underpinned by the notion that it is up to the patient to weigh the values at stake. A decision based wholly or in part upon personal values cannot be “reasonable” or “unreasonable” because values themselves are not inherently based on reason.<sup>99</sup>

Arguably, this is also the case with the decision regarding consent to participate in research. Not only does the ordinary doctrine of informed consent apply in the research paradigm, the standard of disclosure is at least as high, if not higher. Thus,

... [t]he subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.<sup>100</sup>

The situation in research may parallel, in part, that of elective procedures in which there is a greater standard of disclosure.<sup>101</sup> Because the procedure is not

<sup>95</sup> *Ibid.* at para. 15.

<sup>96</sup> This has led to criticism that the Supreme Court of Canada missed the opportunity to address this issue even though it was addressed by Lambert J.A. in the British Columbia Court of Appeal in that case: *ibid* at para. 10; Gochnauer & Fleming, *supra* note 87 at 495.

<sup>97</sup> Dickens, *supra* note 65 at 125.

<sup>98</sup> F. McClellan, “Informed Consent to Medical Therapy and Experimentation—The Case for Invoking Punitive Damages to Deter Impingement of Individual Autonomy” (1982) 3 J. Legal Med. 81 at 98.

<sup>99</sup> Gochnauer & Fleming, *supra* note 87 at 491.

<sup>100</sup> This was first discussed in one of the few cases litigated about research: *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) at 444 [hereinafter *Halushka*]. This is echoed by K. Cranley Glass, “Research Involving Humans” in J. Downie and T. Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) at 386; G. Sharpe & D.N. Weisstrub, “The Ethics of Deception in Biomedical Research” (1996) 16(4) Health L. in Can. 101 at 103; L. Doyal, “Informed Consent in Medical Research” (1997) 314 BMJ 1107 at 1108.

<sup>101</sup> Elective procedures are also given a generous and wide definition: Picard & Robertson, *supra* note 64 at 126–7.

based on any emergency or on any medical need, courts are more apt to believe that a plaintiff would not have consented to the procedure. Shultz points to a category of cases involving what she terms "heightened electiveness" in which courts are more apt to value patient choice.<sup>102</sup> These cases do not involve the treatment of a disease *per se*, but rather involve patients seeking an affirmative outcome, often relying on highly personal decisions. Whether courts are less apt to view concerns in these cases as "unreasonable" or whether the plaintiff's assertions are generally viewed in a more generous light, elective procedures may lend themselves more easily to the full protection of autonomous decision-making.

The characterisation of elective procedures seems in many ways to echo the instance of non-therapeutic research: there is no disease to treat, only a choice as to whether or not to participate in order to benefit society, science, and others. This can only be described as a personal decision. In the case of therapeutic research, a personal decision would entail whether or not to benefit both oneself and others, therefore, the decision may be more apt to be protected.<sup>103</sup>

This is equally true of opinions regarding the commercialisation and funding of research. While many patients might not be troubled by the commercial sponsorship of research, by the patenting of genetic material, or by the per-patient fees paid to researchers, there may be a sizable minority of patients who would be troubled by these very things.<sup>104</sup> Is it unreasonable to fear these consequences merely because a strict majority of patients do not? Is it unreasonable to fear the unknown consequences of the influence of commercial pressures on the protection of research and its subjects? Surely not, given the concern expressed by academics, regulators, and others discussing conflicts of interest and the commercialisation of research.

Although "unreasonableness" is the approach chosen by the courts, this does not seem to be the correct approach in determining the content of the duty to disclose in research. In order to truly respect autonomous decision-

---

<sup>102</sup> This category includes elective procedures, as well as procreation cases such as pregnancy, and in vitro fertilisation: Shultz, *supra* note 61 at 264.

<sup>103</sup> Perhaps the causation test in research negligence ought to be subjective, as is the case for medical product manufacturers: *Hollis v. Dow Corning Corp.* (1995), 129 D.L.R. (4<sup>th</sup>) 609 (S.C.C.). If the research sponsor stands to make a profit, there is no reason why all information about this ought not to be disclosed. While the learned intermediary rule may limit the utility of this argument, it may be possible to bring a suit against the sponsor of the research if all commercial plans were not told to the researcher in order that it be possible to inform potential subjects.

<sup>104</sup> Rodwin fears that disclosure may be made in such a way as to minimize the appearance of conflict, which would in fact protect the maker and not the recipient of the disclosure: M.A. Rodwin, "Physicians' Conflicts of Interest—The Limitations of Disclosure" (1989) 321(20) NEJM 1405 at 1406.

making, and in order to give purposive effect to the doctrine of informed consent, a more logical approach is to ask a single question: would this information cause a potential subject to change their decision regarding consent?<sup>105</sup> In its simplest and purest formulation, information regarding consent to research is material to that decision if it would cause some potential subjects to refuse to consent. There are those—including the Tri-Council responsible for the regulation of research—who have grave concerns over the existence of conflicts of interest, over the commercialisation of research and of its results, and over the mechanisms of funding themselves. Therefore, this information ought to be disclosed to potential subjects. Increasingly, this is the conclusion of commentators.<sup>106</sup> It ought to be the reality for possible research subjects as well.

No doubt there are those who feel that this is an excessive burden to place on researchers. However, mere inconvenience or tediousness is no reason to avoid adequate disclosure.<sup>107</sup> It is a valid concern that physicians cannot be expected to read patients' minds or to know every aspect of their patients' psyches. It is not a sufficient excuse with regard to the financial and commercial aspects of research, however, given the attention this issue has received from regulators, institutions,<sup>108</sup> commentators, and the public.<sup>109</sup> Researchers cannot claim ignorance of the controversies engendered in these areas. While it is not possible to quiet all fears about the future scope of the informing of potential subjects, in the case of financial and commercial aspects of genetic research, the duty seems clear. If these disclosures cause a depletion of the numbers of subjects volunteering for this type of research, this is merely the price that we all

---

<sup>105</sup> Gochnauer & Fleming propose the following question as a means of simplifying causation issues: Would a reasonable person have consented if the information was disclosed? *Supra* note 87 at 497.

<sup>106</sup> Smith, *supra* note 57 at 257–8 states that uses of findings and commercial connections ought to be disclosed; P.R. Reilly *et al.*, "Ethical Issues in Genetic Research: Disclosure and Informed Consent" (1997) 15 *Nature Genetics* 16 at 18 state that commercial partners, uses, and products ought to be disclosed; D.S. Shimm, *et al.*, "Conflicts of Interests in Relationships Between Physicians and the Pharmaceutical Industry" in R.G. Spece, *et al.*, eds., *Conflicts of Interest in Clinical Practice and Research* (New York: Oxford University Press, 1996) 321 at 325 state that sources of funding, mechanisms of funding, stockholding, and that some see these things as conflicts ought to be disclosed; Greely, *supra* note 24 at 625 states that uses, commercial aspects, and intellectual property interests ought to be disclosed; B.M. Knoppers & C. Laberge, "Research and Shared Tissues - Persons and Sources, Samples as Persons?" (1995) 274(22) *JAMA* 1806 at 1806 state that possible future uses and commercial aspects ought to be disclosed.

<sup>107</sup> Clayton *et al.*, *supra* note 20 at 1789.

<sup>108</sup> For example, university conflict of interest guidelines.

<sup>109</sup> For example, fears about commercialisation and patenting of genes, Caulfield & Feasby, *supra* note 19 at 352 ff.

must pay for the protection of autonomy.<sup>110</sup>

Unfortunately, even if a clear duty to disclose this information were established, this would not automatically ensure liability.<sup>111</sup> Although Laskin C.J.C. appeared to indicate in *Hopp* that the fact not disclosed need not be the cause of the injury in question,<sup>112</sup> this may then lead to a question of remoteness, whereby researchers may not be found responsible for completely unforeseeable injuries.<sup>113</sup> In fact, most medical negligence suits are not successful,<sup>114</sup> and a finding that undisclosed information is not material is a finding of fact, which would make an appeal even more difficult.<sup>115</sup> A further difficulty is the question of injury: unless there is a negative medical consequence to the participation in research, even a finding of negligence might not result in damages. While some commentators have called for recognition of “dignitary injuries,”<sup>116</sup> this result is not likely unless a researcher’s actions were egregious—where there may be punitive damages—or unless there were definable psychological harm. The traditional approach of grounding negligence in the control of touching certainly does not work as it ought to in order to provide true protection for patient and subject autonomy. Further protection is needed to compensate and deter encroachments on autonomous decision-making.

### C. Fiduciary Obligations

Another<sup>117</sup> possible basis for the duty to disclose lies in the realm of fiduciary

---

<sup>110</sup> Doyal, *supra* note 100 at 1109.

<sup>111</sup> An additional factor in this analysis is the fact that any duty of disclosure indicated by the Tri-Council statement, and other regulatory mechanisms may help define the standard of care in a negligence suit: Glass, *supra* note 100 at 380–1; Weiss, *supra* note 53 (quoting the Helsinki Declaration). Therefore this so-called regulatory or “soft law” may have great persuasive effect in legal cases: see A. Campbell & K.C. Glass, “The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research” (2001) 46 McGill L.J. 473.

<sup>112</sup> If the lack of disclosure influences consent: *Hopp*, *supra* note 71 at 78 (approving of similar finding in *Halushka*, *supra* note 100).

<sup>113</sup> Picard & Robertson, *supra* note 64 at 161.

<sup>114</sup> *Ibid.* at 162.

<sup>115</sup> *Ibid.* at 129.

<sup>116</sup> For example, Sharpe & Weisstrub, *supra* note 100 at 102; Shultz, *supra* note 61 at 276.

<sup>117</sup> Other bases have been proposed, such as professional disciplinary actions, an obligation in contract, or a separate action for breach of medical choice. Current approaches to the regulation of genetic research may also be divided into a human rights approach, a statutory approach, an administrative approach, and a market-driven approach: B.M. Knoppers, M. Hirtle & K.C. Glass, “Commercialization of Genetic Research and Public Policy” (1999) 286 Science 2277. For the sake of brevity, these will not be discussed further.

law. Although this has been described as an “elusive concept,”<sup>118</sup> or even as a “catch-all” phrase,<sup>119</sup> and although many theoretical explanations have been expounded for its existence,<sup>120</sup> basic features of the doctrine can still be established.<sup>121</sup> First, it is an equitable doctrine that has as its goal the protection of socially valuable relationships.<sup>122</sup> Second, it is a relationship of trust and confidence.<sup>123</sup> The fiduciary is expected to act with the utmost good faith and loyalty.<sup>124</sup> This means that she or he must do what is in the best interest of the beneficiary, even if this is contrary to her or his own interests, or those of interested third parties.<sup>125</sup> Third, the relationship is often thought to involve an imbalance of power, and hence the beneficiary is owed the protection of the highest ethical duties.<sup>126</sup> People are thought to be more likely to submit to this necessary and valuable type of relationship if these protections are offered to them.<sup>127</sup>

The doctor-patient relationship has been characterized as being fiduciary in nature.<sup>128</sup> However, this does not end the analysis, even for physician-

---

<sup>118</sup> L.I. Rotman, “Fiduciary Doctrine: A Concept in Need of Understanding” (1996) 34 *Alta. L. Rev.* 821 at 822.

<sup>119</sup> The fact that this problem has attracted judicial notice may indicate a serious problem with the concept: *ibid.* at 823–4.

<sup>120</sup> Rotman identifies 7 theories: property, reliance, inequality, contract, unjust enrichment, utility, power and discretion: *ibid.* at 839 ff.

<sup>121</sup> In short, the indicia of a fiduciary relationship are (1) discretion or power on the part of the fiduciary, (2) the fiduciary can unilaterally exercise this power to affect the position of the beneficiary, and (3) the beneficiary is vulnerable: per Wilson J. in *Frame v. Smith* (1987), 42 D.L.R. (4<sup>th</sup>) 81 at 136 (S.C.C.) [hereinafter *Frame*].

<sup>122</sup> Rotman, *supra* note 118 at 826

<sup>123</sup> *Kenny v. Lockwood* (1932), 1 D.L.R. 507 (Ont. C.A.).

<sup>124</sup> Picard & Robertson, *supra* note 64 at 4.

<sup>125</sup> Caulfield & Feasby, *supra* note 19 at 376; C.B. Perry, “Conflicts of Interest and the Physician’s Duty to Inform” (1994) 96 *Amer. J. Med.* 375 at 375.

<sup>126</sup> This, in contrast with the equal footing of parties in the contract setting: B.M. Dickens, “Medical Records—Patient’s Right to Receive Copies—Physician’s Fiduciary Duty of Disclosure: *McInerney v. MacDonald*” (1994) 73 *Can. Bar Rev.* 234 at 234. See also Shultz, *supra* note 61 at 261. However, the imbalance within the relationship need not exist outside that relationship or prior to the formation of the relationship: L.I. Rotman, “Balancing the ‘Scales of Justice’: Fiduciary Obligations and *Stewart v. CBC*” (1999) 78 *Can. Bar Rev.* 445 at 457.

<sup>127</sup> Rotman, *supra* note 118 at 827.

<sup>128</sup> *Henderson v. Johnston* (1956), 5 D.L.R. (2d) 524, *aff’d* (1957), 11 D.L.R. (2d) 19 (Ont. C.A.), *aff’d* (1959), 19 D.L.R. (2d) 201 (S.C.C.) [hereinafter *Henderson*]; *McInerney v.*

researchers. The determination of a fiduciary relationship is situation-specific, depending upon the nature and circumstances of the relationship.<sup>129</sup> This analysis remains necessary even if a court has characterized a relationship as having a fiduciary character: it would be contrary to the inherent equitable purpose of the doctrine to create a list of those relationships automatically garnering these ethical duties. Consequently, a relationship may be characterized as fiduciary in one instance or for one purpose, and not for another.<sup>130</sup> These duties can even be found to continue after the completion of the formal relationship<sup>131</sup> and need not breach professional rules or norms of conduct in order to constitute a breach of equitable principles such as a fiduciary duty.<sup>132</sup>

The fiduciary relationship also creates the obligation to make complete disclosure of relevant information.<sup>133</sup> This duty is based on the need to be honest<sup>134</sup> and therefore there is no room for the withholding of material facts.<sup>135</sup> Can this form the basis for a disclosure of the financial and commercial aspects of research? If the researcher were also the subject's physician, the fiduciary analysis would seem to be an easy fit. Certainly, "[t]he fact that the patient's trust in his physician is a crucial factor in the patient's willingness to participate in the clinical study cannot be refuted."<sup>136</sup> Just as the physician in practice—assuming the other indicia of a fiduciary relationship are present—would have the obligation to disclose material facts and to ensure that there was no conflict in his or her duties to the patient, so too would the physician-researcher share those duties. This direct comparison would only hold true if the physician-researcher were found to be continuing to act in a role analogous to that of the physician.

There was a finding that a case for breach of fiduciary duty could be made out against the physician-researcher in *Moore v. The Regents of the University of*

*MacDonald* (1992), 93 D.L.R. (4<sup>th</sup>) 415 (S.C.C.) [hereinafter *McInerney*]; *Norberg v. Wynrib* (1992), 92 D.L.R. (4<sup>th</sup>) 449 (S.C.C.) [hereinafter *Norberg*]. See also *Rowe v. Grand Trunk Railway Co.* (1866), U.C.C.P. 500 at 506.

<sup>129</sup> Rotman, *supra* note 118 at 829.

<sup>130</sup> *McInerney*, *supra* note 128 at 423.

<sup>131</sup> See for instance *Stewart v. Canadian Broadcasting Corporation* (1997), 150 D.L.R. (4<sup>th</sup>) 24 (Ont. Gen. Div.) [hereinafter *Stewart*]. For commentary on this case, see Rotman, *supra* note 126. The fiduciary relationship has been found to outlast the formal doctor-patient relationship: *Vasdani v. Sehmi*, [1993] O.J. No. 44 (Gen. Div.), online: QL.

<sup>132</sup> Rotman, *ibid.* at 463.

<sup>133</sup> There is also a duty to disclose any conflict of interest: *Henderson*, *supra* note 128.

<sup>134</sup> *Hopp*, *supra* note 71 at 75.

<sup>135</sup> *Glass*, *supra* note 100 at 377.

<sup>136</sup> *Goldner*, *supra* note 17 at 392.

*California*.<sup>137</sup> In that case, Moore's physician developed an immortalized cell line from Moore's tissue, without his knowledge or consent. Before removing Moore's spleen, arrangements were made by his physician (Golde) and by a researcher employed by the Regents of the University of California (Quan) that research was to be performed upon splenic tissue. This research had no relation to Moore's medical care and he was not informed of the plans to profit from his biological materials. Moore continued to travel to the UCLA Medical Center from his home in Seattle at Golde's behest in order that further samples be taken. Eventually, a patent was issued on the cell line developed from Moore's tissue, naming Golde and Quan as inventors and the Regents as assignee. Further contracts were negotiated with the Genetics Institute and Sandoz for the commercial development of the cell line. The Court, in looking at Dr. Golde's fiduciary duties, concluded that

(1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.<sup>138</sup>

The court determined that "the law already recognizes that a reasonable patient would want to know whether a physician has an economic interest that might affect the physician's professional judgment."<sup>139</sup> This economic interest not only must be disclosed to effect true informed consent, it may lead to a conflict of interest which must be disclosed.

In addressing similar claims against the other defendants, the majority's decision quickly precluded these claims:

The Regents, Quan, Genetics Institute, and Sandoz are not physicians. In contrast to Golde, none of these defendants stood in a fiduciary relationship with Moore or had the duty to obtain Moore's informed consent to medical procedures.<sup>140</sup>

Given the brevity of this statement, and given the majority's failure to provide reasons for this finding, this statement does not appear to offer a principled answer to the question of fiduciary duties in non-physician researchers or in physician researchers without a prior therapeutic relationship to the subjects of a particular research trial. Broussard J., dissenting on the dismissal of the fiduciary actions against the remaining defendants, stated that these defendants might be held liable for the continuing postoperative conduct. The majority appears to assume that because the "transactions" between patient/subject and doc-

<sup>137</sup> Moore, *supra* note 29.

<sup>138</sup> *Ibid.* at 129.

<sup>139</sup> *Ibid.*

<sup>140</sup> *Ibid.* at 133.



tor/researcher were fronted by a physician already involved in a therapeutic relationship, this precludes another's responsibility for informed consent or fiduciary-based disclosure. This assumption, although unexplored by the Court, may indeed be sensible—unless the third parties knowingly participated in a breach of a fiduciary duty. However, what would a court make of the duties of a researcher meeting a potential subject for the first time?

The fiduciary doctrine is founded on the principles of equity, therefore its boundaries are not restricted. It is meant to fill the gap where the vulnerable party is not completely protected by other arms of the law. If the researcher were found to be in a position of trust<sup>141</sup> and power (much as the lawyer's and the doctor's authority is based on the possession of a superior knowledge base) and, applying the *Frame* indicia, if the subject were found to be vulnerable<sup>142</sup> (as is implied by the protection of subjects inherent in international documents, and regulatory statements such as that of the Tri-Council), and if the researcher were found to be able to unilaterally affect the position of the subject (as indicated by her or his control of medical information), she or he could be found to be a fiduciary. It may appear odd that a physician is presumptively a fiduciary, but that a researcher is not, given that the duties expected of a researcher are at least as great as those expected of a physician.<sup>143</sup> The likelihood that a researcher would be found to be a fiduciary would depend not only on the specifics of the relationship, but may also depend on the willingness of a court to infer that the relationship of researcher-subject was as much built on trust as that of the doctor-patient relationship.

Applying the fiduciary analysis of the Supreme Court of Canada, several representative elements of a fiduciary relationship may be discerned.<sup>144</sup> From *R. v. Guerin*<sup>145</sup> comes the notion that a fiduciary undertakes to act in the beneficiary's best interest. For instance, a researcher may be understood to have (likely figuratively) undertaken to protect the health of the subject, or may have undertaken to protect the confidentiality of the subject's medical information unrelated to the study. From the decisions of LaForest J. in *Hodgkinson*, and *Lac Minerals* comes the idea that a beneficiary to a fiduciary relationship is understood to have certain reasonable expectations of the actions of the fiduciary,

---

<sup>141</sup> As indicated by the Tri-Council Statement, *supra* note 1.

<sup>142</sup> Some debate surrounds the question whether vulnerability is a requirement in a fiduciary relationship: see *Hodgkinson v. Simms*, [1994] 3 S.C.R. 377 [hereinafter *Hodgkinson*] and *Lac Minerals v. International Corona Resources*, [1989] 2 S.C.R. 574 [hereinafter *Lac Minerals*].

<sup>143</sup> See text accompanying note 100 above.

<sup>144</sup> For a more detailed description of this approach, see C. Feasby, "Fiduciary Obligations and Exculpatory Clauses" (1998) 36 *Alta. L. Rev.* 923 at 928.

<sup>145</sup> (1984), 13 D.L.R. (4<sup>th</sup>) 321 (S.C.C.).

and that the beneficiary must have relied upon those expectations.<sup>146</sup> A research subject could be found to have reasonably expected disclosure of plans for the commercialisation of research results. A subject may be found to have relied on the maintenance of the privacy of their medical information.<sup>147</sup> Thus the presence of these elements may lead to the declaration of a fiduciary relationship, and their nature may lead to the delineation of the duties attendant on the relationship in question.

The most important impediment to the finding that a clinical researcher owed fiduciary duties to a research subject may rest in the nature of the fiduciary doctrine itself.<sup>148</sup> While it may be technically possible to fit the researcher within the confines of the *Frame* indicia, or within the elements of the undertaking/reasonable expectation/reliance analysis, this fit may be forced. What is truly required is the obligation that the fiduciary be bound to secure the paramountcy of the beneficiary's interests.<sup>149</sup> Thus,

... what must be shown is that the actual circumstances of a relationship are such that one party is entitled to expect that the other will act in his interests in and for the purposes of the relationship. Ascendancy, influence, vulnerability, trust, confidence or dependence doubtless will be of importance in making this out, but they will be important only to the extent that they evidence a relationship suggesting that entitlement.<sup>150</sup>

It is true that guidelines such as the Tri-Council statement adopt a subject-centred approach, however, this may imply only that the interests of subjects "in general" are paramount, not that the interests of a "particular" subject ought to be paramount. After all, research with no therapeutic value is often undertaken selflessly by subjects, not in the hope that their interests be paramount. However, research with some therapeutic potential for its subjects, or research

<sup>146</sup> Professional standards (and perhaps regulatory guidelines such as the Tri-Council statement) may be evidence of reasonable expectations: per LaForest J. in *Lac Minerals*, *supra* note 142 at para. 168, and in *Hodgkinson*, *supra* note 142 at para. 41.

<sup>147</sup> The level of reliance necessary is not clear: see the judgments of LaForest J. and of Sopinka and McLachlin JJ. in *Hodgkinson*, *ibid.*

<sup>148</sup> Another real impediment may be the quantification of damages. Fiduciary duties are not meant merely to compensate for monetary losses: *McInerney*, *supra* note 128 at 423. See also the decision of Wilson J. in *Frame*, *supra* note 121 and that of McLachlin J. in *Canson Enterprises v. Broughon & Co.* (1991), 85 D.L.R. (4<sup>th</sup>) 129 (S.C.C.) [hereinafter *Canson*]. For a critique of this reasoning, see E. Lee, "Fiduciary Duty and Family Obligations: The Supreme Court of Canada Signals Change" (1993) 57 Sask. L. Rev. 457. However, it may be easiest if the fiduciary or those knowingly participating in the breach are made to account for their profits. See *infra* note 151 and accompanying text.

<sup>149</sup> P.D. Finn, "The Fiduciary Principle" in T.G. Youdan, ed., *Equity, Fiduciaries and Trusts* (Scarborough: Carswell, 1989) 1 at 27.

<sup>150</sup> *Ibid.* at 46.

undertaken with particular implied protections may be sufficient to ground a finding of a fiduciary relationship even absent a previous therapeutic relationship—or absent the researcher's status as physician. As well, a general undertaking to protect the interests of subjects may be sufficient to show an undertaking of a particular fiduciary relationship.

If the researcher-subject relationship were found to be of a fiduciary nature, it might not be overly difficult to demonstrate a breach of the ensuing duties.<sup>151</sup> A court, were it to characterize a relationship as fiduciary in nature, might well find that a conflict of interest such as the commercialisation of research findings, or the payment of per-patient fees, or the failure to disclose either of these, constituted a breach of a fiduciary duty to research subjects.<sup>152</sup> Once it has been proven that the relationship is fiduciary in nature, and once a *prima facie* case of breach has been shown, a reverse onus places the burden of proof on the fiduciary.<sup>153</sup> This onus cannot be rebutted by showing that a breach was undertaken in good faith, that loss to the beneficiary was inevitable, that a beneficiary also profited from the breach,<sup>154</sup> or even that benefit to third parties insulates the fiduciary from liability.<sup>155</sup> Therefore, if a researcher were found to be a fiduciary and to have breached this duty, it would be no defence that the public benefited from the research undertaken.<sup>156</sup> As well, just as is true of conflicts of interest generally, no actual benefit must be proven. The nature of the fiduciary relationship dictates that the potential for abuse prevents a fiduciary from prof-

---

<sup>151</sup> Although, as already noted, the issue of ensuing damages may not be as clear. The issue of causation in relation to damages for breach of fiduciary duty is by no means clear: see D.M. Waters, "The Reception of Equity in the Supreme Court of Canada (1875–2000)" (2001) 80 Can. Bar Rev. 620 at 689.

<sup>152</sup> The court then may force the researcher to disgorge any profit s/he made from the breach: for instance, in *Stewart*, the defendant was to hand over net profits. However, even though the breach was considered to be flagrant, no punitive damages were awarded because the conduct was neither extreme, nor deserving of full condemnation and punishment: *Stewart*, *supra* note 131 at 208. Rotman, *supra* note 126 at 483 has criticized this result as embracing a defence of ignorance of law (even though the defendant in question was a lawyer).

<sup>153</sup> Rotman, *ibid.* at 470.

<sup>154</sup> The prohibition against unauthorized profit applies regardless whether or not the beneficiaries could themselves have profited: M.V. Ellis, *Professional Fiduciary Duties* (Scarborough: Carswell, 1995) at 20–42, explaining the principle enunciated in *Keech v. Sandford* (1726), 25 E.R. 223 and *Canadian Aero Service v. O'Malley*, [1974] S.C.R. 592.

<sup>155</sup> Rotman, *supra* note 126 at 471.

<sup>156</sup> Although the application of the reverse onus was not considered in the *Stewart* case. In that case, it was determined that the public benefit argued would have existed even if the defendant had not benefited from the breach, therefore this was no defence to the action: *ibid.* at 472. This is also true of researchers—the benefits of research will also exist if they do not personally profit.

iting from the relationship, regardless of the benefit to the beneficiary.<sup>157</sup>

In *Norberg* and in *McInerney* the Supreme Court of Canada has allowed for fiduciary duties to create a separate head of analysis and action for medical claims.<sup>158</sup> As well, Lambert J.A. in the British Columbia Court of Appeal's judgment in *Arndt*, calls for the use of the fiduciary doctrine in cases where there is no single reasonable medical choice. However, the scope of this remedy may have been considerably restricted in the judgment of McLachlin J. in *Arndt*. Because the judgment in *Reibl* rejected the notion that a failure to allow a patient to choose would lead to an action in battery, McLachlin J. states:

For the same reasons, I would reject the alternative approach of fiduciary obligation proposed by the respondent. As with battery, the effect would be to replace the factual analysis standard of care and causation appropriate to negligence actions with a choice-based analysis that makes recovery virtually automatic upon proof of failure to provide relevant information.<sup>159</sup>

She indicates therefore that fiduciary claims ought only to be allowed in the medical context if there is an indication of fraudulent misrepresentation or of abuse of power.

While this judgment was a minority decision, it may be taken to preclude a separate claim under fiduciary principles in the ordinary negligence situation.<sup>160</sup> Therefore this type of fiduciary claim, absent fraudulent misrepresentation or abuse of power, may face an uphill battle. What has been considered a broad and advantageous remedy,<sup>161</sup> may unfortunately be viewed by the courts as being altogether too generous. This reading, however, does not give full expression to the inherent purpose and maxims of equity, which "are not rules that must be rigorously applied but malleable principles intended to serve the ends of fairness and justice."<sup>162</sup> In many instances, there may be no other cause of action for failing to allow patients autonomous medical or research decision-

---

<sup>157</sup> *Ibid.* at 477.

<sup>158</sup> See also *Henderson*, *supra* note 128.

<sup>159</sup> *Reibl*, *supra* note 81 at 63.

<sup>160</sup> In a dissenting opinion, Hetherington J.A. relied on McLachlin J.'s decision in *Arndt* to preclude the analysis of whether a failure to disclose an alternative treatment was a breach of a fiduciary duty: *Seney v. Crooks* (1998), 223 A.R. 145 (C.A.), rev'd (1996), 189 A.R. 21 (Q.B.) (where fiduciary principles had been used to find the defendant liable). The majority of the Court did not address this issue as the decision of Conrad J.A. held the trial judge's comments regarding fiduciary duties to be inessential to the determination of the doctor's liability.

<sup>161</sup> Shultz, *supra* note 61 at 261-2; Dickens, *supra* note 126 at 239. It may also be used to side-step statutes of limitation: *Picard & Robertson*, *supra* note 64 at 6. As well, it may give remedy for "dignitary injuries": *Sharpe & Weisstrub*, *supra* note 100 at 102.

<sup>162</sup> La Forest J. in *Canson*, *supra* note 148 at 151.

making. This may be the appropriate instance for equity to fill this gap.

#### IV. CONCLUSION: ADEQUATE PROTECTION FOR SUBJECTS' CHOICE?

WHEN TAKEN SEPARATELY, REGULATORY, TORT, or fiduciary duties may not be sufficient to allow for the protection of potential subjects' autonomous decision-making. Fiduciary duties may be carefully circumscribed by the courts, tortious duties may only provide after-the-fact compensation for proven injuries, and regulatory schemes are only as good as their enforcement. As Vollman and Winarr chillingly point out, there was in fact an ethical code regarding research in Nazi Germany when wartime atrocities took place.<sup>163</sup> McNeill reiterates that

...codes on their own are not sufficient to safeguard research subjects and ensure ethical experimentation. The obvious illustration is the comprehensive rules of research ethics enshrined in the German Reichlinien of 1931 and the utter disregard of those provisions by the German doctors and scientists in Nazi concentration camps during the Second World War. Codes of conduct can be at best a statement of principle which will be adhered to and at worst, a public relations document which serves to hide unethical conduct which continues unchecked.<sup>164</sup>

The patchwork regulation of research as it now stands may not be up to the task of protecting the decisional rights of potential research subjects. As the process of commercialisation of genetic research continues, these subjects may themselves begin the push to increase the availability of information regarding the financial aspects of research. Just as the protection of the physical health of subjects has been enshrined in the oversight of research protocols, the protection of the subject's dignity and right to choose must also be strenuously guarded. If there is little public knowledge of or input into the regulation of the research enterprise, and if oversight of research trials involves merely the more technical aspects of the prevention of medical harm, we are in essence leaving it up to individual subjects to make the hard choices. These subjects deserve at least a full complement of information on which to base their decisions. The changing face of research must allow for the real protection of subjects' interests, lest commercialisation truly taint what remains of its noble purpose.

---

<sup>163</sup> J. Vollman & R. Winarr, "Informed Consent in Human Experimentation Before the Nuremberg Code" (1996) 331 *BMJ* 1445.

<sup>164</sup> McNeill, *supra* note 13 at 50.

