

# Subject Comprehension, Standards of Information Disclosure and Potential Liability in Research

Daryl Pullman\*

## I. Introduction

The history of modern research ethics can be traced to the ten articles of the *Nuremberg Code*, a response to the atrocities that Nazi physicians had perpetrated upon their hapless victims in so-called “medical experiments.” Informed consent to research was the first and most prominent of those ten articles. In spite of this attempt to regulate human subjects research, however, some twenty years later Dr. Henry K. Beecher published a critical survey of twenty-two research projects conducted in the United States in the years subsequent to Nuremberg.<sup>1</sup> Beecher observed that in the vast majority of cases research subjects were never adequately apprised of the nature of the research conducted upon them. He reiterated the need for informed consent as a necessary component of morally acceptable research on human subjects. At the same time, however, he acknowledged that in practice it is often difficult to obtain adequately informed consent. Hence Beecher insisted on a second component in order for patients to be safeguarded in the research process, namely “intelligent, informed, conscientious, compassionate, responsible investigators.”<sup>2</sup>

There can be no doubt that the conduct of ethical research rests ultimately in the hands of persons of integrity. Yet Beecher’s own investigations indicated that we would be foolish to assume this high standard is always or usually attained. In the years subsequent to Beecher’s article a consensus has emerged that independent review of proposed research on human subjects is essential. This is the position set forth in the World Medical Association’s *Declaration of Helsinki*,<sup>3</sup> and it serves as the historical basis of the contemporary Research Ethics Board (REB). Prior review by a duly constituted committee has become the ethical *sine qua non* of modern human subjects research.

Despite the widespread implementation of REB review, however, difficulties persist with regard to the matter of ensuring informed consent on the part of

---

\*Daryl Pullman is an Associate Professor of Medical Ethics at Memorial University of Newfoundland, St. John’s, Newfoundland.

<sup>1</sup>H. K. Beecher, “Ethics and Clinical Research” (1966) 274 *New Engl. J. Med.* 1354.

<sup>2</sup>*Ibid.* at 1360.

<sup>3</sup>World Medical Association, *Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (Declaration of Helsinki)*, 18<sup>th</sup> World Medical Assembly (1964), as amended.

prospective research subjects.<sup>4</sup> The 1980 Supreme Court decision in *Reibl v. Hughes*<sup>5</sup> established the Canadian standard for informed consent to therapeutic treatment. However, the leading Canadian case for consent in the context of research and experimentation was established some 15 years earlier in *Halushka v. University of Saskatchewan et al.*<sup>6</sup> In *Halushka* Justice Hall argued that the duty owed by researchers toward prospective subjects is greater than that owed by medical practitioners to their patients.<sup>7</sup> A stricter standard of disclosure in the research context is now generally accepted in law.<sup>8</sup> To quote one authority on the subject, it is “the most exacting duty possible, requiring ‘full and frank disclosure’ of all risks, no matter how remote or how rare.”<sup>9</sup>

Canadian legal<sup>10</sup> and ethical<sup>11</sup> commentators continue to cite *Halushka* as the leading case on informed consent to research. This is understandable in that it is one of the few cases of this nature that has made its way through the courts.<sup>12</sup> It is also the case that established that the standard for consent to research is stricter than that applied to therapy. However, it can be argued that *Halushka* in fact invoked a weaker standard of informed consent than that which was later applied in *Reibl v. Hughes*. Since so much commentary on consent to research continues to invoke *Halushka*, it is necessary to examine what this judgment did in fact establish, how it is related to the later judgment in *Reibl*, and to consider the combined implications of these and subsequent cases for consent to research.

---

<sup>4</sup>See e.g. J. Katz, “Disclosure and Consent” in A. Milunsky & G. Annas, eds., *Genetics and the Law II* (New York: Plenum Press, 1980) 122; R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986); R.J. Levine, *Ethics and Regulation of Clinical Research*, 2<sup>nd</sup> ed. (New Haven, Conn.: Yale University Press, 1986); W.A. Silverman, “The Myth of Informed Consent: in Daily Practice and in Clinical Trials” (1989) 15 J. of Med. Ethics 6.

<sup>5</sup>*Reibl v. Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1, 33 N.R. 17 [hereinafter *Reibl* cited to D.L.R.].

<sup>6</sup>*Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) [hereinafter *Halushka*].

<sup>7</sup>*Ibid.* at 443-44.

<sup>8</sup>E.I. Picard & G.B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Scarborough: Carswell, 1996) at 88, 149.

<sup>9</sup>K.C. Glass, “Research Involving Humans” in J. Downie & T. Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) 375 at 386.

<sup>10</sup>*Ibid.*

<sup>11</sup>See F. Baylis et al., eds., *Health Care Ethics in Canada* (Toronto: Harcourt Brace, 1995) at 323, 325-28; D.J. Roy, J.R. Williams & B.M. Dickens, *Bioethics in Canada* (Scarborough: Prentice Hall, 1994) at 330-31; E-H.W. Kluge, *Biomedical Ethics in a Canadian Context* (Scarborough: Prentice Hall, 1992) at 162; E-H.W. Kluge, ed., *Readings in Biomedical Ethics*, 2d ed. (Scarborough: Prentice Hall, 1999) at 243, 259-61.

<sup>12</sup>The only other Canadian case involving research conducted with a protocol in which there was no intended benefit for the subject is *Weiss v. Solomon* (1989), 48 C.C.L.T. 280 (Que. S.C.).

This paper considers what can be learned from *Halushka v. University of Saskatchewan, Reibl v. Hughes* and subsequent decisions<sup>13</sup> with regard to consent to participate in clinical trials. In particular it is argued that the standard of information disclosure utilized currently in many clinical trials fails to meet the strict standard set in *Reibl v. Hughes*. Researchers who proceed on an inadequate standard of information disclosure and comprehension may fail in both their legal and moral obligations to ensure that prospective research subjects are given an opportunity to provide valid consent. The paper concludes with some suggestions as to how the role of the REB should be redefined with regard to the informed consent process.

## ***II. Halushka v. University of Saskatchewan and Reibl v. Hughes: A Comparative Review***

*Halushka v. University of Saskatchewan et al.* is a case of non-therapeutic, experimental research. Inasmuch as it is one of the few cases of this type in North America that has produced a legal judgement, it has set the standard.

The case arose in 1961 when Walter Halushka, a student at the University of Saskatchewan, volunteered to participate in a clinical trial to test a new drug. Although Mr. Halushka signed a consent form that authorized the procedure, the physician researchers failed to inform him that the drug was a new anaesthetic about which they had little knowledge and with which they had no prior experience. They did not inform him he might be exposed to certain unknown risks. Instead they assured Mr. Halushka there was nothing to worry about. Furthermore, while he was informed that the test would require that a catheter be inserted into a vein in his arm, it was not explained that this catheter would be pushed up the vein and through his heart as the experiment proceeded. In fact, when the catheter was advanced through the heart chambers and the anaesthetic was administered, Mr. Halushka suffered a complete cardiac arrest. It took approximately one minute and thirty seconds to open his chest and separate his ribs so that manual heart massage could be performed. Although the physician researchers were able to resuscitate Mr. Halushka, he suffered some brain damage with a resulting diminution of mental ability.

Justice Hall makes several significant points in ruling on this case. First, he acknowledges that ordinarily both medical therapy and medical research require prior informed consent from patients/subjects. Second, he notes that the differences between the therapeutic situation and the research situation may permit a different standard of informed consent in each context. This is because of therapeutic privilege, the legal doctrine that permits physicians to withhold information from patients or their proxies if they reasonably believe it would not be in the patient's best interests to receive it, or if they believe such information could interfere with

---

<sup>13</sup>See for example, *Videto v. Kennedy* (1981), 125 D.L.R. (3d) 127 (Ont. C.A.); *Weiss v. Solomon, ibid.*; and *Finch v. Carpenter*, [1993] B.C.J. No. 1918 (QL) (SC).

the patient's treatment or cure.<sup>14</sup> In such cases physicians may have to "balance the probable effect of lack of treatment against the risk involved in treatment itself."<sup>15</sup> Hence in some situations it may be permissible to proceed with treatment without prior fully informed consent. Although the emerging consensus is that therapeutic privilege "should be construed very narrowly and applied only in the most exceptional circumstances,"<sup>16</sup> no such privilege applies in the research context. When the research is for scientific purposes only with no foreseeable therapeutic benefit for the patient there is clearly no "therapeutic privilege" in view. Thus Justice Hall argues that the research situation places a stricter duty and higher standard of disclosure on the physician researcher than that required in the therapeutic context. He states:

In my opinion the duty imposed upon those engaged in medical research . . . to those who offer themselves as subject for experimentation . . . is at least as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirement of disclosure in the case of research as there may well be in ordinary medical practice . . . . The example of risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The 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>17</sup>

In stating his position Justice Hall invokes the *reasonable person* standard of information disclosure.<sup>18</sup> As its name implies, this standard requires that researchers disclose as much information as any reasonable person would expect to have in order to make an informed decision whether or not to participate in a clinical trial. The reasonable person standard is generally viewed as a compromise between the professional practice standard and the subjective person standard. The former requires researchers to disclose only as much information as other researchers working in the field would normally disclose.<sup>19</sup> Had the court relied upon the professional practice standard in *Halushka*, it would have called for expert witnesses from the research community to testify with regard to standard practice. If it were demonstrated that other researchers doing similar research would have

---

<sup>14</sup>The scope of therapeutic privilege has been narrowed considerably in Canadian case law since *Halushka*. For a detailed discussion see B.M. Dickens, "Informed Consent" in Downie & Caulfield, *supra* note 9, 117 at 137-40. See also Picard & Robertson, *supra* note 8 at 147-49.

<sup>15</sup>*Halushka*, *supra* note 6 at 436.

<sup>16</sup>Picard & Robertson, *supra* note 8 at 148.

<sup>17</sup>*Halushka*, *supra* note 6 at 436.

<sup>18</sup>For a more detailed discussion of the nature and justification for this standard see T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*, 4th ed. (New York: Oxford, 1994) at 148-49.

<sup>19</sup>*Ibid* at 147-48.

disclosed similar information in a similar manner, we can assume that Justice Hall would have ruled against the plaintiff. By invoking the reasonable person standard, however, Justice Hall implicitly rejected the professional practice standard. Furthermore, by requiring “full and frank disclosure” he set aside any appeal to therapeutic privilege as a justification for non-disclosure of information.

While the professional practice standard is considered inadequate in that it puts prospective research subjects at the mercy of the research community, the subjective person standard suffers from the opposite problem. This standard requires that the information given be that which the specific patient or research subject feels is necessary for him or her to gain an informed understanding of, and appreciation for, that to which he or she is asked to consent. Although some ethicists recommend that this is the preferred standard from a moral point of view,<sup>20</sup> the law has recognised that it puts the researcher at the mercy of the research subject’s “bitter hindsight.”<sup>21</sup> For even if consent has been obtained, after the fact a subject could claim not to have been fully informed about some particular detail that he or she now considers to be of material importance.

Although the reasonable person standard has emerged as the standard of choice in most North American jurisdictions,<sup>22</sup> it is not without its detractors. Katz has argued the reasonable person standard “promises more than its construction in case law has delivered.”<sup>23</sup> In some jurisdictions where the standard has been adopted the courts have judged that a signed consent document constitutes a valid consent, even though the actual subject did not understand it.<sup>24</sup> Concerns about the subjective person standard notwithstanding, the Canadian courts have been reluctant to provide the same wide range of interpretation and application to the reasonable person standard. Indeed, *Reibl v. Hughes* moves decidedly in the direction of the subjective standard even as it remains firmly anchored in the reasonable person standard. The result is a “modified objective test.”<sup>25</sup>

*Reibl v. Hughes* involved a Mr. Reibl, then 44 years of age, who underwent surgery in 1970 for the removal of an occlusion in the left internal carotid artery. The surgery was performed competently by Dr. Hughes, a neurosurgeon. However, Mr. Reibl suffered a massive stroke either during or immediately after the surgery that left him completely paralysed on the left side of his body, and impotent. Although Mr. Reibl had formally consented to the surgery, he alleged that his consent was not informed. In fact Dr. Hughes had not informed Mr. Reibl specifically of the irreducible risks of such a stroke occurring during or immediately following surgery. He had discussed only the possibility of a stroke if the surgery was not undertaken.

---

<sup>20</sup>*Ibid* at 149-50.

<sup>21</sup>Dickens, *supra* note 14 at 123. See also Roy, Williams & Dickens, *supra* note 11 at 119.

<sup>22</sup>Beauchamp & Childress, *supra* note 18 at 148.

<sup>23</sup>Katz, *supra* note 4 at 122.

<sup>24</sup>North Carolina General Statutes, § 90-21.13 (1975).

<sup>25</sup>Picard & Robertson, *supra* note 8 at 118.

Although the surgery Dr. Hughes proposed and performed was reasonable and indicated for Mr. Reibl's condition, Supreme Court Justice Laskin upheld the lower court judgment against Dr. Hughes. His judgment was based on the fact that Mr. Reibl was not in an emergency situation at the time of the surgery. Furthermore, he was only a year and a half away from fulfilling the minimum eligibility requirements for a lifetime retirement pension and extended disability benefits from his job with the Ford Motor Company. Mr. Reibl claimed that had he known of even a minimal risk of stroke associated with the surgery, he would have opted not to proceed, at least not until he had qualified for his pension and benefits.

Although Judge Laskin invoked the reasonable person standard in making his judgment, he specified that the standard must be applied to someone in the patient's particular situation: "What the doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge. . . . To allow expert medical evidence to determine what risks are material, and hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty."<sup>26</sup> In stipulating this condition the Supreme Court invoked a modified objective test.<sup>27</sup> Insofar as it is objective, the physician is still protected from the patient's subjective whims. Nevertheless, the particularity condition modifies the standard to ensure that physicians consider what information a reasonable person in the patient's particular situation would require in order to make an informed decision.

### **III. Quantity, Quality and Comprehension in Informed Consent Documents**

If the relationship between information and the various standards of information disclosure was represented by a mathematical function, on the face of it the relationship would appear to be inverse between the level of expertise assumed and the amount of information required. Part of the rationale for this assumption can be found in the history of medical paternalism. The professional standard emerged at a time before patient autonomy became a central concern in medical ethics, and when medical paternalism was standard practice. Disclosure, like treatment, was a task that belonged to physicians because of their professional expertise and their commitment to the well being of the patient. Given that physicians were expected to act always in the best interests of their patients, the need for detailed explanations was thought unnecessary.<sup>28</sup> Hence the general

---

<sup>26</sup>*Reibl*, *supra* note 5 at 12-13.

<sup>27</sup>B. Sneiderman, J.C. Irvine & P.H. Osborne, *Canadian Medical Law* (Toronto: Carswell, 1989) at 55.

<sup>28</sup>Beauchamp & Childress, *supra* note 18 at 148.

tendency was for professionals to discuss less with their patients, even though they might discuss individual cases at length with their colleagues.

One would expect that a professional practice standard of information disclosure would require that less detailed information need be disclosed than would be the case with a reasonable person standard. The operating assumption is that the average reasonable person without expertise in a given field will require more information in order to comprehend the nature of a given research project than what professionals normally disclose in their discussions with patients or research subjects. By parity of reasoning the subjective standard would, on the face of it, require more information than would the reasonable person standard. The assumption once again is that more information would be required to satisfy each individual subject's idiosyncratic knowledge requirement than would be necessary for the average reasonable person. Note, however, that these are only *prima facie* assumptions. In practice the professional practice in any given situation might be to disclose a great deal of detailed information. Then again, a particular individual's level of knowledge might be so high as to obviate the need for detailed information. This is often the case, for example, with patients with chronic illnesses who have learned a great deal about their conditions and various treatment options. Hence any individual patient might want or require less information than would the average reasonable person. Such contingencies are accounted for in the modified objective test that requires attention to the actual patient's circumstances.

As already noted, *Halushka v. University of Saskatchewan* established the reasonable person standard as the appropriate standard of information disclosure for research involving humans. *Reibl v. Hughes* modified and strengthened that standard by stipulating that it must apply to a reasonable person in the patient's particular situation. Given this evolution it is curious that legal commentators continue to refer to *Halushka* as the more onerous standard of consent.<sup>29</sup> The explanation seems to lie in the history of therapeutic privilege and the expectation that more latitude is allowed in clinical situations with regard to the amount of information that must be disclosed. Justice Hall allowed for no such latitude in the "full and frank disclosure" requirement for research in which there is no expectation of therapeutic benefit. Even if there are potential therapeutic benefits to the patient, such benefits are by definition unknown in the research context, and hence cannot serve as a justification for withholding information.<sup>30</sup>

If we rely upon the previously discussed assumptions about standards of information disclosure, we would expect that consent documents would require more information to satisfy the standard set in *Reibl v. Hughes* than to satisfy that set in *Halushka*. The more we emphasize the reasonable subject's particular situation the greater will be the amount of information that needs to be disclosed.

---

<sup>29</sup>Picard & Robertson, *supra* note 8 at 150. See also Glass, *supra* note 9 at 386.

<sup>30</sup>For example, REBs should not allow researchers to list "potential benefits" in consent documents, since the ostensible purpose of and justification for the research is to ascertain whether or not such benefits do in fact exist.

Again we acknowledge that any given subject might be a well informed individual and hence would not require an extensive and detailed explanation. However, informed consent documents for purposes of research are generally not directed to individual subjects but rather to prospective subjects that meet the inclusion criteria of the study. Hence the trend is toward disclosure of increasingly more information as a condition of sound medical practice.<sup>31</sup>

Although both *Halushka* and *Reibl* emphasize the amount of information a subject must receive in order to make an informed decision, missing from the discussion (or given only passing reference at best), is consideration of the subject's capacity to comprehend the information given. Although the courts have stipulated that the burden rests with the therapist (and, we would assume, the researcher) to ensure patient or subject comprehension of information,<sup>32</sup> the tendency to give the matter of comprehension short shrift in legal commentary is disturbing. The common suggestion is that fulfilling this obligation will be a relatively simple matter of taking reasonable steps to communicate necessary information in appropriate language.<sup>33</sup> To require that researchers or clinicians ensure that subject/patients have comprehended the information would require that physicians enter into the heads of their subject/patients. This would impose too great a burden.<sup>34</sup> However, to minimize the matter of comprehension while encouraging greater quantity of information disclosure could undermine the moral purpose of the entire process of informed consent.

Consistent with the trend toward disclosure of increasing amounts of information, research indicates that consent documents have increased in length over the years.<sup>35</sup> However, this has done little to satisfy any particular standard of comprehension. Indeed research has also shown that the vast majority of consent forms are written at a level well beyond the comprehension of the average research subject. For example, because standard literacy levels in the general population are relatively low,<sup>36</sup> it is commonly accepted in the research community that consent documents should be written at about an eighth grade level of comprehension. However, Levine<sup>37</sup> cites research that indicates more than 75% are written at the level of scholarly or academic publications, or higher (i.e. post-secondary or graduate level). Only 2% of the 1526 protocols considered were "fairly easy or easy" to read. Other studies have consistently shown that the situation has not

---

<sup>31</sup>Sneiderman et al, *supra* note 27 at 64. See also Picard & Robertson, *supra* note 8 at 160.

<sup>32</sup>*Ciarlariello v. Schacter* (1993), 100 D.L.R. (4<sup>th</sup>) 609 (S.C.C.).

<sup>33</sup>Picard & Robertson, *supra* note 8 at 137, 151. See also Glass, *supra* note 9 at 386; Dickens, *supra* note 14 at 132.

<sup>34</sup>Picard & Robertson, *supra* note 8 at 137.

<sup>35</sup>M.E. Loverde, A.V. Prochzka, & R.L. Byyny, "Research consent forms: continued unreadability and increasing length" (1987) 35:1 Clinical Research 131A.

<sup>36</sup>See *Reading the Future: A Portrait of Literacy in Canada*. Statistics Canada Catalogue no. 89-551-XPE.

<sup>37</sup>R.J. Levine, *Ethics and regulation of clinical research*, 2d ed. (Baltimore: Urban & Schwarzenberg, 1986) at 128.

improved over the years.<sup>38</sup> The point is that while stricter standards of information disclosure would appear to require more information, more information does not translate into better comprehension. Longer consent documents with highly technical information may serve only to confuse and frustrate prospective subjects.

Quantity of information correlates with comprehension if and only if the information is comprehensible, and even then, only within limits. Even when information is comprehensible, one can expect what economists describe as “declining marginal utilities.” That is, understandable information contributes to greater comprehension only up to a certain optimal point. After that point more information could serve to decrease comprehension, in part because research subjects might be disinclined to read excessively long explanations.<sup>39</sup> Others report that the trust participants place in their physicians will often result in their signing documents that they have not read.<sup>40</sup>

If consent documents do not contribute to the level of comprehension of patients or research subjects regarding that to which they ostensibly give their consent, we must ask what purpose these increasingly lengthy, often highly technical documents serve. The answer seems to be that many consent documents are designed to satisfy some perceived legal requirements of consent. Only secondarily, and in many cases incidentally, do such documents address the moral requirements.

#### **IV. The Roles and Functions of REBs: Two Kinds of Consent**

The primary moral purpose of informed consent documents must be to inform prospective subjects of the nature of the research and its potential risks and discomforts. Consent documents fulfill this moral purpose only when prospective subjects comprehend that to which they give consent. The reasonable person standard established in *Halushka* and modified and strengthened in *Reibl* is meant to ensure that this moral purpose is fulfilled. However, consent documents that are written to satisfy a perceived legal requirement of consent may fail to meet the moral requirements the law is intended to achieve in the first place.

---

<sup>38</sup>M.C. Silva & J.M. Sorrell, “Factors influencing comprehension of information for informed consent: ethical implications for nursing research” (1984) 21:4 *Int’l J. Nursing Stud.* 233; C.D. Meade & D.M. Howser, “Consent forms: how to determine and improve their readability” (1992) 19:10 *Oncology Nursing Forum* 1523; S.J. Jubilier, J.C. Linton & S.M. Magnetti, “Reading versus comprehension: implications for patient education and consent in an outpatient oncology clinic” (1994) 9:1 *J. Cancer Educ.* 26; K.J. Tarnowski et al., “Readability of pediatric biomedical research consent forms” (1990) 85:1 *Pediatrics* 58.

<sup>39</sup>L.C. Epstein & L. Lasagna, “Obtaining informed consent: Form or substance?” (1969) 123 *Arch. Intern. Med.* 682.

<sup>40</sup>N.E. Kass *et al.* “Trust: The fragile foundation of contemporary biomedical research” (1996) 26:5 *Hast. Cen. Rep.* 25.

Although a version of the reasonable person standard is now recognized by the courts as the appropriate standard of information disclosure *vis-à-vis* informed consent to research, the manner in which that standard is invoked and applied is contingent upon the contexts and purposes of informed consent practice. In the case of medical research, such contexts and purposes are created and shaped by the roles and functions of Research Ethics Boards (REBs).

Difficulties with achieving an adequate standard of informed consent to research stem in part from the dual roles that REBs have come to play.<sup>41</sup> REBs are charged with the moral responsibility to protect prospective subjects from poor or unethical research. In this role REBs review research protocols to ensure that the proposed research is worthwhile, will be properly conducted, will not expose subjects to unnecessary risks, and so forth. Also, they review consent documents to make sure they accurately represent the nature of the research and the various risks to which prospective subjects may be exposed. In this role REBs serve the interests of prospective research subjects, and their motivation is primarily moral.

In their second role REBs serve institutional ends. Inasmuch as most jurisdictions have some kind of regulatory requirement for REB review of human subjects research, the vast majority of institutions that conduct such research have established their own REBs. The work REBs do in this second role does not differ markedly from that of the first role. What differs is the motivation. In this second role REBs must ensure that the institutions they serve have met their legal obligations and are protected from liability for any untoward events that might transpire as a result of research conducted under their auspices. In this role REBs serve institutional ends, and their motivation is primarily legal.

In theory it is quite conceivable that moral and legal motivations could converge. If in fact this were usually or always the case, it would be more accurate to describe REBs as having a single role with two distinct but compatible purposes. In practice, however, these distinct purposes have often pulled REBs in different directions. The evidence of this polarization can be seen in the emergence of “two common, entrenched, and starkly different meanings of ‘informed consent.’”<sup>42</sup>

The first form of consent (sense<sub>1</sub>) aims to satisfy the moral requirement to respect the autonomy of persons. This is the intent of the *Nuremberg* and *Helsinki Codes* respectively, and it is the moral basis of various legal statutes that specify standards of informed consent. Sense<sub>1</sub> consent is valid only when prospective subjects receive an appropriate amount of information, when they display adequate understanding of that information, and when there is a substantial lack of controlling influences that might compromise the subject’s capacity to make an autonomous decision. However, insofar as sense<sub>1</sub> consent is a moral notion it is difficult to specify precisely what constitutes an appropriate amount of information,

---

<sup>41</sup>See D. Pullman, “Conflicting interests, social justice and proxy consent to research” *J. of Med. & Phil.* (forthcoming).

<sup>42</sup>Faden & Beauchamp, *supra* note 4 at 276.

how to determine when each subject has displayed adequate understanding, or when controlling influences have become so great as to compromise voluntary consent. Since individual research subjects vary considerably in the amount of information each requires, in their abilities to understand information, and in their susceptibility to various controlling influences, it is difficult to identify when the moral conditions necessary for sense<sub>1</sub> consent have been met.

Sense<sub>2</sub> consent does not suffer from the ambiguities of interpretation and application that plague sense<sub>1</sub>. The aim of sense<sub>2</sub> consent is to satisfy the requirement for a legally valid consent. This is largely a procedural matter. In Canada, the Therapeutics Products Program and various granting agencies<sup>43</sup> provide guidelines which describe how REBs must be constituted, what their responsibilities will be, how they should go about ensuring they carry out these responsibilities, and so forth. Similar demands are placed on Institutional Review Boards (IRBs) in the U.S.,<sup>44</sup> although the regulatory environment in that country differs from that of Canada in a number of important respects. As far as informed consent is concerned, such guidelines and regulations specify what kinds of information must be included in consent documents.<sup>45</sup>

Canadian research guidelines and U.S. regulations are modeled on the *Declaration of Helsinki* which specifies the necessary content of a valid informed consent:

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 subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent. . .<sup>46</sup>

---

<sup>43</sup>See Medical Research Council of Canada (MRC), National Sciences and Engineering Research Council of Canada (NSERC) & Social Sciences and Humanities Research Council of Canada (SSHRC), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Medical Research Council of Canada, 1998). This documents represents a joint statement of the three major granting agencies for research funding in Canada.

<sup>44</sup>U.S., Food and Drug Administration (FDA), *Information sheets for institutional review boards and clinical investigators* (Rockville, MD: FDA, 1995). Much research conducted in Canada originates in the United States, and is under direct jurisdiction of the FDA. This has important implications for the standard of information disclosure that is adopted for informed consent documents.

<sup>45</sup>Picard & Robertson, *supra* note 8 at 151.

<sup>46</sup>World Medical Association, *supra* note 3, art. 22.

When the regulations governing research have been specified, the conditions necessary for a legally valid consent (sense<sub>2</sub>) are known. Meeting these conditions is then largely a procedural matter. But even though such procedures are established and the legal conditions for sense<sub>2</sub> consent are satisfied, there is continuing concern that the moral conditions for sense<sub>1</sub> consent may not have been met. Indeed, some have argued that the legal regulations of sense<sub>2</sub> consent have effectively overwhelmed the moral requirements of sense<sub>1</sub>. As one commentator has put it, “[t]his judicially imposed obligation . . . [has allowed] the idea of informed consent to wither on the vine.”<sup>47</sup>

In order to understand how the legal role REBs have come to play can undermine their moral responsibilities to ensure that research subjects give a valid consent, we must consider in more detail the nature of information about research and how it is conveyed to prospective subjects.

### **V. Professional Practice, Reasonable Persons, and *Reibl v. Hughes***

The modified objective test aims for an ideal that allows for consideration of information about the prospective subject’s particular situation, without lapsing into complete subjectivity. It could well be that legal advisors who instruct research sponsors, research institutions, and the REBs who serve them, believe the documents they approve do approximate the standard established in *Reibl*. Perhaps they accept the unexamined assumption that the nearer one approximates a subjective person standard, the greater the amount of information required. However, as noted previously, this assumption is false, and does not withstand careful scrutiny.

The consent document is only part of the consent process, and a signed document does not in itself constitute informed consent. Nevertheless, the document itself serves different functions in the therapeutic and research environments respectively. In the therapeutic environment a physician or nurse has a therapeutic relationship with the patient. The nature of this relationship affects the manner of communication. Therapists generally spend time explaining the nature of tests and procedures, and the consent document then summarizes this discussion in a somewhat abbreviated manner. In this process the consent document is largely a record of a consent that has already taken place. Hence consent documents for therapeutic intervention are often relatively brief, and may be only one or two pages in length.

The converse is often the case in the research context. First, the relationship between researcher and subject is often more formal and less intimate than the therapeutic relationship. Test procedures are often reviewed briefly by either the researcher or a research nurse, after which the subject is presented with a summary

---

<sup>47</sup>Katz, *supra* note 4 at 128.

of the protocol which they are expected to review and sign. This document is often a vehicle intended to convey information to research subjects in order to educate them to the point at which they can provide consent. Hence consent documents are often six to eight pages or more in length. It is little wonder that many subjects sign them without ever reading them.<sup>48</sup>

Given that the modified objective test represents the principled position of the Canadian courts with regard to informed consent, we can assume that research organizations and their legal advisors endeavor to meet that standard. Yet the *de facto* standard that has emerged is a professional practice standard after all. The professional standard in this case, however, is not that of professional researchers working in the field, but rather a perceived professional legal standard. The “full and frank disclosure of all the facts,” as stated by Justice Hall, is often taken literally by researchers and research sponsors alike. This standard of information disclosure is evident in the highly technical consent documents that prospective research subjects are asked to sign. While such documents may satisfy some perceived legal requirement of sense<sub>2</sub> consent, they fail to meet the high moral standard of sense<sub>1</sub> consent established historically at Nuremberg, reaffirmed at Helsinki, and emphasized in Canadian case law.

Any who have served on REBs will recognize the symptoms of the legal professional standard. REBs often spend an inordinate amount of time attempting to revise consent documents so as to make them more readable and comprehensible. In so doing they strive conscientiously to satisfy sense<sub>1</sub> requirements. However, it is not uncommon in these proceedings to learn that the sponsors will not allow certain omissions or rephrasing. In cases where revisions are made the consent documents must often be vetted once again by the legal department of the sponsoring institution. This is done to ensure that all the legal bases are covered. Such legal vetting is of course prudent and necessary, but insofar as this process often results in consent documents that are longer and more technically cumbersome, the effect is that the moral concerns of sense<sub>1</sub> are displaced by the perceived legal demands of sense<sub>2</sub>.

While legal advisors and those they represent may enjoy a certain sense of security in knowing the requirements of sense<sub>2</sub> consent have been met, our review would suggest this security may be illusory. Inasmuch as *Reibl v. Hughes* has established the modified objective test as the acceptable legal *and* moral standard for informed consent in Canada, a legal professional practice standard may not withstand the scrutiny of the courts. In fact, in *Finch v. Carpenter* the courts have already moved in this direction with regard to the therapeutic environment.<sup>49</sup> In that case an oral surgeon was held not to have properly informed the patient of the possibility that an impacted wisdom tooth might be displaced into the sinus cavity during surgery. Although the patient had been provided with an information sheet

---

<sup>48</sup>See Kass et al., *supra* note 40 at 25.

<sup>49</sup>*Finch v. Carpenter*, *supra* note 13.

that listed possible complications and risks, these were placed in the final paragraph of the document and were presented in technical language. The trial judge ruled that the language of the statement “entry into the maxillary sinus in the case of some impacted teeth in the upper jaw,” together with its placement at the end of the document, would “detract substantially from its impact on an understandably tense patient.”<sup>50</sup>

When the reasoning presented in *Finch*<sup>51</sup> is coupled with the stricter standard required for research established in *Halushka* and modified and strengthened in *Reibl*, it would appear that the lengthy, complex, and often incomprehensible informed consent documents that are all too common in contemporary research are failing to meet this high standard. While research sponsors and/or REBs may believe they have satisfied some perceived legal standard by insisting on such documents, the precedents set by these cases would indicate otherwise. As long as research sponsors, REBs, and the institutions they serve continue to rely upon such an inferior standard they will continue to put themselves at legal risk, even as they fail to meet their moral obligations to prospective research subjects.

## VI. Conclusion

Although *Reibl v. Hughes* has established the modified objective test as the appropriate standard of information disclosure for consent to both treatment and research, the *de facto* standard in much contemporary research has evolved into a misperceived legal professional practice standard. The *de facto* standard fails on two counts. First, it fails to protect research subjects in that it does not provide them with information that is comprehensible for the purposes of informed consent. Second, if the courts are consistent in applying to the research context the standard set in *Reibl v. Hughes* and argued in *Finch v. Carpenter*, the legal professional practice standard will fail to provide legal protection for researchers and their sponsors in the event of litigation. Indeed, given the relative incomprehensibility of many consent documents and the duress that many prospective patients/subjects are already experiencing at the point when they are invited to participate in a clinical trial, a research subject’s signature on such a document might be used as evidence that the consent could not possibly have been informed, rather than the reverse.

Meeting the modified objective test for informed consent to research will require modification to the role of REBs *vis-à-vis* informed consent, and to the documents that prospective subjects are given to sign. While the details of these modifications cannot be addressed here, it has been argued elsewhere<sup>52</sup> that REBs should be granted the legal and moral responsibility to act as provisional proxies for prospective research subjects. The rationale here is that in many cases the REB

---

<sup>50</sup>*Ibid.* at 10-11.

<sup>51</sup>*Ibid.*

<sup>52</sup>D. Pullman, “General Provisional Proxy Consent to Research: Redefining the Role of the Local Research Ethics Board” (1999) 21:3 IRB Review of Human Subjects Research 1.

collectively is the only body that can fully comprehend all the scientific and moral implications of a proposed research protocol. As such REB approval of a research protocol would constitute a provisional proxy consent for all prospective subjects. It is important to note that such a proxy would be only provisional. Prospective subjects would still be presented with general information about the research study and be required to assent to participation. However, once a duly constituted REB had reviewed the research and provided a provisional consent, the actual consent document could be scaled down considerably to meet the informational needs of actual subjects. Hence these documents would more nearly approximate the moral standard set in *Reibl v. Hughes* even though such documents would include less rather than more information.

Given *Reibl v. Hughes* and *Finch v. Carpenter* the courts should be inclined to view a shorter form as comprehensible by someone in the prospective subject's particular situation. Of course, the onus would be on REBs, researchers, and others who must explain the nature of the research to prospective subjects, to assess the informational needs of prospective subjects in their particular situations. But here again a simpler document would be more likely to facilitate this process. While there are no guarantees that researchers or their representatives will be willing and able to communicate effectively with prospective subjects, shorter, more comprehensible consent documents will increase the likelihood that prospective subjects will be able to act more autonomously in the consent context. Of course, as Dr. Beecher acknowledged already in 1966, the key to the protection of human subjects resides ultimately in the "the presence of an intelligent, informed, conscientious, compassionate, responsible investigator."<sup>53</sup>

---

<sup>53</sup>Beecher, *supra* note 1 at 1360.