# Research ethics approval for human and animal experimentation: Consequences of failing to obtain approval – including legal and professional liability

Tracey Tremayne-Lloyd*
Dr. Gary Srebrolow**

Tracey Tremayne-Lloyd

Dr. Gary Srebrolow

Undertaking human and animal testing raises a number of ethical and legal issues. Unlike countries such as the United States and France, Canada has no overarching statutory structure regulating ethics for human experimentation. As such, it is the task of Research Ethics Boards (REBs), tort law, provincial health legislation, Regulatory Colleges such as the College of Chiropractors of Ontario (CCO), and criminal law to protect test subjects and ensure that animal and other human experiments are conducted in a safe and socially responsible manner.

REBs have the power to refuse or revoke funding for experiments that do not meet ethical requirements. In addition to these financial considerations, investigators face

* Tracey Tremayne-Lloyd, LLB, BA, is a Health Law Lawyer (Partner) and Chair of the Health Law Group at Gardiner Roberts LLP.
** Dr. Gary Srebrolow, LLB, DDS, BSc, is a Health Law Lawyer at Gardiner Roberts LLP.
The authors wish to acknowledge the assistance of Angela Chu, Student-At-Law at Gardiner Roberts LLP.

personal and professional consequences for conducting experiments that do not conform to appropriate guidelines. Civil liability for failing to adhere to the established standard of care can include damages for negligence, battery and trespass to person. Moreover, the CCO has the authority to reprimand members and/or suspend or revoke licenses to practice. Lastly, prohibited criminal offences, such as assault, criminal negligence and cruelty to animals may also have applicability in the context of human and animal experimentation.

This article will briefly review the REB system and then turn to the legal and professional liability that can arise from human and animal testing. In particular, this article will discuss an investigator's standard of care and the heightened requirements for obtaining informed consent when conducting human testing which has no therapeutic benefit for a research subject.

## Research Ethics Board Review

REB reviews are generally only conducted where the test will be funded by an organization that requires ethics review. If an investigator is able to fund research by alternative means, it is possible to avoid a REB review altogether.

Most organizations with REBs follow similar sets of ethical guidelines. If, for example, an investigator is receiving federal research funds from the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), or the Social Sciences and Humanities Research Council of Canada (SSHRC), he or she *must* certify that the experiment is in compliance with the *Tri-Council Policy Statement* – an ethics guideline on research involving humans.[1] Private organizations that fund medical research typically follow international guidelines, such as those of the Declaration of Helsinki, the International Conference on Harmonisation, or the Council on International Organizations of Medical Sciences.[2]

Conducting clinical trials on experimental drugs and devices is one exception to the general observation that a REB review takes place only if required by the organization providing the funding. Clinical trials on experimental drugs are federally controlled by Health Canada and therefore, all clinical drug testing is subject to the Health Products and Food Branch regulations. Any pharmaceutical trial must undergo a parallel REB process. Investigators must monitor the use of medications, indicate any serious incidents following administration and submit a detailed report.[3]

With regard to legislation dealing with the ethical conduct of human and experimental testing, Canada does not have comprehensive, overarching legislation governing human research and there is no statutory requirement that private bodies establish any sort of ethics review prior to granting funding. The end result is that ethical guidelines, such as the *Tri-Council Policy Statement,* do not have the force of law and at best, may only provide some degree of persuasion before a court with regard to appropriate standards.

Overall, when investigators do not obtain REB approval prior to conducting human or animal experimentation, or if investigators do not comply with ethical requirements during an experiment, the only remedy of the REB is financial, by way of refusing or revoking funding. There is no "direct" legal liability that otherwise attaches when breaching an ethical guideline.

## Liability

### *Civil Liability*

In addition to the financial consequences of failing to obtain REB approval, there are a number of "indirect" legal liability issues that arise when an investigator fails to meet the minimum standard of care concerning the conducting of an experiment. In particular, Canadian courts have grappled with what is required of health care professionals when obtaining a subject's informed consent.

In *Halushka v. University of Saskatchewan et al.,*[4] the defendants were physicians conducting research in the field of anesthesia. They wished to experiment with a new anaesthetic drug and the plaintiff test subject decided to participate after being told that the experiment was a "safe test" and that there was nothing to be concerned about. However, he was not told about the risks of using the drug, nor about the risks inherent in the procedure and the participants did not receive any therapeutic benefits from the test. Furthermore, he was not fully informed of the method by which the experiment would be carried out. Though he was expected to be able to return home shortly after the testing, Halushka suffered a heart attack as a result of the experiment and remained unconscious

for four days and in hospital for ten days. Halushka, who was a student at the time, was unable to return to school as he suffered from concentration problems and fatigue. He sued the doctors for trespass to person and negligence. He was awarded $22,500 at trial and this judgment was upheld on appeal.

In reaching their decision in *Halushka,* the Saskatchewan Court of Appeal concluded that an actionable trespass occurs in the medical context unless consent is informed and freely given.[5] In determining what constitutes 'informed' consent, Justice Hall held that it is a physician's duty to give a fair and reasonable explanation of the proposed treatment, including probable effects, and special or unusual risks.[6] In ensuring that informed consent is obtained, the court also stated that disclosure must be consistent with what "competent medical men would have done in a similar situation."[7] In addition, because Halushka was a medical research subject who did not receive any therapeutic benefit from the experiment, he was deemed by the court to be entitled to a full and frank disclosure of all facts, probabilities and opinions which a reasonable person might be expected to consider before consenting to the test.[8]

Subsequent courts have been quite clear that informed consent requires health professionals to provide patients with enough information, such that he or she is able to make an informed decision.[9]

In *Hopp v. Lepp,*[10] the defendant, who was an orthopedic surgeon, performed a disc operation with the patient's general consent. However, a blockage in the spinal canal was discovered and the surgeon removed part of the disc. The patient's condition did not improve and he required additional extensive surgery which left him with a permanent disability. The Supreme Court of Canada dismissed the patient's claim for negligence and battery. Chief Justice Laskin held that the scope of the duty of disclosure depends on a case-by-case basis.[11] Laskin also observed that the case law indicates that a surgeon should generally answer a patient's specific questions and disclose the nature of the operation, its gravity, material risks, and any special or unusual risks.[12] In particular, Chief Justice Laskin concluded that special or unusual risks include "serious consequences in the particular instance, even if the risk be a mere possibility."[13]

In *Reibl v. Hughes,*[14] the Supreme Court had another opportunity to rule on the issue of informed consent. The plaintiff patient underwent major, but competently performed surgery and suffered a massive stroke, which resulted in paralysis and impotence. Stroke, paralysis, and death were risks associated with *both* the surgery and with a refusal to undergo the operation. While the plaintiff asked questions (and received answers) about the possibility of stroke, the defendant surgeon did *not* properly inform him of the possibility of paralysis. At trial, the plaintiff was awarded damages for battery and negligence on the grounds that the consent was not informed. Chief Justice Laskin held that in determining the content of disclosure, the physician must consider what the particular patient would feel is relevant to his or her decision.[15] In this sense, therefore, liability is not entirely determined by an objective standard or based solely on expert medical evidence, but it depends on whether a reasonable person in the circumstances of the patient would have consented to the procedure, once they were informed of all material and special risks.[16]

Though *Hopp* and *Reibl* involved the performance of surgeries, rather than medical experiments, the principles of informed consent could apply equally to non-therapeutic human testing. In fact, the court in *Halushka* noted that the standard of care for disclosure of risks in human experimentation is at least as great (if not greater) than that required in a physician-patient therapeutic relationship.[17] Indeed, on the issue of the duty of disclosure, the court in *Zimmer et al. v. Ringrose*[18] distinguished the facts before it from those in *Halushka.* Judge Prowse held that the standard was not as high in cases where the medical purpose was therapeutic in nature.[19] In *Halushka,* the plaintiff received no medical benefit by participating in the experiment, while in *Ringrose* the patient was injured during the course of a therapeutic procedure (abortion). As such, the court concluded that the standard for disclosure for "innovative" therapy, where there is some therapeutic benefit, is not as high as it is in circumstances where there is *no* benefit and the procedure is purely experimental.[20]

### *Professional Liability*

In addition to potential civil liability, an investigator must also be aware that a failure to obtain informed consent in the context of human testing could result in professional liability for misconduct, including disciplinary action by their regulatory College.

Under the Professional Misconduct Regulation of the *Chiropractic Act, 1991,*[21] members are not permitted to perform any health-related functions without consent, if consent is required by law.[22] To provide guidance, the CCO established a Standard of Practice on the issue which states that every member must ensure that a patient undergoing examination or treatment must provide consent that is:

1. Fully informed;
2. Voluntarily given;
3. Related to the patient's condition and circumstances;
4. Not obtained through fraud or misrepresentations; and
5. Evidenced in a written form signed by the patient or otherwise documented in the patient record.[23]

These guidelines mirror the informed consent provisions as set out by the *Health Care Consent Act, 1996.*[24]

Although the above regulations, practice directions and related legislation pertain to examination and treatment and do not specifically include medical experimentation, one can conclude that these guidelines would similarly apply to consent required for human testing in the medical context. As noted above, *Halushka* imposes on investigators conducting human experimentation a standard of care that is at least as great, if not greater, than that required by practicing physicians.

In terms of what constitutes 'informed' consent, the CCO Practice Standard follows closely what is required by investigators under the common law. Under the Practice Standard, chiropractors must discuss the effects, material risks and side effects of any examination or treatment. In particular, there must be disclosure of improbable risks, especially if the potential effects are serious. For example, members must advise patients of the rare risk of stroke associated with cervical manipulation. The Practice Standard also notes that consent is an on-going process and that a patient's consent will have to be renewed whenever new treatments are introduced, the patient's condition changes significantly or where there are significant changes in material risks. In addition, patients are permitted to withdraw their consent at any time. Finally, the Standard of Practice provides that Chiropractors must provide patients with the opportunity to ask questions and these queries must be answered prior to any examination or treatment being performed. The CCO concludes that the standard for disclosure will be dictated by "what a reasonably person in the patient's position would need to know to make an informed decision."[25]

### *Criminal Liability*

Aside from civil and professional liability, an investigator may also face criminal consequences for injury or death caused through research experiments. Though the *Criminal Code*[26] has generally not been used as a mechanism to control experiments, there are a number of criminal offences that investigators should nevertheless be aware of that are particularly relevant in the circumstances where an experiment has deviated from ethical guidelines.

In the context of human experimentation, section 265 of the *Code* provides that assault is committed where there is no consent and force is intentionally applied.[27] To this end, consent is considered to not have been obtained if it was obtained by force, under threat, by fraud, or by way of an exercise of authority (i.e. significant power imbalance between the parties).

Section 219 of the *Code* provides that a person is criminally negligent where he or she is under some legal duty, imposed by statute or common law, and "shows wanton or reckless disregard for the lives or safety of other persons."[28] The conduct, therefore, must be a marked and significant departure from the standard of a reasonably prudent person in the circumstances.[29]

Section 216 of the *Code* may also apply to human experimentation, as it provides that persons undertaking surgical or medical treatment that may endanger life are under a legal duty to "have and to use reasonably knowledge, skill and care in so doing." [30] Although the provision refers specifically to treatment, it also applies to anyone undertaking an act that endangers life and therefore, may apply in the context of a medical experiment.

Lastly, section 446 of the *Code* may apply specifically to animal experimentation as this Criminal Code provision specifically prohibits the wilful causing of any unnecessary pain, suffering or injury to an animal, including that which results from a failure to exercise reasonable care.[31]

In "Working Paper 61: Biomedical Experimentation Involving Human Subjects," the Law Reform Commission published a recommendation that non-therapeutic

biomedical experimentation should be considered legal under criminal law, provided that the investigator has properly obtained the subject's free and informed consent and where the risks incurred by the subject are acceptably proportionate to the expected benefits from the testing.[32] This suggestion mirrors the civil system in Quebec, the only province in Canada to impose statutory regulations for human experiments. The *Civil Code* requires investigators to (1) obtain the subject's consent, and (2) show that the risks incurred are proportionate to the benefit anticipated.[33]

## Conclusion

Aside from the exception for experimental drugs and devices, there is no all-inclusive mechanism for monitoring human or animal experimentation or enforcing ethical guidelines. To the extent that REB reviews are capable of regulating testing, sanctions for inadequate standards are limited to financial recourse. Of perhaps more serious consequence, personal liability can arise in the civil, professional and criminal contexts for failing to meet the appropriate standard of care and failing to obtain informed consent prior to conducting a test.

As a result, researchers carrying out human testing should ensure that they are mindful that any experiment they conduct includes a full explanation of the experiment, disclosure of material and special risks and adheres to a reasonable practitioner standard, not only to meet funding requirements, but also to insulate themselves from legal and professional liability. Furthermore, all practising chiropractors should pay particular attention to the elevated level of informed consent required in cases where the treatment being performed may be seen by some as experimental in nature and perhaps, with questionable therapeutic benefit.

## References


1 Government of Canada. Policy Statement – Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Oct 18, 2005; Online at Interagency Advisory Panel on Research Ethics: http://www.pre.ethics.gc.ca/english/policystatement/introduction.cfm.
2 Glass KC. Questions and Challenges in the Governance of Research Involving Humans: A Canadian Perspective. In Lemmens T. & Waring D. eds. Law and ethics in biomedical research: regulation, conflict of interest and liability. Toronto: University of Toronto Press Inc., 2006: 35 at 41.
3 Law Reform Commission of Canada. Biomedical Experimentation Involving Human Subjects, Working Paper 61. Ottawa: Law Reform Commission of Canada, 1989: 12.
4 Halushka v. University of Saskatchewan et al. (1965), 53 D.L.R. (2d) 436 (Sask. C.A.)[Halushka].
5 Ibid. At paras. 25–26.
6 Ibid. At para 26.
7 Ibid. At para. 27. Quoting Natanson v. Kline. (1960) 350 P 2d 1093.
8 Ibid. At para. 29.
9 Zimmer et al. v. Ringrose (1981). 124 D.L.R. (3d) 215 (Alb. C.A.) [Zimmer].
10 Hopp v. Lepp. [1980] 2 S.C.R. 192 (S.C.C.) [Hopp].
11 Ibid. At 210.
12 Ibid.
13 Ibid.
14 Reibl v. Hughes [1980] 2 S.C.R. 880 (S.C.C.) [Reibl].
15 Ibid. At 898–900.
16 Ibid.
17 Halushka. Supra note 4 at para. 29.
18 Supra note 9.
19 Ibid. At para. 18.
20 Ibid.
21 Chiropractic Act, 1991. S.O. 1991, c. 21.
22 Ontario Regulation 852/93 (Professional Misconduct) under the Chiropractic Act, 1991 at section 1(3).
23 College of Chiropractors of Ontario, Standard Practice S-013 (Amended November 26, 2004). Online at http://www.cco.on.ca/standard_of_practice_s-013.htm.
24 Health Care Consent Act, 1996, S.O. 1996. C. 2. Sched. A at section 11 [HCCA].
25 Supra note 23.
26 Criminal Code, R.S., 1985, c. C-46 [Code].
27 While consent may be a defence to assault, this is not the case if death occurs (see section 14 of the Code, which states that a person cannot consent to death).
28 Supra note 26 at s. 219.
29 R. v. Waite [1989] 1 S.C.R. 1436 (S.C.C.).
30 Supra note 26 at s. 216.
31 Supra note 26 at s. 446.
32 Supra note 3 at 24.
33 Civil Code of Québec, C.c.Q., Section 20.