

Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards

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Introduction

Recent high profile incidents involving the death or injury of individuals participating in medical research projects have “shaken confidence in the protections afforded human subjects of biomedical research.”¹ In 1999, 18 year old Jesse Gelsinger died while participating in a clinical trial conducted by the University of Pennsylvania Institute for Gene Therapy. Jesse suffered from a mild form of a rare metabolic disorder called ornithine transcarbamylase deficiency (OTC). The experiment involved the injection of genetic material into Jesse’s bloodstream using a viral vector. This triggered multiple organ system failure, ultimately bringing about Jesse’s untimely death.² It was later revealed that the investigator may have stood to benefit financially from this research. In the complaint filed by the Gelsinger family, it was alleged that the researchers involved had used a virus vector *known* to be more dangerous than other vectors, because they held patents on that particular virus.³

Along with other, similar incidents the Gelsinger case has thrust the problems associated with the regulation of clinical research into the spotlight. Among the numerous difficult issues raised by these cases is the matter of the potential liability of the institutional research ethics board (REB) with respect to adverse outcomes of particular trials. Are there standards of care for REBs? What constitutes negligence on the part of an REB? What happens when there is a conflict of interest at any stage of the research approval process? This paper examines the issue of REB liability for negligence in detail. In Part I, I explain what an REB is, and what the regulatory structure for human subjects research is like in Canada. In Part II, I discuss the problems associated with REBs, such as conflict of interest, using recent cases as illustrations. I also provide an analysis of the nature of liability and tort law with respect to REBs — for example, issues of duty of care, standards, and causation — with reference to existing jurisprudence. In Part III, I consider the advantages and disadvantages of using the tort system as a means of dealing with REB negligence. Finally, I discuss the recent regulatory reform initiatives in both

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¹ Daniel J. Powell, “Using the False Claims Act as a Basis for Institutional Review Board Liability” (2002) 69 U. Chi. L. Rev. 1399 at 1399 (LEXIS).

² Mary R. Anderlik & Nanette Elster, “Currents in Contemporary Ethics” (2001) 29 J.L. Med. & Ethics 220 (LEXIS).

³ *Gelsinger v. Trustees of the University of Pennsylvania* (Phila. Cnty. Ct. of C.P. filed September 18, 2000), online: Sherman, Silverstein, Kohl, Rose and Podolsky Law Offices <<http://www.sskrplaw.com/links/healthcare2.html>>.

Canada and the US, and examine the various recommendations that have been set forth with respect to improving REB functioning and accountability.

Part I: REBs and The Regulation of Clinical Research in Canada

a) Regulation in Canada: The Historical Context

Research involving human subjects has changed dramatically over the last half-century.⁴ Evidence of appalling experiments on human beings conducted by the Nazis, together with other reports of gross misconduct from around the world, prompted the creation of ethical guidelines for research with human subjects. The first international document stipulating voluntariness and informed consent as prerequisites for medical research on human subjects was the *Nuremberg Code*, established in 1948.⁵ This was followed by the World Medical Association's *Declaration of Helsinki* in 1964, which articulated that informed consent from research participants is obligatory, and that the risks of research should not exceed the benefits.⁶ In 1974, largely in response to fallout from the Tuskegee Syphilis Study⁷, the US government passed the *National Research Act*, which created the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.⁸ In 1979, the Commission released the *Belmont Report*, which pronounced three guiding principles for research: respect for persons, beneficence, and justice.⁹ The *Nuremberg Code*, the *Declaration of Helsinki*, and the *Belmont Report* are the foundations for most laws and standards governing the protection of human subjects in medical research, including those of Canada.

⁴See generally Kathleen Cranley Glass & Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d. ed. (Toronto: Butterworths, 2002) 459.

⁵*The Nuremberg Code* (1947) in Alexander Mitscherlich & Fred Mielke, *Doctors of infamy: the story of the Nazi medical crimes* (New York: Schuman, 1949) [*Nuremberg Code*].

⁶World Medical Association, *Declaration of Helsinki* (1964, rev 1975, 1983, 1989) in Warren T. Reich, ed., *Encyclopedia of Bioethics* (New York: Simon & Schuster Macmillan, 1995) at 2765-7 [*Declaration of Helsinki*].

⁷The Tuskegee study was carried out by the United States Public Health Service from 1932 to 1972 in Tuskegee, Alabama. Physicians purposefully failed to inform four-hundred African American males that they were infected with syphilis. These men were followed for a period of 40 years so investigators could study the "natural" course of the disease. Many of these men died of the disease throughout the course of the study. In 1973, the study became known to the public, and was subsequently shut down. See James H. Jones, *Bad Blood: The Tuskegee Syphilis Experiment* (New York: Free Press, 1993).

⁸Pub. L. No. 93-348, 88 Stat. 342 (1974) (LEXIS).

⁹National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, Md.: The Commission, 1978) at 1-8 [*Belmont Report*].

b) Regulation in Canada: Different Schemes for Different Jurisdictions

While a more cohesive regulatory structure for research is currently under development, medical research involving human subjects in Canada is currently regulated differently across different jurisdictions due to the constitutional allocation of matters of health care, and property and civil rights to the provinces. Regulation “encompasses state control through legislation, regulation by guidelines of funding agencies and self-regulation through professional and industry guidelines and codes”.¹⁰ Biomedical research in Canada is therefore not governed by one single statutory regime. In the province of Quebec, for example, experimentation with humans is regulated by articles 20 and 21 of the Civil Code of Quebec.¹¹ In the common law provinces, research is regulated indirectly through the common law rules with respect to negligence and informed consent, and the requirements of the different government funding agencies.¹²

c) The Tri-Council Policy Statement

While there is no single, official regulatory scheme governing research in Canada, research is indirectly controlled through the guidelines of government funding agencies with respect to ethics and medical research involving humans. The major funding agencies in Canada adhere to the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*.¹³ Released in 1998, the *Tri-Council Policy Statement* embodies the principles articulated in the *Nuremberg Code*, the *Declaration of Helsinki* and the *Belmont Report*, and is the result of a collaborative effort between the Medical Research Council (now the Canadian Institute for Health Research, or CIHR), the Natural Sciences and Engineering Council (NSERC) and the Social Science and Humanities Research Council (SSHRC).¹⁴ These government funding agencies will consider only those proposals which comply with the *Tri-Council Policy Statement* when making funding decisions.

The *Tri-Council Policy Statement* is based on guiding ethical principles that express “common standards, values, and aspirations of the research community.”¹⁵ These include respect for human dignity, respect for free and informed consent, respect for vulnerable persons, balancing harms and benefits, minimizing harm,

¹⁰Nicholas Pengelley & Trudo Lemmens, “Research Involving Humans: Ethics Law and Regulation” (2002), online: Bora Laskin Law Library, University of Toronto <<http://www.law-lib.utoronto.ca/resguide/medical.htm>>.

¹¹ Arts. 20 & 21 C.C.Q.

¹²Lemmens, *supra* note 10.

¹³*Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 2003) [*Tri Council Policy Statement*].

¹⁴*Ibid.*

¹⁵*Ibid.* at i.5.

and maximizing benefit. The *Tri-Council Policy Statement* emphasizes respect for justice, equality, and confidentiality.

d) Research Ethics Boards

Article 1.1 of the *Tri-Council Policy Statement* stipulates that all proposals for research involving human subjects must be submitted to local, institutional Research Ethics Boards (REBs) for review.¹⁶ All research ethics boards must include at least five members. For biomedical research, one member must be knowledgeable in ethics; two must possess expertise in the fields of research covered by the board; one must be familiar with the relevant law; and at least one member must be from the general community, and must not be affiliated with the institution.¹⁷ The function of the REB is to help ensure that the ethical principles articulated in the *Tri-Council Policy Statement* are adhered to in all research conducted with human beings. According to Article 1.9, REBs must meet face-to-face to review research proposals. Further, REB review must be based on fully detailed research proposals (and, where applicable, progress reports). Article 1.6 emphasizes that an REB should adopt a proportionate approach to ethics assessment, based on the general principle that “the more invasive the research, the greater should be the care in assessing the research.”¹⁸ Proportionate review is intended to ensure that the most ethically challenging research undergoes the most “intensive scrutiny”. As per Article 1.2, institutions “must respect the authority delegated to the REB...[and] may not override negative REB decisions reached on grounds of ethics without a formal appeal mechanism as set out below.”¹⁹ With respect to continuing review, this is generally only required for research posing significant risks. In such cases, the REB should receive reports on the progress of any research project at predetermined intervals. These reports should include an assessment of “how closely the researcher and the research team have complied with the ethical safeguards initially proposed.”²⁰

Part II: REBs: Problems, Issues and Tort Law

a) What has Gone Wrong? Recent Cases

Four recent, highly publicized incidents involving research mishaps in the US and Canada have “sharpened the focus” on the activities of research ethics committees approving proposals.²¹ With respect to the three American cases, two involved the death of a research subject, and all three were found to have violated

¹⁶ *Ibid.* at Art. 1.1.

¹⁷ *Ibid.* at Art. 1.5.

¹⁸ *Ibid.* at Art. 1.9.

¹⁹ *Ibid.* at Art. 1.2.

²⁰ *Ibid.* at 1.11.

²¹ Powell, *supra* note 1 at 1403.

US federal guidelines with respect to human research protection. The fourth case, the Canadian case involving Nancy Olivieri, provides insight into problems related to conflicts of interest and research ethics boards in the Canadian context.

i) The Gelsinger Case

In the *Gelsinger* case, as described above, it was alleged that the investigator's financial ties to the protocol in question may have jeopardized the integrity of the project.²² Moreover, the potential conflict of interest had not been revealed to Jesse Gelsinger or his family. While the Gelsingers later settled out of court with the University for an undisclosed amount, the case brings to light the problems associated with conflict of interest in biomedical research.²³ Moreover, while the Institutional Review Board (the American equivalent of the REB) was not specifically named in the *Gelsinger* complaint, University of Pennsylvania bioethicist Arthur Caplan, who was consulted in establishing the study protocol, was indeed named.²⁴ The case raises issues about the scope of liability in research-related complaints, and can therefore be applied to the issue of research committee liability.

ii) The Robertson Case

The second major event was the *Robertson* case at the University of Oklahoma Health Sciences Centre-Tulsa.²⁵ In 1997, the Centre's Institutional Review Board (IRB) had approved a Phase I cancer vaccine study intended for patients with melanoma.²⁶ A large proportion of the individuals participating in the trial had been unresponsive to all standard treatment measures, and had been given a prognosis of two to six months.

Beginning in 1999, the trial's nurse coordinator advised the IRB chair of problems with "quality control, patient care, reporting of adverse events, and adherence to study protocol".²⁷ In the summer of 2000, the Office of Human Research Protection (OHRP) found that the IRB chair had unilaterally approved retroactive changes to the research protocol, and that continuing review had not been properly carried out. As well, due to their terminal illness, many of the subjects qualified as "vulnerable" persons, but the IRB "failed to ensure that additional safeguards were included in the study."²⁸ Moreover, the consent forms approved failed to adequately describe the study's risks, and "overstated its foreseeable

²² Anderlik & Elster, *supra* note 2 at 220.

²³ *Ibid.*

²⁴ *Ibid.* However, Caplan was later dropped from the suit.

²⁵ *Robertson v. McGee*, No. 01CV00G0H(M) (N.D. Okla. filed January 29, 2001), online: Sherman, Silverstein, Kohl, Rose and Podolsky Law Offices <<http://www.sskrplaw.com/gene/robertson/complaint.html>> [*Robertson*].

²⁶ Anderlik & Elster, *supra* note 2 at 221.

²⁷ *Robertson*, *supra* note 25; Anderlik & Elster, *supra* note 2 at 221.

²⁸ Anderlik & Elster, *ibid.*

benefits.”²⁹ Problems were also uncovered with respect to privacy and confidentiality.

Participants in the trial filed suit in January of 2001. All members of the IRB that approved the study were named in the complaint as defendants, a move described as “unprecedented”.³⁰ While it is not unheard of for an IRB to be named in a legal action, never before had the members each been named individually. It was alleged that the IRB had behaved in a negligent manner with respect to their review and approval of the protocol.

iii) The Ellen Roche Case

A third high profile incident occurred in 2001 at Johns Hopkins University. Ellen Roche, a healthy 24 year-old volunteer, died while taking part in a study on asthma.³¹ She had inhaled an unapproved substance used to induce asthmatic symptoms. The OHRP accused the IRB of:

...significant violations of the federal regulations. Specifically, the IRB failed to obtain adequate information to evaluate the risks of the research protocol, did not sufficiently review ongoing research, failed to fully consider the needs of vulnerable subjects, and kept insufficient records.³²

As a result, all research funded by the federal government was shut down at the University until officials could devise a plan to attend to the findings of the OHRP.

iv) The Nancy Olivieri Case

The fourth incident, which received attention worldwide, occurred in Canada at the Hospital for Sick Children in Toronto. Physician and researcher Nancy Olivieri contracted with the pharmaceutical company Apotex to study deferiprone, a drug intended for the treatment of thalassemia. The contract included a clause preventing the release of findings without prior authorization by the company.³³ Partway into the trial, Dr. Olivieri became concerned that the drug had serious adverse effects, a claim which was dismissed by Apotex. The drug company terminated Olivieri, who went on to publish her findings in the *New England Journal of Medicine*.³⁴ While the

²⁹Vida Foubister, “Clinical trial patients sue IRB members” *American Medical News* (26 February 2001), online: American Medical Association <<http://www.ama-assn.org/amednews/2001/02/26/prsb0226.htm>>.

³⁰*Ibid.*

³¹“Report on a Research Death Faults Review Board” *New York Times* (31 August 2001) A16.

³²Powell, *supra* note 1 at 1404.

³³Robert A. Phillips & John Hoey, “Constraints of Interest: Lessons at the Hospital for Sick Children” (1998) 159 *Can. Med. Assn. J.* 955 at 955.

³⁴N.F. Olivieri *et al.* “Long-term safety and effectiveness of iron-chelation therapy with deferiprone for thalassemia major” (1998) 339 *New Engl. J. Med.* 417.

REB did require that Olivieri change the contract to reflect her new concerns regarding the drug, it had not examined the contract during the initial approval of the trial. In the *Report of the Committee of Inquiry on the Case Involving Nancy Olivieri*, the authors indicate that:

The Research Ethics Board (REB) of HSC approved protocols ... without reviewing the associated contracts to ensure that the contracts did not breach ethical standards or norms. [The contract] had an inappropriate confidentiality clause — it specified that Apotex had the right to suppress information during the trial and for one year after its termination. The REB also did not require inclusion of provisions in the protocol to protect the interests of trial participants in the event of premature termination by the industrial sponsor.³⁵

The Nancy Olivieri case, like the *Gelsinger* case, highlights the problems that can arise with respect to conflicts of interest in a clinical trial. Commentators on the Olivieri debacle have emphasized the need for review by REBs of industry contracts.³⁶

b) Negligence and REBs

Scholars suggest that the most likely cause of action in a suit against an REB is one based in negligence.³⁷ The components of a successful negligence claim include establishing a duty of care, a breach of the relevant standard(s) of care and causation. In a research related lawsuit, negligence could be alleged on several bases. These include failing to ensure informed consent standards were adequately met; failing to ensure proper screening of subjects; negligently approving unethical study designs; procedural negligence; and finally, failing to disclose conflicts of interest.

c) Elements of Negligence: Establishing a Claim

i) Duty of Care

Does an REB have a legal duty of care towards individual subjects in a clinical trial? In establishing duty of care, courts usually turn to the concepts of foreseeability and reasonableness. With respect to REBs, it is clear that there exists a duty of

³⁵ Jon Thompson, Patricia Baird & Jocelyn Downie, *Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto, and Apotex Inc.* (Ottawa: Canadian Association of University Teachers, 2001) at 25, online: Dalhousie University <www.dal.ca/committeeofinquiry> [*Report on Nancy Olivieri*].

³⁶ Phillips & Hoey, *supra* note 33. See also Jennifer L. Gold, Michelle S. Laxer & Paula A. Rochon, "Monitoring Contracts with Industry: Why Research Ethics Boards Must be Involved" (2003) 11:3 Health L. Rev. 13.

³⁷ Anderlik & Elster, *supra* note 2 at 224. See also Sharon Hoffman, "Continued Concern: Human Subject Protection, the Institutional Review Board, and Continuing Review" (2001) 68 Tenn. L. Rev. 725 at 745 (LEXIS).

care toward research participants. The purpose of an REB is to ensure that research with human subjects is conducted in an ethical fashion; its very existence is to protect subjects from wrongful conduct by investigators. It is therefore foreseeable that an REB would have research subjects within its reasonable contemplation. Indeed, in *Weiss v. Solomon*, the Quebec Superior Court held that research committees are responsible for the safety of subjects, including proper disclosure of risks and other relevant information.³⁸ Freedman and Glass suggest that two distinct elements of responsibility may be detected in the judgment: the responsibility to detect any risks posed by the research, and the responsibility to act to remove or minimize those risks.³⁹ Therefore, it is plain that a duty of care towards research participants by REBs exists in Canada.

ii) Standard of Care

In the United States, federal regulations governing research with human subjects “arguably set forth the standard of conduct to which IRBs should be held.”⁴⁰ While research is largely not directly regulated through legislation in Canada, the guidelines set forth by the *Tri-Council Policy Statement* clearly provide a set of standards to which REBs may be held in this country. Further, it is possible a court would consider codes of conduct such as the *Declaration of Helsinki* or the *Nuremberg Code* in determining whether the standard of care for research review has been breached.

The *Tri-Council Policy Statement* sets the standard to which REBs will be held in Canada. Guidelines are provided on everything from procedural matters, such as meetings and attendance and record keeping, to more substantive issues such as conflicts of interest and review for ongoing research. The guidelines indicate that REBs must ensure that the mechanisms in place for obtaining informed consent are adequate. They must also make certain that potential subjects are presented with “an acceptable balance of potential benefits and risks”.⁴¹ As well, the REB must make sure that the process for selecting research participants is equitable. According to the *Tri-Council Policy Statement*, REBs are to be guided by a standard of “minimal risk”. The standard of minimal risk is generally defined as follows:

if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of

³⁸ *Weiss v. Solomon*, [1989] R.J.Q. 731(C.S. civ.)(QL) [*Weiss*].

³⁹ B. Freedman & Kathleen Cranley Glass, “Weiss v. Solomon: A Case Study in Institutional Responsibility for Clinical Research” (1990) 18 *Law, Medicine & Health Care* 395.

⁴⁰ Anderlik & Elster, *supra* note 2 at 224.

⁴¹ Charles Wiejer, “Regulation of Research”, online: [researchethics.ca <http://www.reb.ca/assets/documents/educational/UnitI.htm>](http://www.reb.ca/assets/documents/educational/UnitI.htm).

scrutiny and greater provision for the protection of the interests of prospective subjects.⁴²

Thus, while there is no legislated standard of care in Canada with respect to research review, the guidelines of the *Tri-Council Policy Statement* clearly articulate standards to which a Canadian REB would likely be held.

iii) Causation

In order to succeed in a negligence suit, a plaintiff must also be able to demonstrate that there is a causal link between the actions of the defendant and the injury in question. This may be difficult to demonstrate if the case involves subjects who were ill (as is often the case), since it may not be possible to demonstrate conclusively that it was the research, and not the underlying illness itself, that led to the injury.⁴³ It would need to be adequately demonstrated that the intervention accelerated or aggravated the existing illness, resulting in injury.

It may also need to be demonstrated that the deviation of the REB was so proximate to the injury that it may be held responsible. It is possible that the actions of an REB may be found to be too remote to be considered causally linked to the plaintiff's injury. The actions of the study investigator and the other researchers or clinicians involved in a trial may be viewed by a court as "breaking" the chain of causation. However, it is much more likely that a court may consider the investigator's actions in a study to follow *directly* from the approval granted by the research ethics board, and therefore be causally linked to any injuries sustained by subjects in that study.

d) Bases for Negligence Against REBs

i) Failure to Ensure Proper Informed Consent

The law requires that the consent of research participants be obtained prior to entering a research project. At common law, "treating a patient on the basis of inadequate informed consent constitutes negligence."⁴⁴ As well, statutes such as Ontario's *Health Care Consent Act, 1996* describe the necessary components of consent.⁴⁵ Therefore, individuals who are recruited to participate in clinical research must be informed of "the nature and extent of the known risks of participation, the possibility that participation may present unknown risks, and the intended benefit of the study to participants and others."⁴⁶ According to Article 2.2 of the *Tri-Council*

⁴² *Tri-Council Policy Statement*, *supra* note 13 at 1.5.

⁴³ Anderlik & Elster, *supra* note 2 at 225.

⁴⁴ Edward Etchells *et al.*, "Bioethics for Clinicians: Consent" (1996) 155 *Can. Med. Assn. J.* 177 at 178.

⁴⁵ *Health Care Consent Act, 1996*, S.O. 1996, c 2, Sch. A, s. 11.

⁴⁶ C. Weijer, B. Dickens & E. M. Meslin, "Bioethics for Clinicians: Research Ethics" (1997) 156 *Can. Med. Assn. J.* 1153 at 1155.

Policy Statement, free and informed consent must be “voluntarily given, without manipulation, undue influence, or coercion.”⁴⁷

The duty of a clinician to obtain consent from a patient is well established in Canadian jurisprudence. In 1980, the Supreme Court of Canada handed down its judgment in the case of *Reibl v Hughes*.⁴⁸ The case concerned a surgeon who had failed to inform his patient of the risk of stroke during a medical procedure. The Court decided that the relationship between surgeon and patient gives rise to a duty of disclosure of all material risks of a given procedure. It was also established that “merely because medical evidence established the reasonableness of a recommended operation does not mean that a reasonable person in the patient’s position would necessarily agree to it.”⁴⁹ The test for informed consent, therefore, moved away from a practitioner-determined standard to a patient-based one. After *Reibl*, it was no longer possible for a doctor to decide for herself, based on professional norms or standards, what it was in the best interests of a patient to know. As was later stated in *Ciarlariello v. Schachter*, “although expert medical evidence on this issue is still relevant, it is no longer decisive in determining whether or not sufficient information was given to a patient...”⁵⁰ The standard, then, as articulated in *Reibl*, and later refined in *Arndt v. Smith*, is that the physician must consider what information a reasonable person in the patient’s position would require to make an informed choice; a “modified objective” test.⁵¹

In *Halushka v. University of Saskatchewan*, the duty to obtain informed consent was extended to the research context. Now, an investigator who fails to disclose information relevant to the choice a person is asked to make may be found negligent.⁵² The same standard was found by the Quebec Superior Court to be applicable to a research ethics board in *Weiss*.⁵³

1. *Halushka v. University of Saskatchewan*

The leading Canadian case on informed consent and human research participation is *Halushka*.⁵⁴ The plaintiff, Walter Halushka, was a healthy student at the University of Saskatchewan who volunteered to participate in a research study on a new medication. He signed a consent form, but had not been informed that the drug under study was a new anaesthetic the researchers knew very little about.⁵⁵ Further, while he had been informed that a catheter would be inserted into his vein,

⁴⁷ *Tri-Council Policy Statement*, *supra* note 13 at Art. 2.2.

⁴⁸ [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1, 33 N.R. 17 [*Reibl* cited to D.L.R.].

⁴⁹ *Ibid.* at 16.

⁵⁰ *Ciarlariello v. Schachter* (1993), 100 D.L.R. (4th) 609 at 617 (S.C.C.).

⁵¹ *Arndt v. Smith*, [1997] 2 S.C.R. 539, 148 D.L.R. (4th) 48.

⁵² (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) [*Halushka*].

⁵³ *Weiss*, *supra* note 38.

⁵⁴ D. Pullman, “Subject Comprehension, Standards of Information Disclosure and Potential Liability in Research” (2001) 9 Health L.J. 113 at 115. See also *Halushka*, *supra* note 52.

⁵⁵ Pullman, *ibid.*

the investigators neglected to mention that this catheter would be pushed through his heart during the course of the experiment. When this procedure was performed, the student went into cardiac arrest, and subsequently suffered brain damage that left him with reduced mental ability. The judge held in favour of Halushka, stating that research participants are entitled to “full and frank disclosure” of all “facts, probabilities and opinions” that a reasonable person would wish to consider prior to providing consent.⁵⁶ This case established that consent to research participation will be held by the court to an even higher standard than consent to treatment.

2. *Weiss v. Solomon*

In *Weiss*, a surgeon recommended to a 62-year-old patient, who had undergone cataract surgery, that he consider participating in a study on the ability of an eye drop solution to diminish the retinal swelling that tends to follow that operation. The patient decided to volunteer for the study, which required him to undergo three angiograms involving the injection of dye. The consent form, in its final draft as approved by the institutional REB, stated that:

Some patients may develop a minor allergic reaction to this injection, but the majority of patients have no side effects...I have been told of the possible side effects and unfavourable reactions that can happen and what my alternatives are. I have had a chance to ask questions to the doctor, and have received acceptable answers.⁵⁷

Unfortunately, within seconds of being injected with the dye for the angiograms, the patient’s blood pressure dropped and he subsequently died.

The man’s wife and children brought a lawsuit against the recruiting surgeon, the investigator and the hospital. In his decision, the judge indicated that the investigator and the hospital (in the role of its REB) had the responsibility to protect research participants and to inform all prospective subjects of “the nature of the study and the risks they will undergo.”⁵⁸ The risk of death was known, but had not been disclosed to the patient. The judge stated that the REB and the investigator had both failed to meet the requisite standard.

3. REBs and Informed Consent

Halushka and *Weiss* both demonstrate that the standard for informed consent in the research context is high in Canada. In *Halushka*, Justice Hall emphasizes the fact that because there is no so-called therapeutic privilege involved in research, the standard for informed consent is in fact higher for research than for mere treatment. While that case does not make reference to REBs, it establishes that with respect to

⁵⁶ *Halushka*, *supra* note 52 at 444.

⁵⁷ *Weiss*, *supra* note 38 at paras. 28-29. See also Freedman & Glass, *supra* note 39 at 396.

⁵⁸ Freedman & Glass, *ibid.* at 396.

research, investigators are held to a very high standard of disclosure. It was also a stepping-stone for the ensuing decision in *Weiss*, in which REBs were held to the same high standard as investigators. Justice De Blois stated in that judgment:

The Research Committee of the hospital must be aware of that which its participants and members know. Even if the consent form to be obtained from the research subjects does not fall under any regulations, we should ask ourselves why the risk...was minimized in the consent form, whereas it should have been explained in detail (Translated from the French).⁵⁹

In *Guckin v. Nagle*⁶⁰, a recent suit filed in the US, IRB members at a hospital were accused of negligence on a number of grounds, including failing to meet requisite standards for informed consent. It is alleged that in that case, a woman agreed to an experimental procedure after she was told that even if the operation was not successful, it would not leave her any worse off. In fact, the procedure left the plaintiff with a lack of sensation or control over her bowel movements. According to attorney Alan Milstein, the consent forms neglected even to mention the terms "experiment" or "clinical trial", referring only to a "study".⁶¹ Milstein stated: "All they say is study...[Y]ou can study aspirin to see how quickly it cures headaches. That doesn't make it a clinical trial."⁶²

Milstein also suggests that, in general, the nature of informed consent and decision-making in treatment as opposed to research is very different. In the treatment context, an individual is required to make a decision related to his or her own benefit. The information provided assists the patient in making a therapeutic decision. In the clinical trial setting, however informed consent is "to ensure that someone understands that they are choosing to participate in an experiment not only for their own benefit but for society's benefit. They are being asked to make a *moral choice*, not simply a medical decision."⁶³

In *Grimes v. Kennedy Krieger Institute Inc.*, another incident involving Johns Hopkins University, the IRB approved a study intending to investigate the effect of lead exposure on children.⁶⁴ The study involved the exposure of young children to lead in the home, and researchers "encouraged" landlords involved in the study to rent to families with children.⁶⁵ Researchers then measured the lead levels in the children's blood, and compared them with the amount of lead dust present in the

⁵⁹ *Ibid.* at 399 quoting *Weiss*, *supra* note 38 at para. 116.

⁶⁰ (Pa. Ct. Com. Pl., No. 1425, complaint filed 6/11/02).

⁶¹ Susan Carhart, "Lawsuit Claims Investigator, IRB Liability In Study of Fecal Incontinence Control Device", online: Sherman, Silversteinm Kohl, Rose and Podolsky Law Offices <<http://www.sskrplaw.com/publications/6-11irb.html>>.

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ 366 Md. 29, 782 A.2d 807 (Md. 2001)

⁶⁵ Powell, *supra* note 1 at 1405.

home. The IRB involved failed to require that the research team obtain informed consent from the families, and in fact actually “suggested word modifications in the research protocol that would help hide the fact that children were acting as a control group.”⁶⁶ The Maryland Court of Appeals recently issued their “landmark decision” on this case, reversing the judgment of a district court that had found for the defendants.⁶⁷ The case was remanded to trial to determine if the University is liable to the study participants.

4. Special Considerations: Conflict of Interest and Informed Consent

Conflict of interest is a growing problem with respect to full disclosure in the research context. A recent study on university-industry partnerships in Canada indicated that the amount of research funded by private companies jumped to 12% in 1996 from 2% twenty years earlier.⁶⁸ When an investigator has a financial interest in the outcome of a clinical trial, he or she has tremendous incentive to produce results. In the *Gelsing* case, Dr. James Wilson, the director of the University of Pennsylvania’s Institute for Gene Therapy, had financial ties in the order of US\$13.5 million to the company whose product was the subject of the trial.⁶⁹ It is reasonable to believe, then, that an investigator may be reluctant to disclose any potential conflicts of interest to an REB, for fear that the research will be shut down or delayed, affecting his or her personal finances.

As indicated above, the standard for informed consent in the research setting is very high. Human research participants should thus have access to all information that may cloud the objectivity of the investigator. An investigator’s financial investment in a clinical trial is relevant to the research subject’s decision of whether or not to participate in a given project, and should therefore be known to any potential research subject. Frances Miller writes: “Most people would consider knowledge of the divided loyalties such an economic conflict engenders to be material to their informed consent to participate in the study.”⁷⁰ It follows from this that it is within the scope of duty of REBs to ensure all information regarding conflicts of interest is provided when a protocol is submitted. The REB then has the responsibility to ensure this information is passed along to the subjects themselves.

There are those, however, who believe that informed consent and full disclosure are not sufficient means of dealing with the problem of conflict of

⁶⁶ *Ibid.*

⁶⁷ Hazel Glenn Beh, “The Role of Institutional Review Boards in Protecting Human Subjects: Are we Really Ready to Fix a Broken System?” (2002) 26 *Law & Psychol. Rev.* 1 (LEXIS).

⁶⁸ Anne Cote, “Adequate Protection for the Autonomous Research Subject? The Disclosure of Funding and Commercialisation in Genetic Research Trials” (2002) 28 *Man. L. J.* 347 at 349 (LEXIS).

⁶⁹ Frances H. Miller, “Trusting Doctors: Tricky Business When it Comes to Clinical Research” (2001) 81 *B.U.L. Rev.* 423 at 426 (LEXIS).

⁷⁰ *Ibid.* at 440.

interest. The dean of Harvard Medical School, Dr. Joseph Martin, believes that in no circumstance should an investigator receive a supplemental income from the results of his or her research.⁷¹ In an article in the *New England Journal of Medicine*, Martin stated that even full disclosure would not adequately protect the interests of research subjects.⁷² Similarly, the American Society for Gene Therapy has taken the position that researchers in gene therapy should “own no equity, stock options, or other interests in the companies whose products they are evaluating through clinical trials.”⁷³

Whether or not a Canadian court would view disclosure of conflicts of interest as sufficient to excuse an REB from liability is unknown. However, the matter is currently under review by the Interagency Advisory Panel on Research Ethics, and will likely receive attention as the planning for a Canadian system of oversight for the governance of research involving human subjects continues.⁷⁴

ii) Failure to Ensure the Adequate Screening of Subjects

The common law concept of the “reasonable practitioner” dictates that a physician has a duty to “undertake research with skill and diligence, meeting a certain standard, that of a reasonable and prudent researcher in the circumstances.”⁷⁵ In *Weiss*, the protocol’s screening process did not require that a general physical be conducted on subjects before participation in the study. The plaintiffs claimed that the patient should not have been included in the study due to his cardiac history, and that this may have been revealed had he been required to undergo a physical exam.⁷⁶ The judgment in *Weiss* states that the patient should, indeed, have been screened. Potential participants found to have a contraindicating condition should have either been excluded from the study, or, if included, been very carefully monitored.⁷⁷

Similarly, in the *Gelsing* case, an investigation following Jesse’s death concluded that he should never have been allowed to enrol in the trial, since he did not meet the criteria for participation.⁷⁸ Officials of the Food and Drug Administration reported that Jesse should have been deemed ineligible for participation in the

⁷¹ *Ibid.* at 441.

⁷² J.B. Martin & D.L. Kasper, “In whose best interest? Breaching the academic-industrial wall” (2000) 343 *New Engl. J. Med.* 1646.

⁷³ Miller, *supra* note 69 at 441.

⁷⁴ “Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans” (2002), online: Interagency Advisory Panel on Research Ethics (PRE). <http://www.pre.ethics.gc.ca/english/pdf/Governance_01.pdf>[PRE].

⁷⁵ Freedman & Glass, *supra* note 39 at 396.

⁷⁶ *Ibid.*; *Weiss*, *supra* note 38 at paras. 3-7.

⁷⁷ Freedman & Glass, *ibid.* at 397; *Weiss*, *ibid.* at para. 96.

⁷⁸ Sheryl Gay Stolberg “FDA Officials Fault Penn Team in Gene Therapy Death” *New York Times* (9 December 2001) A22.

clinical trial, and should not have undergone the gene therapy, as his liver was not functioning well enough at the time of treatment.⁷⁹

The duty of the REB therefore includes ensuring that investigators properly screen all subjects before they are allowed to participate in a given study. People with known or suspected contraindications to participation should be excluded, or, if deemed appropriate, enrolled with strict monitoring and supervision, including any necessary safety precautions. Should an REB fail to ensure that the investigators are adequately screening potential subjects, it may be found liable.

iii) Negligent Approval of Study Design

In the *Robertson* case, all members of the IRB at the University of Oklahoma Sciences Centre at Tulsa who were involved in the approval of the cancer vaccine protocol were named in the lawsuit filed by the plaintiffs.⁸⁰ The plaintiffs' attorney, in explaining why IRB members were included in the complaint, stated "federal regulatory agents made specific reference to the inadequate job of supervision that the IRB did."⁸¹ Similarly, in the *Guckin* complaint, IRB members are accused of negligence for approving the design of the study. The complaint states that the IRB defendants had a duty to protect clinical trial subjects from ethically questionable research practices. In the *Gelsing* case too, the OHRP criticized the IRB, citing numerous deficiencies regarding their approval of the gene therapy trial.⁸² These included a failure to obtain sufficient information in reviewing the protocol, approval of a poor consent form that falsely implied that the study was therapeutic in nature, and inadequately described risks in view of similar research conducted on animals.⁸³

In the Ellen Roche incident at Johns Hopkins, officials reported that the IRB had failed to obtain adequate information with respect to evaluating the risks associated with the research protocol.⁸⁴ The substance inhaled by Ms. Roche was hexamethonium, which was not FDA approved for human use or for administration via inhalation.⁸⁵ Moreover, it was uncovered that the substance had known lung toxicity. Had the IRB done even a routine MEDLINE literature search, they would have discovered this fact.⁸⁶ Further, it was claimed that the IRB had "failed to obtain sufficient information regarding the source, purity, quality, and method of preparation and delivery of the hexamethonium used in the research."⁸⁷ It was also stated by officials that the IRB had approved an informed consent form that "failed to

⁷⁹ *Ibid.*

⁸⁰ Foubister, *supra* note 29.

⁸¹ *Ibid.*

⁸² Beh, *supra* note 67 at 31.

⁸³ *Ibid.*

⁸⁴ *Ibid.* at 32.

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

adequately describe the research procedures...and the reasonably foreseeable risks and discomforts.”⁸⁸

Research ethics committees are charged with the duty to protect research participants from harm. If the review conducted by an REB is inadequate or deficient, that duty has been breached. In light of the high standards imposed on REBs by the *Tri-Council Policy Statement* and the decision in *Weiss*, a board that fails to take the necessary steps to ensure that the protocols they are approving are ethically and scientifically sound could very well be found negligent by a court.

iv) Procedural Negligence

Negligence against an REB could also be alleged on the grounds that there were gross violations of procedural standards for review. In the *Roche* case, federal investigators as well as external reviewers appointed by the university found numerous problems with Johns Hopkins’ IRB system. Most notably, it was discovered that IRB members failed to review research protocols at a convened meeting.⁸⁹ It was stated that the system “limits, by its design, active discussion by the full committee, and loses the expertise that committee members bring to review.”⁹⁰ Further, it was uncovered that minutes had not been transcribed by the IRB for the year and a half prior to the investigation. The external review committee wrote:

The protocol review process is grossly inadequate and does not conform to current standards. Most importantly, there is no required discussion by the whole IRB of each proposal. Indeed, there was no such discussion of Dr. Togias’ proposal. The minutes were not transcribed in a timely fashion so as to permit their use in preparing the letter to the PI. At the time of the writing of this report, they are still not available.⁹¹

Procedural problems were also uncovered in the *Robertson* and *Gelsing* cases. In the *Robertson* investigation, the OHRP established that not only had the IRB failed to conduct “substantive and meaningful continuing review” for that trial, but in general “‘regularly’ failed to satisfy requirements for continuing review for ‘essentially all’ protocols.”⁹² Continuing review, which is required in clinical trials according to US federal regulations, is aimed at protecting research subjects by periodically ensuring that researchers are complying with the protocols as they were approved by the IRB. It was similarly uncovered in the *Gelsing* probe that there had been no continuing review of the study, which in that case “could have revealed

⁸⁸ *Ibid.*

⁸⁹ Letter from Samuel Hellman, Chair, External Review Committee, to William R. Brody, President, Johns Hopkins University (August 8, 2001), online: Johns Hopkins Medicine <www.hopkinsmedicine.org/external.pdf> at 4.

⁹⁰ *Ibid.*

⁹¹ *Ibid.* at 7.

⁹² Anderlik & Elster, *supra* note 2 at 221.

the serious side effects of treatment suffered by other research participants and might have led to a suspension...before [Jesse's] death."⁹³

In Canada, the *Tri-Council Policy Statement* clearly states at Article 1.9 that REBs must meet face-to-face to review research proposals.⁹⁴ Therefore, any REB that fails to have meetings in person could potentially be deemed negligent for failing to meet the standards as set out by the *Tri-Council Policy Statement*. With respect to the issue of continuing review, the *Tri-Council Policy Statement* indicates that it is generally only required for research posing significant risks. In a case where it is deemed necessary, the REB should receive reports on research project's progress at predetermined intervals, including an assessment of "how closely the researcher and the research team have complied with the ethical safeguards initially proposed."⁹⁵ Hence, if it could be established that the subject matter of a given protocol was of a serious enough nature to require continuing review, an REB could be found negligent for failing to mandate it and follow up accordingly.

v) *Conflicts of Interest*

Conflict of interest is a problem not only with respect to investigators, but with respect to REB members as well. As indicated above, the proportion of research financed by private, for-profit companies increased six-fold between 1976 and 1996.⁹⁶ Those individuals sitting on committees may stand to profit from the research protocols they review, or may be reluctant to impede or criticize research they know may financially benefit their institution. In the case of *Wright v. Fred Hutchinson Cancer Research Center*⁹⁷, a trial conducted at the Center persisted in the face of evidence that it had caused the premature deaths of some 20 research participants. It was uncovered that the investigators as well as the Center may have had a financial stake in the research. While the IRB had asked about potential conflicts of interest, the project investigators had denied that any existed, and the IRB failed to follow up on the matter. It was revealed that criticism voiced by the IRB was "chilled through intimidation".⁹⁸ The lead investigator reprimanded the IRB, stating that it is their responsibility not only to consider the ethics of the research, but also to "assist the researchers and not hinder the research."⁹⁹

In Canada, a test for conflict of interest was proposed in 1988 in *Cox v. College of Optometrists of Ontario*.¹⁰⁰ In that case, an optometrist rented an office

⁹³ Hoffman, *supra* note 37 at 726.

⁹⁴ *Tri Council Policy Statement*, *supra* note 13 at Art. 1.9.

⁹⁵ *Ibid.* at 1.11.

⁹⁶ Cote, *supra* note 68 at 349.

⁹⁷ No. 01-2-008376 (Kitsap County Ct. for the State of Wash. Filed 29 March 2001), online: Sherman, Silverstein, Kohl, Rose and Podolsky Law Offices <<http://www.sskrplaw.com/gene/wright/complaint1.html>>.

⁹⁸ Beh, *supra* note 67 at 29.

⁹⁹ *Ibid.*

¹⁰⁰ (1988), 65 O.R. (2d) 461 at 463 (Ont. Div. Ct.) [*Cox*].

from an optical company for a day or two per week for \$125. The office was situated in the company's location in a shopping centre. It was separated physically from the store, and set up as an office with a reception area. The College of Optometrists of Ontario found the optometrist to be guilty of "professional misconduct on the basis of conflict of interest", and he had subsequently appealed that decision to the court for judicial review.¹⁰¹

The Court established the test for conflict of interest as "whether it can be said that no reasonable person could conclude that the prohibited private interest could influence... professional conduct."¹⁰² Thus, conflict depends not on the *actual* benefits incurred by a professional, but on the "appearance of a possibility that an interest will distort or corrupt the conscientious judgment exercised in the patient's best interests."¹⁰³ Therefore, even though the optometrist did not own the store himself, the fact that he rented space from the owner nonetheless resulted in the *appearance* of a conflict of interest. The court held that even the appearance of conflict could potentially jeopardize decision-making in the best interests of his patients.

It is apparent, then, that in the Canadian context, even the appearance of conflict would require a given REB member to excuse herself from reviewing a particular protocol. With respect to institutional pressures, the *Tri-Council Policy Statement* clearly sets out at Article 1.2 that institutions must respect the authority delegated to the REB, and cannot override that authority save in exceptional circumstances.¹⁰⁴ REBs have a duty to review research in an independent and impartial manner. An REB that fails to maintain this high standard of impartiality may therefore be found negligent. In the Nancy Olivieri case, as described above, the REB failed to review the contract between Dr. Olivieri and the drug company. The subsequent report on the matter pointed out this shortcoming, and stated that in the future REBs must be "vigilant" with respect to the examination of contracts and investigator agreements with industry.¹⁰⁵

Part III: Arguments For and Against REB Liability

While REBs in Canada are indeed currently liable for negligence as per the decision in *Weiss*, it is important nonetheless to examine the policy considerations resulting from this extension of liability. Proponents for REB liability argue that legal liability is a valid "medium through which society ultimately holds all its

¹⁰¹ *Ibid.* See also Bernard M. Dickens, "Conflicts of Interest in Canadian Health Care Law" (1995) 21 Am. J. L. & Med. 259 (LEXIS).

¹⁰² Dickens, *ibid.* at 271.

¹⁰³ *Ibid.*

¹⁰⁴ *Tri Council Policy Statement*, *supra* note 13 at Art. 1.2.

¹⁰⁵ *Report on Nancy Olivieri*, *supra* note 35 at 18 of the Report Summary.

citizens to account.”¹⁰⁶ Opponents, conversely, argue that if legal liability is routinely extended to REBs and their members, it will be difficult to find people willing to serve on them, hindering the progress of biomedical research activities. The position of each camp is discussed in turn.

a) Arguments For Liability

Anderlik and Elster writes that “given the slow pace of the response to recommendations of internal and external critics of the IRB system, lawsuits may be one of the few ways of expediting the needed changes, as fear can often be a motivating force.”¹⁰⁷ In *Brown v. Anderson County Hospital Association*, the South Carolina Supreme Court stated that “immunity fosters neglect and irresponsibility, while liability encourages the exercise of due care.”¹⁰⁸ To this end, Robin Fretwell Wilson proposes several reasons for holding ethics committees legally responsible for their actions, including that it promotes good decision-making; it compensates those who have been harmed; and it guarantees that independent and objective decisions are made.¹⁰⁹

First, liability may encourage good decision-making. The threat of legal action acts as a “consistent reminder of the importance and gravity of decisions being made”.¹¹⁰ The looming possibility of a lawsuit could have the effect of motivating REB members to devote the appropriate time and resources to making ethically and legally justifiable decisions.

Second, liability provides a mechanism through which people who have been wrongfully harmed may seek compensation. Research subjects who have sustained serious injuries as a result of their participation in a given study should have the opportunity to seek redress from the REB who negligently approved the protocol.¹¹¹ Merritt writes that in a legal system such as ours, which “couples responsibility with liability”, protecting ethics committees from legal action seems unfitting.¹¹²

Third, liability ensures that REBs make independent and objective decisions. As was observed in the *Wright* case, an REB, as an institutional entity, may “internalize and perpetuate the interests and biases of its parent hospital.”¹¹³ Further,

¹⁰⁶ Julian Savulescu, Ian Chalmers & Jennifer Blunt, “Does Setting Good Practice Standards for Research Ethics Committees Increase Their Legal Liability?” (1997) 341 *Brit. Med. J.* 1833 at 1833.

¹⁰⁷ Anderlik & Elster, *supra* note 2 at 225.

¹⁰⁸ *Brown v. Anderson County Hospital Association*, 234 S.E.2d 873, 877 (S.C. 1977).

¹⁰⁹ Robin Fretwell Wilson, “Rethinking the Shield of Immunity: Should Ethics Committees be Accountable for their Mistakes?” (2002) 14 *HealthCare Ethics Committee Forum* 172.

¹¹⁰ *Ibid.* at 177.

¹¹¹ *Ibid.* at 178.

¹¹² Andrew L. Merritt, “The Tort Liability of Hospital Ethics Committees” (1987) 60 *S. Cal. L. Rev.* 1239 at 1297 (LEXIS).

¹¹³ Wilson, *supra* note 109 at 180. See also L.S. Rosenberg, “Clinical ethicists and hospital ethics

as discussed previously, members of REBs may have individual conflicts of interests based on financial investments or personal associations with researchers. Giles Scofield, writing on hospital ethics consultants, has stated that “one need only ask who hires them, who they are accountable to, and what group they wish least to offend to appreciate how easily [they] can lose the critical distance needed to exercise...independent, objective judgment.”¹¹⁴ This statement may easily be extrapolated and applied to the question of REB liability. By rendering REBs legally accountable for their decisions, members will be forced to engage in decision-making that is objective and independent of institutional or financial interests.

b) Arguments Against Liability

Those who oppose using the tort system as a means of dealing with a problematic REB state that imposing liability will make it difficult to find volunteers willing to serve on them. Moreover, the looming threat of legal action has the potential to make REBs overcautious and hesitant to approve any research that smacks of controversy. Gary Chadwick, executive director of the Research Subjects Review Board at the University of Rochester in New York stated:

Why would I even want to risk the chance of being named in a lawsuit? With the amount of done at any major research university or academic medical centre, there will be people who have adverse events and there will be people who die. If the default is as soon as that happens the IRB gets sued, there will be no more IRBs and there will be no more research because you can't do research without IRBs.¹¹⁵

Another argument against liability is that legal actions are “an arbitrary way of setting and enforcing standards.”¹¹⁶ Lawsuits are by their very nature fact-specific, and may therefore fail to generate rules that are global in their applicability, creating a patchwork system of potentially inconsistent precedents for REBs to work with.¹¹⁷ Finally, there is no guarantee that imposing liability on REBs would have any effect on the quality of their decision-making. Studies on other areas of health care have suggested that there is little or no correlation between negligence and malpractice claims.¹¹⁸

consultants: The nature of their ‘clinical’ role” in John C. Fletcher, Norman Quist & Albert R. Jonsen, eds., *Ethics Consultation in Health Care* (Ann Arbor, MI: Health Administration Press, 1989).

¹¹⁴ Wilson, *ibid.* at 180 quoting Giles R. Scofield, “Ethics consultation: The least dangerous profession?” (1993) 2 Cambridge Qrtly Healthcare Ethics 417.

¹¹⁵ Foubister, *supra* note 29; Anderlik & Elster, *supra* note 2 at 225.

¹¹⁶ Anderlik & Elster, *ibid.*

¹¹⁷ *Ibid.*

¹¹⁸ *Ibid.* See also D.M. Studdert *et al.* “Negligent Care and Malpractice Claiming Behaviour in Utah and Colorado” (2000) 38 Medical Care 250.

Part IV: Directions for the Future

a) Canadian Reform: A System of Oversight for the Governance of Research Involving Human Subjects

Health Canada has acknowledged that the present system in Canada governing research with human subjects is “complex, decentralized and multi-sourced... it poses problems in terms of consistency of ethics review, transparency and accountability”.¹¹⁹ As discussed above, there is currently no uniform set of standards regulating research involving human subjects in Canada. The governance of research activities is “uneven with no viable monitoring system in place.”¹²⁰ The Interagency Advisory Panel on Research Ethics (PRE) has put forth a set of seven principals on which to base the development of a Canadian governance system for ethical research conduct.¹²¹

1. Transparent Consultation

The system must be developed in an open and collaborative fashion. Any consultations must be transparent, and provide for “synergistic exchanges of perspective”.¹²² It must include representatives from all major stakeholders, including government, academia, the private sector and even potential research participants themselves. Consultations should “foster critical dialogue”, allowing all parties to share their ideas and proposals.¹²³

2. Deliberative Planning

The important and serious nature of the efforts to establish uniform regulations governing human subjects research necessarily implies careful and deliberative planning. The PRE accordingly states that the development of this system should not be carried out in “an atmosphere of quick fix and crisis.”¹²⁴

3. Public Participation and Accountability

The new system should ensure not only that research subjects are protected, but that members of the public have trust in research activities in general. Accord-

¹¹⁹ Tim Flaherty, “A Canadian System of Oversight for the Governance of Research” (Feb 2002) Health Canada, Ethics Division, online: Health Canada <http://www.hc-sc.gc.ca/sab-ccs/feb2002_governance_subject_e.html>.

¹²⁰ *Ibid.*

¹²¹ PRE, *supra* note 74.

¹²² *Ibid.* at 3.

¹²³ *Ibid.*

¹²⁴ *Ibid.*

ingly, the development process must include, and be accountable to, members of the Canadian public.¹²⁵

4. *The Spectrum of Research Involving Humans*

Any system developed must protect research subjects “across the entire range of disciplines engaged in research.”¹²⁶ Therefore, the variety of research methods, and the corresponding risks to “individuals, groups, communities and collectives” must be acknowledged.¹²⁷

5. *International Perspectives*

Researchers in Canada conduct their research in a “global context”.¹²⁸ The development of the governance structure must, then, necessarily take into account various international standards with respect to human subjects research.

6. *Feasibility*

Any governance system developed must recognize the “fiscal realities of governments and institutions”, and the abilities of the research community and the general public to play a part in its administration. The PRE accordingly states “the crucial role of volunteers in the administration of ethics must be fully recognized.”¹²⁹

7. *Build Upon Available Resources and Expertise*

The process of development should make full use of any existing resources, and “build on the current foundations for governing research ethics.”¹³⁰

The Canadian government is currently evaluating the logistics and merits of a national governance system for research involving human subjects. Health Canada has accordingly commenced the process of conducting “wide-ranging consultations with stakeholders”¹³¹, and has indicated the following as the goals of a national governance system:

- Education for the broad research community and particularly education, training and certification for members of research ethics boards;

¹²⁵ *Ibid.*

¹²⁶ *Ibid.*

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ *Ibid.*

¹³⁰ *Ibid.*

¹³¹ Flaherty, *supra* note 119.

- Accreditation of research ethics boards based upon a national policy and standard that take into consideration various research methodologies, contexts, and levels of risk;
- National level review of certain types of research which may involve serious conflicts of interest, novel research, high risk research and community-based research; and
- Research into the research involving human subjects in order to provide empirical evidence for continuous review of the oversight system.¹³²

b) American Reform: Report of the Institute of Medicine

In the fall of 2002, an Institute of Medicine (IOM) committee released a set of recommendations for “overhauling the nation’s fractured system of human research protections.”¹³³ The report proposed major changes at all levels, including “comprehensive monitoring” of all research activities; an overhaul of institutional review boards; and “providing litigation-free compensation” for subjects harmed while participating in a research study.¹³⁴

The IOM report proposes establishing three separate boards to take over different functions all currently carried out by IRBs. One committee would exist to review the scientific merit of a given proposal; the second would analyze any and all conflicts of interest that could exist among investigators; and the third would be a “research ethics review board”.¹³⁵ This “ERB” would be responsible for poring over and integrating all relevant issues. The report also advises that ERBs be regional, as opposed to institutional, whenever possible. It is suggested that a regional board would be more objective than the traditional, institutional IRBs. Further, to “rebuild patient trust and ensure transparency of the process”, community members should account for no less than 25% of the composition of ERBs.¹³⁶

In addition, the IOM proposal recommends an overhaul of the consent process. The Committee Chair, Daniel Federman, explains that researchers must understand informed consent as “an ongoing practice rather than a discrete, isolated moment.”¹³⁷ He states that risks involved in a given trial must be explained continually to participants throughout the study.

¹³² *Ibid.*

¹³³ B. Vastag, “New focus on research participant protection” (2002) 288 *J. Am. Med. Assn.* 1973 at 1973. See also Institute of Medicine, “Responsible Research: A systems Approach to Protecting Research Participants” (2003), online: The National Academies Press <<http://books.nap.edu/books/0309084881/html/index.html>>.

¹³⁴ Vastag, *ibid.* at 1973.

¹³⁵ IOM, *supra* note 133 at 9.

¹³⁶ Vastag, *supra* note 133 at 1973.

¹³⁷ *Ibid.*

The third element of the proposal is the creation of a compensation scheme for participants harmed during the course of the research.¹³⁸ It is explained that since no research is completely devoid of risk, it should be recognized that those who volunteer to participate in research may infrequently be harmed. A no-fault scheme would enable injured individuals to bypass costly litigation and obtain reimbursement for "medical bills, lost wages, and other costs."¹³⁹ The IOM report suggests that the federal government consider establishing a compensation program analogous to that established by the National Childhood Vaccine Injury Compensation Act.¹⁴⁰ Alternatively, individual institutions would be responsible for compensation, likely resulting in the development of corresponding insurance programs.¹⁴¹

Conclusions

Issues pertaining to the protection of human subjects in medical research have received a growing amount of attention over the past several years. Cases such as that of Jesse Gelsinger and Ellen Roche have led many to debate the issue of whether a research ethics committee should be found legally liable for the negligent approval of a given clinical trial. While it is clearly possible given the current jurisprudence that research ethics boards and their members may in certain cases be found by a court to have incurred liability, questions remain as to whether this is the best course of action.

Canada is currently looking to establish an oversight system for the governance of research involving human subjects. Improving the research review process through education, accreditation, and standardization will clarify the role and function of REBs in Canada. Clear ethical standards and national systems of oversight are steps that must be taken if research-related tragedies like those that have occurred recently in the US are to be prevented from happening here. Anderlik and Elster write that "The ultimate goal is to integrate protection of human subjects into conceptions of good science and good medicine, so that reviews are seen as part and parcel of the process rather than an obstacle to research".¹⁴² Indeed, the reform of research governance in Canada should be motivated by a general desire to change the underlying institutional culture, making the protection of participants seem congruent with the advancement of research.

¹³⁸ IOM, *supra* note 133 at 193.

¹³⁹ Vastag, *supra* note 133 at 1973.

¹⁴⁰ IOM, *supra* note 133 at 194.

¹⁴¹ *Ibid.*

¹⁴² Anderlik & Elster, *supra* note 2 at 226.