

Translating Ethics into Law: Duties of Care in Health Research Involving Humans

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In the field of health research, good governance has two primary goals: to ensure that the research conducted is scientifically valid, and that it is conducted in an ethical manner, protecting the physical and psychological integrity of the research participant. Since the emergence of research ethics boards (REBs) in Canada, responsibility for good governance is too often conflated with the responsibility for research review. Ideally, however, good governance results from an assumption of obligations by all those engaged in the research enterprise. Research ethics boards are not the sole repository of this responsibility. As a recent statement by medical journal editors pointed out: “In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly.”¹ This statement applies not only to clinical research but equally to all types of research involving humans.

The first goal of this paper is therefore to identify the actors who make up *the research enterprise* and, very briefly, to sketch the nature of the role that each of them may play in the good governance of research involving humans. Some of these obligations are set by statute or regulation, some by ethics policies or guidelines. I will then consider which of these ethical obligations may constitute a *duty of care* under the common law.²

Finally, I will briefly discuss how ethics policies, guidelines and practices can be integrated into or adopted by the legal system through incorporation into statutes and regulations or by judicial interpretation. Through such integration, they

can help to establish the *standard of care* that defines the nature and extent of these legal duties.

The Research Enterprise

For the purposes of this very brief article, I will simply list the range of actors in the research enterprise and sketch in point form some of their diverse obligations for the proper conduct of health research involving humans. This by no means exhaustive list permits a preliminary consideration of which of these obligations may form the basis for a legal duty of care.

1. The Researcher

- Conducts the research, and is therefore directly responsible for the welfare of the participant.
- Is responsible for conducting the research in accordance with the protocol as designed, and as approved by any review body; the researcher is therefore accountable not only to the participant but also to the designer of the protocol (if the researcher did not design it him/herself), to the sponsor of the research, to the review body, and to any regulatory body.

2. The Research Sponsor

- Funds the research and is therefore responsible for ensuring that the research is both scientifically and



ethically valid, respects applicable laws and regulations and follows relevant policy guidelines.

- Where the sponsor is a public body, it must also consider whether the proposed research serves the public interest.
- Sponsors have an obligation to make the results of trials publicly available, so that the scientific community and ultimately, society in general, may benefit from the knowledge acquired through the unpaid participation of members of the public.

3. The Research Institution

- Institutions where research involving humans is conducted have an obligation to the participants to ensure that the research is both valid and ethical; they also owe this obligation to the general public, as trust in the review process builds faith in the research enterprise, without which many people would not agree to participate in research.
- Research institutions also have an obligation to ensure that their employees and those carrying out research on their premises, or using their name (and reputation) conduct themselves in accordance with institutional policies and ethical standards.
- Those who establish or hire REBs (that is, research institutions with institutional REBs or corporations making use of private REBs) also have an obligation to ensure that these bodies are able to operate independently, by putting in place the necessary safeguards against conflict of interest.

4. The Review Body

- The research ethics board, whether public or private, is responsible for reviewing the research design to ensure that it is scientifically valid and ethically sound; in performing this review, its primary obligation is to protect the research participant.
- It must also ensure that the research serves a meaningful scientific purpose.

5. Government

- Both the provincial government and the federal government have a role to play in regulating the conduct of research involving humans;

- For the federal government, this obligation derives from its responsibility for the regulation of drugs and medical devices;
- For provincial governments, it derives from their responsibility for matters relating to health as well as their responsibility for the regulation of professionals, especially health professionals.

6. Public Agencies

- Public bodies, such as the Canadian Institutes of Health Research (CIHR), that fund research involving humans, may require compliance with ethical standards or other contractual terms as a condition of funding.
- The imposition of ethical standards or rules of conduct as a condition of funding means that the public body may suspend or withdraw funding for lack of compliance.
- It is not clear, however, where the obligation to ensure compliance resides – with the funding body or with the institution where the research is conducted; CIHR’s enabling statute does not expressly confer the jurisdiction to monitor compliance or to investigate allegations of non-compliance, and in fact it relies on research institutions to monitor the conduct of researchers, although some interpret its obligations as being more direct.³

Duties of Care

Under Canadian law, a duty of care requires that a relationship between two parties is sufficiently close that the harm suffered (by the plaintiff) is reasonably foreseeable. This is the test articulated by the Supreme Court of Canada in the case of *Kamloops City v. Nielsen*:

(1) is there a sufficiently close relationship between the parties (the [defendant] and the person who has suffered the damage) so that, in the reasonable contemplation of the [defendant], carelessness on its part might cause damage to that person? If so (2) are there any considerations which ought to negative or limit (a) the scope of the duty and (b) the class of persons to whom it is owed or (c) the damages to which a breach of it may give rise?⁴

Where the conditions of proximity and foreseeability of the first part of the test are established, it is then up to the court



to determine whether there are considerations which ought to limit the duty in any way. Based on this definition, in which of the relationships reviewed can we plausibly find that the obligations noted amount to a legal duty of care?

1. Researcher

Given the direct relationship between the researcher and the research participant, there is no doubt that the researcher owes a duty of care, enforceable at law, to the research participant. This has been part of Canadian common law at least since the case of *Halushka v. University of Saskatchewan*⁵ in 1965. In that case the Saskatchewan Court of Appeal held that a researcher who fails to adequately disclose the risks of a clinical trial to a prospective participant is liable in negligence. The thrust of this decision was upheld under the civil law of Quebec in the case of *Weiss v. Solomon*.⁶

2. Research Ethics Board

The *Weiss* case also established for the first time in Canada that a research ethics board may be held liable for failing to adequately protect a research participant. In that case the hospital where the research was conducted was held jointly liable with the physician investigators for failing to ensure that the recruitment procedure and the consent materials were adequate to screen out participants for whom the trial posed an unacceptable risk. In this case, the materials did not reveal that the research presented a risk for patients with a certain medical condition. While the risk was remote, and would not have been a barrier to undergoing the procedure if the patient were to benefit from it, the risk was sufficient to constitute an exclusion criterion for this trial. It is therefore clear that in Canada, research ethics boards owe a direct legal duty to research participants and may be held liable for a breach of that duty.

3. Research Institution

In order to be eligible to accept research funding from one of the three Canadian public granting agencies, the onus is on the research institution to establish a research ethics board in conformity with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998*⁷. Whether

or not the research is publicly funded, a research ethics board provides the research institution with a vehicle for ensuring that the research conducted on its premises or by its personnel receives appropriate review. As the legal entity responsible for acts done on its behalf by its boards and committees, a research institution such as a hospital or university will be found to have a duty of care to those who participate in research conducted under its auspices. Accordingly, the hospital was found jointly liable with the investigator for the death of the research participant in the *Weiss* case.

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The proper functioning of a research ethics board depends in many respects upon the human and financial resources and support accorded to it by the institution. There are a variety of ways in which an institution can help to ensure that its REB functions well. It could, for example, provide training for REB members, or it could recognize the importance of their REB work by granting staff members release time for their REB duties, so that this is part of their recognized work

and not in addition to it. It should also provide adequate funding for the support services that an REB requires in order to function efficiently and effectively. Some aspects of REB support are policy decisions on the part of a public research institution and therefore not subject to a claim in negligence. Where a public institution establishes the parameters for the functioning of a REB and fails to ensure that those parameters are fulfilled or respected, it may well expose itself to legal liability.

4. Professional Body

Where research is conducted by a professional who is answerable to a licensing body, that body has an obligation to help to ensure the protection of research participants. It can do so by recognizing the distinct nature of the research function, and ensuring that appropriate research conduct is covered by its rules of professional conduct. In this way, the professional body takes responsibility for the conduct of its members specifically with respect to research.

In addition to a disciplinary function, professional bodies may themselves undertake to review research proposals to



ensure that eventual participants are adequately protected. To date, the Alberta College of Physicians and Surgeons is the only provincial medical licensing body to have established its own committee for the review of research conducted by its members through a by-law passed under its governing statute.⁸

While the Alberta College may be the only provincial medical licensing body which has a statutory duty of care to the participants in research conducted by physicians outside of a research institution, an argument may be made that all provincial medical licensing medical bodies have a duty to ensure that their members conduct themselves competently and ethically when carrying out research activities involving humans. The Albert College of Physicians and Surgeons has assumed a direct responsibility for the review of this category of research. It is therefore likely to satisfy the test of reasonable proximity and foreseeability that establishes a legal duty of care. Even under the common law, and without the establishment of a specific research ethics committee, however, it is arguable that all provincial colleges have a responsibility to human research participants, as part of their basic mandate to protect the public. A recent decision of the Supreme Court of Canada, while dealing with a legal rather than a medical licensing body, supports the view that a licensing body may be held liable where it fails to address the misconduct or incompetence of its members in a timely and effective manner.⁹

5. Research Sponsor

Arguably, the research sponsor has an obligation to design research that will minimize the harm to participants and provide the maximum utility in terms of the information it yields. Research, however, may be designed in ways that are acceptably safe and informative, yet do not yield the most objectively useful information. For example, a pharmaceutical company may design a trial, within all ethics guidelines, for the purpose of demonstrating that its product is effective. From a public policy or patient perspective, however, it would be more significant to determine whether the product is more effective than a similar one produced by another company.

There are scientific and economic arguments both for and against testing a product against placebo versus testing it against a rival product. This is an area of serious debate which is well beyond the scope of this paper. It is worth considering, however, whether it is sufficient for a sponsor to propose research that is ethically and scientifically valid, or whether a sponsor has a further obligation to ask the most pressing scientific question, the one that will yield the most information possible in return for the risks assumed by research participants. In other words, can one posit an obligation of sponsors to research participants that extends beyond the sponsor's obligation to its shareholders? While it may be difficult to argue that such an obligation could amount to a legal duty of care, it is more plausible to argue that there is such an obligation from an ethical perspective.

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6. Governments and Government Agencies

A government may incorporate the requirement for research review into legislation or regulations. This is the case, for example, with Ontario's new health protection legislation,¹⁰ which permits a health custodian to disclose personal health information only if the researcher submits, among other things, a decision by a research ethics board approving the research plan.¹¹ Alberta's *Health Information Act*¹² has a similar provision. The *Civil Code of Quebec* sets out certain requirements governing research involving humans.¹³

A government agency may require compliance with ethical guidelines as a condition of research funding. This is the case, for example, with the three major public research agencies, which require compliance with the *Tri-Council Policy Statement* as a condition of funding. It is also the case in Quebec, where a ministerial action plan¹⁴ promulgated by the health minister mandates the province's research ethics oversight body, the Fonds de la recherche en santé du Québec, to monitor and advise on compliance at the province's 19 research institutions.

To what extent do these requirements create an obligation on the government or public agency to ensure compliance with such policies or guidelines? A proper discussion of the complex question of Crown liability for research involving



humans is beyond the scope of this paper.¹⁵ I raise it nevertheless, as the uncertainty surrounding the nature and scope of the public duty in the governance of research involving humans highlights both the need for consistent and comprehensive standards in the review of such research as well as the absence of adequate mechanisms to ensure compliance with such standards.

Standard of Care

If one can establish a legal duty of care in various aspects of the research enterprise, the next question is how to determine the standard of care by which such a duty will be judged. The standard of care for research involving humans is still largely undeveloped in Canada, as there have been very few judicial decisions concerning the negligent conduct of research.

In the case of *Halushka*¹⁶ the issue was the standard of care owed by the physician investigators. It therefore took as its starting point the standard of care owed by physicians, and considered whether the standard owed by investigators was different. The Saskatchewan Court of Appeal found that investigators were to be held to a higher standard of disclosure than physicians for the purpose of obtaining informed consent given that research participants, unlike patients, can expect no therapeutic benefit from their participation.

When considering the standard to be applied to the duty of care of research ethics boards, courts cannot base their reasoning on a comparison with the standard applied to physicians, because research ethics boards do not have the same types of duties as clinical investigators.

What standard can courts use to measure the adequacy of research review, a procedure that was not in place at the time of the *Halushka* case? The *Weiss v. Solomon* case referred to earlier demonstrates how a court may use an ethics policy to assist in its evaluation of a legal standard of care. In that case, the trial judge referred to the standard of disclosure required in *Halushka* with respect to the standard of care of the physician investigator. In addition, the court referred to specific provisions of the World Medical Association's *Declaration of Helsinki*¹⁷ to help determine not only the standard of care required of the investigator, but also the standard for the hospital, through its REB, in its review and oversight of the research protocol.¹⁸

In a study of how professional norms and codes of conduct may be adopted as the legal standard of care,¹⁹ the authors focus on how courts may look to professional practice, including ethical obligations outlined in international guidelines such as the *Declaration of Helsinki*, to determine a legal standard for physicians and researchers.

Where no legal norm exists in a statute or regulation or in case law, the guideline, professional norm, or both will have a significant, perhaps even decisive, impact on a judge's conclusion. This essentially results in the professional community, rather than the legislator or the court, determining the legal standard of care.²⁰

It is more difficult to refer to a professional community in the case of research ethics boards because, unlike physicians, REBs are not subject to any official licensing or other regulatory or self-regulatory standard. A study of research ethics boards in medical faculties across Canada produced evidence of very differing practices²¹ but it did not result – in fact it could not have resulted – in sanctions or disciplinary action against those boards. This is because there is no cohesive body at the provincial or national level, with the exception of Quebec to some extent, with responsibility for standards of competence and conduct for research ethics boards. This would not prevent a court from holding a research ethics board to a standard of care of the court's own devising, based on whatever relevant statutes, regulations, policies or guidelines it could apply. Certainly the *Tri-Council Policy Statement*²² is widely accepted in Canada as a standard for the conduct of health research involving humans. The lack of an authoritative body in Canada highlights the need, however, to construct a coherent framework for the governance of research involving humans, to provide a context within which to judge the conduct of research ethics boards.

Conclusion

Canada lacks a coherent and comprehensive structure for the governance of health research involving humans. There are a variety of ethics policies, guidelines and practices that address certain aspects of governance, or certain categories of research. These ethics policies may be and in some instances are being integrated into the legal system, either by incorporation into statutes or regulations, or through judicial interpretation of standards of care. Such inclusion in the legal system may add weight to the force of these policies, guidelines and practices. Given its ad hoc and piece-



meal evolution, however, this patchwork form of governance does not alleviate the need for a planned and comprehensive framework for the governance of health research involving humans, one that will include all actors in the research enterprise.

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1. Catherine De Angelio, *et al.* "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors" (2004) 351 *New England Journal of Medicine* 1250.
2. The *Civil Code of Quebec* in arts. 18-21 C.C.Q sets out certain specific duties with respect to the conduct of research involving humans. I will not discuss these in this paper.
3. See for example Sana Halwani, "Her Majesty's Research Subjects: Liability of the Crown in Research Involving Humans" in Trudo Lemmens & Duff Waring, eds., *New Directions in Biomedical Research: Regulation, Conflict of Interest and Liability*, (Toronto: University of Toronto Press) [forthcoming 2005]. Ms Halwani suggests that CIHR's Standing Committee on Ethics has a responsibility to review the research projects funded by CIHR for compliance with ethical standards, a role that committee has never in fact taken, or is not mandated to take.
4. [1984] 2 S.C.R. 2 at 10-11.
5. [1965] 52 W.W.R. 608 (Sask. C.A.).
6. (1989), 48 C.C.L.T. 280 (Que. Sup. Ct).
7. Tri-Council, *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans (with updates of May 2000 and September 2002)* (Ottawa: Tri-Council, 1998)
8. Under the authority of Alberta's *Medical Profession Act*, R.S.A. 2000, c. M-11 and bylaw 53 passed by the Council (the governing body of the Alberta College of Physicians and Surgeons).
9. *Finney v. Barreau du Québec* [2004] 2 S.C.R. 17. While the case turned on the civil law of Quebec, the Court stated (*obiter*) that given the relationship of proximity of the Barreau and a member of the public who complained about a lawyer's conduct, and given that the harm to the complainant was foreseeable,

"[t]he common law would have been no less exacting than Quebec law on this point." (para. 46)

10. *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3.
11. *Ibid.*, s.44.
12. R.S.A. 2000, c. H-5, s.50.
13. C.C.Q. art.18-21.
14. Gouvernement du Québec, Minist re de la santé et des services sociaux, *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (Québec: June 1998), online: <http://ftp.msss.gouv.qc.ca/publications/acrobat/f/documentation/1998/98_759.pdf>.
15. Liability for the proper governance of research (and public health) is an increasingly important concern of governments and other public bodies in light of the tainted blood controversy and SARS. For a discussion of this issue, see for example Sana Halwani, *supra* note 3.
16. *Halushka*, *supra* note 5.
17. *Ethical Principles for Medical Research Involving Human Subjects* adopted by the 18th World Medical Assembly, Helsinki, 1964, revised Tokyo (1975), Venice (1983), Hong Kong (1989), Somerset West (1996), Edinburgh (2000), Washington D.C. (2002), online: <<http://www.wma.net/e/policy/b3.htm>>.
18. *Weiss v. Solomon*, *supra* note 6. The court referred both to s.6, [currently contained in a revised form in art.21] ("The right of the research subject to safeguard his or her integrity must always be respected", para 98) and to Part III, art. 4 [currently contained in a revised form in art.5] ("In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject", para 115).
19. Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research", (2001) 46 *McGill L.J.* 473.
20. *Ibid.* at 484-85.
21. National Council on Bioethics in Human Research, "Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine," (1995) 6 *NCBHR Communiqué* 3.
22. *Supra* note 7.

