

Canadian governance of health research involving human subjects: is anybody minding the store?

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ABSTRACT (ABSTRACT)

In this paper I consider the state of institutional ethics as exhibited in current Canadian governance arrangements for health research involving the use of human subjects. This paper is based on research that my colleagues and I did for the Law Commission of Canada under the title *The Governance of Health Research Involving Human Subjects*.⁽⁴⁾ The paper has three parts. In the first part, I characterize the state of governance in this area. That characterization leads to the question raised in the subtitle: "is anybody minding the store?" In the second part, I offer suggestions for addressing the major shortcomings in current governance arrangements for health research involving human subjects. In effect, I set out what I see as the key features of an adequate regime for ethical governance of Canadian health research involving human subjects. In the third and final part, I address two key issues. The first is why ethical governance for this area requires an evidence-based ethics of research. The second is how we can make a principled determination of whether we have the right amount and kinds of governance. As indicated in my remarks about methodology, I developed a generalizable normative account of governance in response to a descriptive analysis of current governance arrangements. In broad ethical terms, I see good governance as involving the translation of collective moral intentions into effective and accountable institutional actions.⁽⁸⁾ This translation is made in part through the establishment of oversight arrangements.⁽⁹⁾ Thus, the usual definitions of governance offered by policy analysts centre on oversight processes; for example, one Canadian authority describes governance in terms of "the processes by which human organizations, whether private, public or civic, steer themselves."⁽¹⁰⁾ Governance issues also arise in regard to the interactions of the many organizations and groups involved in health research using human subjects: public and private research institutions, research sponsors, research regulators, researchers, research subjects and the general public. So it is fair to ask, "who is responsible for what aspects of the protection of human subjects in health research?" That is, governance issues arise with respect to the appropriate division of responsibilities for the protection of human subjects amongst the agencies and organizations that conduct, sponsor, and regulate research.

I believe that the ethics review process by the REB has come to be, in the minds of the major institutional actors and their constituents, a surrogate for a comprehensive ethical approach to research involving human subjects. In effect, countries around the world have put in place a social system that loads on to the REB approval process almost the total burden of ethical responsibilities for human subjects research. That is, all the major actors (including research sponsors, institutions, and regulators) behave as if REB approval is all that there is to the ethical conduct of research involving human subjects. The REB process (and with it the focus on the research proposal and the consent form) has become the reification of the sum total of responsibilities and accountabilities for researchers, research institutions, research sponsors, and research regulators. In effect, this rationalizes the avoidance of major responsibilities that arise before, after and on the peripheries of the REB review process.

ABSTRACT

From an ethical perspective, good governance involves the translation of collective moral intentions into effective and accountable institutional actions. With respect to the use of human subjects in Canadian health research, I contend that there have been many good intentions but very little in the way of appropriate governance arrangements. Hence, the question, "who minds the store?" is especially acute with respect to the protection of

vulnerable individuals and groups that are typically recruited as subjects for health research in Canada. Beyond diagnosing failures in governance and their causes, I offer suggestions for significant reforms, including evidence-based ethics assessment, independent oversight, and greater participation of research subjects in governance. I will close with some more general reflections on ethics, law, and governance.

FULL TEXT

I. Introduction

The topic of this paper is one that should be much more central in discussions of bioethics and health law than it currently is. This is the topic of ethically responsible and accountable governance. Governance in the context that I will be discussing--the treatment of human subjects in health research--falls into the broad area of institutional ethics and more narrowly institutional bioethics.(3) In ethics and bioethics, a great deal of attention has been focussed on the opposite ends of the broad spectrum of ethical issues: the personal and the political, or in often used terms, "micro" and "macro" level concerns. Much less concern has been shown in academic literature and in public discussions for the institutional or mesolevel. Yet it is in norms, practices, and cultures of institutions that the political and personal most often meet. The everyday realities of life as a patient and health care provider or research subject and researcher are framed by the institutional settings of health care and research institutions. Moreover, the success of health policies set at macro-levels depends crucially on institutional action at the meso-level.

In this paper I consider the state of institutional ethics as exhibited in current Canadian governance arrangements for health research involving the use of human subjects. This paper is based on research that my colleagues and I did for the Law Commission of Canada under the title *The Governance of Health Research Involving Human Subjects*.(4) The paper has three parts. In the first part, I characterize the state of governance in this area. That characterization leads to the question raised in the subtitle: "is anybody minding the store?" In the second part, I offer suggestions for addressing the major shortcomings in current governance arrangements for health research involving human subjects. In effect, I set out what I see as the key features of an adequate regime for ethical governance of Canadian health research involving human subjects. In the third and final part, I address two key issues. The first is why ethical governance for this area requires an evidence-based ethics of research. The second is how we can make a principled determination of whether we have the right amount and kinds of governance. Along the way, I will offer various comments or, to use a term familiar to readers of this publication, obiter dicta on more general ethical, legal, and political issues. My first obiter dictum is on the methodological approach that my colleagues and I used in our study for the Law Commission.(5) We started with a descriptive account--what is the state of governance for health research involving human subjects--and moved to the normative--the ethical lessons both practical and theoretical. Now this may seem unusual for a project headed by an analytically trained philosopher. In my earlier career as a political philosopher and philosopher of law my inclination would have been to first produce a theory of institutional responsibilities for governance as a template to assess actual practices. Now as an applied ethicist, I take a more empirical approach: starting with a rich description of social phenomena and then developing a normative approach that addresses the social and institutional realities of the situation. In line with this more empirically informed methodology, I will discuss the development of an evidence-based ethics in the final part of this paper.

Part I. The Current State of Canadian Governance for Health Research Involving Human Subjects

In our study of governance, we addressed two major questions:

(1) How is Canadian health research involving human subjects governed in terms of "ensuring ethical research processes?"

(2) How effective are these governance relationships in terms of "consistently achieving effective governance of ethical research?"(6)

The approach we took to answering these questions was both multi-disciplinary and inter-disciplinary - multi-disciplinary in that we looked at the state of governance through several disciplinary lenses (law, ethics, sociology,

etc.) and interdisciplinary in our effort to produce a unified account or picture of the area. A major part of our research was based on qualitative analyses of interviews conducted with Research Ethics Board (REB) members and university administrators at five major Canadian universities and with individuals from national organizations with governance responsibilities in this area.(7)

A. Governance

As indicated in my remarks about methodology, I developed a generalizable normative account of governance in response to a descriptive analysis of current governance arrangements. In broad ethical terms, I see good governance as involving the translation of collective moral intentions into effective and accountable institutional actions.(8) This translation is made in part through the establishment of oversight arrangements.(9) Thus, the usual definitions of governance offered by policy analysts centre on oversight processes; for example, one Canadian authority describes governance in terms of "the processes by which human organizations, whether private, public or civic, steer themselves."(10) Governance issues also arise in regard to the interactions of the many organizations and groups involved in health research using human subjects: public and private research institutions, research sponsors, research regulators, researchers, research subjects and the general public. So it is fair to ask, "who is responsible for what aspects of the protection of human subjects in health research?" That is, governance issues arise with respect to the appropriate division of responsibilities for the protection of human subjects amongst the agencies and organizations that conduct, sponsor, and regulate research.

Conceptualising the ethical challenges in governance in terms of translating collective moral intentions into action has the advantage of focussing attention on two key areas: first, on the moral intentions of the collective agents--in particular on content (what is intended) and motivation (why it is intended)--and second on appropriate implementation and potential obstacles to implementation, particularly organizational barriers to effective and appropriate action. The first set of issues leads to questions about the ethical nature and limits of actions by the various organizations (and their members) that play roles in health research involving human subjects. Here, I think it is fair to say, there is broad general agreement on three main objectives:

- (1) the promotion of socially beneficial research;
- (2) respect for the dignity and rights of research subjects; and
- (3) as an overarching aim, the maintenance of trust between the research community and society as a whole and, particularly, actual and potential research subjects.(11)

However, such consensus on broad objectives does not guarantee agreement on the specific responsibilities of particular agents or agencies. The United States, for example, has established very specific responsibilities, with a strong regulatory process backed by arm's-length processes of verification; Canada has by and large relied on guidelines with only self-verification by researchers and research institutions. Moreover, there is a major moral risk that agencies and agents will try to push responsibilities away from themselves on to others. Within organizations this deflection of moral responsibilities may be up, down or sideways. Amongst organizations, it can involve the unfair and inappropriate off-loading of responsibilities from the regulator to the regulated or the reverse.

This brings me to the second area of major concern, namely, putting collective intentions into effect. Any realistic account of the implementation of governance must take into account typical obstacles to putting collective moral intentions into action. As we note in our study, a central concern with respect to governance is the management of "agency risk," i.e., the tendency of agents to pursue their own agendas rather than those mandated by or for their organizations.(12) Thus, in asking whether anybody is minding the store, I am raising a question about how well the multiple institutions involved in health research deal with the many institutional and personal agendas encountered in such research, whether these be increased profits, more research funding, health advances for specific groups, enhanced individual and institutional prestige, or maintenance of power.

As I argued in a November 2000 lecture at the Royal Society of Canada Conference on Science and Ethics, such oversight implies a multi-tiered normative relationship amongst moral agents.(13) At tier or level one there are agents with various normative responsibilities, for example researchers who have moral and legal responsibilities with respect to subjects participating in their research. Governance relations enter the normative picture when there

are other moral agents at tier two or higher levels charged with various oversight responsibilities, for example to evaluate, approve, or monitor the performance of agents (in this case, researchers) on the first tier. That is, the second tier is instituted to promote appropriate actions at the first level. It does this sometimes through direct accountability and oversight relationships (as well as incentive/disincentive structures) and at other times through indirect oversight (e.g., accreditation, assessment and review of systemic, as opposed to individual performance). Good governance involves both good institutional design and good institutional performance. This is why I said earlier that good governance "involves the translation of collective moral intentions into effective and accountable institutional actions." Governance has much to do then with the fulfilment of institutional responsibilities and with meeting obligations that institutions and their members have to various parties. In his masterwork *Leviathan*, Hobbes very aptly turns to the root sense of the word "obligation"--the Latin word "ligare"--when he speaks about obligation in terms of "bonds by which men are bound or obliged."⁽¹⁴⁾ Thus, we can aptly picture governance as part of the normative bonds or ligatures that bind one agent to another especially with regard to institutional actions. Hobbes' picture is of a chain of obligations linking each person ultimately to the sovereign. If we remove the absolute sovereign from this picture, we can conceive appropriate governance relationships as a normative net of roles, responsibilities, and rights with respect to appropriate parties or stakeholders, whether within the organization (e.g., researchers employed by a hospital) or without (research subjects recruited from the hospital's patient population). In our study, we found that in many instances the governance net for Canadian health research involving human subjects has gaping holes; it does not catch the fish--in some cases, sharks--that it should. In other areas, the net is too finemeshed (in terms of over-reliance on the REB process and informed consent), so it scoops up mostly flotsam and jetsam. Ultimately the net fails to achieve its stated purposes of ensuring the accountability of the research sector for and to the general public and research subjects.

B. The Context of Contemporary Health Research

Four major features mark the international context of contemporary health research:

- (1) rapid scientific and technological innovation and advances;
- (2) multiple disciplinary and interdisciplinary research modalities;
- (3) commercialization and privatization; and
- (4) globalization and harmonization.

Since Canada is only a medium-sized player in the world of health research and development, the effects of these four factors are quite significant. Domestic markets for the products of health research are quite small compared to our main competitors, and these are dominated by offshore companies. Our public and private sector research institutions are in most cases less well funded than their foreign competitors. Canada also faces major internal challenges as it competes in a global market in an era of free trade. Canadian public and private sector research institutions have to take into account disparate and conflicting federal and provincial rules (and with some types of research international and foreign rules) as they engage in collaborative research enterprises. For instance, a multi-site clinical trial of a new pharmaceutical in Canada would be conducted according to the international Good Clinical Practice (GCP) rules, be subject to applicable federal legislation (e.g., Criminal Code prohibitions of assault) and also various provisions of provincial legislation (e.g., on age of consent) and perhaps also be subject to the Tri-Council Policy Statement (TCPS) if the research is conducted in an institution receiving federal funding.⁽¹⁵⁾ Furthermore, if the U.S. National Institutes of Health (NIH) sponsored the research, it would also be subject to U.S. regulations governing research involving humans.

There is fierce competition for scarce research dollars in both the public and private sectors. It is not surprising in such a competitive environment that regulation is generally seen as both an obstacle and an opportunity - an obstacle when imposed on a given organization and an opportunity when it is differentially imposed on others. Moreover, as I will note shortly, Canadian regulators are distracted and generally inattentive to the ethical challenges of health research. The ingredients for a potential "race to the bottom" are all too present in the Canadian health research situation.

Health research in Canada is a complex matter. There are many types of institutional actors, including the

institutions that conduct research, such as universities, health centres, hospitals, pharmaceutical companies, and medical offices; domestic and foreign institutions that sponsor research, like the Alberta Heritage Foundation, Canadian Institutes of Health Research (CIHR) and NIH; companies like Apotex and Myriad Genetics; health charities, like the Kidney Foundation of Canada; regulatory bodies and governments applying standards from provincial, federal and international levels; and professional groups, such as the Council of International Organizations of Medical Associations (CIOMS) in collaboration with the World Health Organization (WHO), and the Canadian Medical Association (CMA). Each of these institutions, their members and stakeholders have both official agendas--such as profit maximization, the public good, and the advancement of science--and unofficial agendas - like the pursuit of reputation, influence, personal advancement, and the like. All of this takes place in a context of rapid scientific advance in a very globalized and increasingly privatized economy.

The results in terms of rules and standards applicable to Canadian health research involving humans are quite complex. Sometimes norms conflict. This of course is unsurprising given the multiple sources of explicit rules for research involving humans. Thus, Bartha Knoppers has identified specific areas of research (e.g., research in an emergency setting and the duty to warn) in which the Quebec Civil Code conflicts with the TCPS and GCP guidelines.(16) But at least it can be said that each of these three norms--Quebec Civil Code, TCPS, and GCP--involve direct and explicit regulation of the use of human subjects in health research. More typically in Canada many of the legal and professional norms that are relevant to the conduct of health research involving human subjects were designed for non-research contexts (like clinical practice, professional self-regulation, age of majority, guardianship or confidentiality of patient records). Hence, Bernard Dickens argues, "[l]aw applies almost inadvertently to the enterprise of biomedical research."(17)

In some crucial areas of health research, there is simply no governance since principal agencies have turned a blind eye. A good example is the general failure of provincial colleges of physicians and surgeons or licensing bodies to oversee research conducted by their members in private offices.(18) The one shining exception is the Alberta College of Physicians and Surgeons, which has established oversight for physicians who in their private capacities conduct pharmaceutical and other types of research.(19)

C. Governance as REB Oversight

In our study for the Law Commission of Canada, we devoted a great deal of attention to the operations of Research Ethics Boards (REBs). In Canada as in other countries, the ethics review board(20) is the primary governance mechanism or instrumentality used to ensure the ethical conduct of research involving humans. REBs receive proposals for research involving humans and determine whether or not the research shall proceed as described, in a modified form, or not at all.(21) We argued that there are major problems with the almost total reliance on REBs for ensuring that health research involving human subjects is ethical. The inadequacy of REB oversight or governance process results not so much from what REBs do (though I will shortly describe problems in that respect), but from what they fail to do and probably could not and should not do even if they had sufficient resources.

I believe that the ethics review process by the REB has come to be, in the minds of the major institutional actors and their constituents, a surrogate for a comprehensive ethical approach to research involving human subjects. In effect, countries around the world have put in place a social system that loads on to the REB approval process almost the total burden of ethical responsibilities for human subjects research. That is, all the major actors (including research sponsors, institutions, and regulators) behave as if REB approval is all that there is to the ethical conduct of research involving human subjects. The REB process (and with it the focus on the research proposal and the consent form) has become the reification of the sum total of responsibilities and accountabilities for researchers, research institutions, research sponsors, and research regulators. In effect, this rationalizes the avoidance of major responsibilities that arise before, after and on the peripheries of the REB review process.

It is essential to understand that research is a process that takes place over time. Research begins with a set of ingredients both intellectual and material (funding, research capacity, opportunities) and ends with products, developments and insights relevant to human health. The ethics review process only covers a narrow, albeit important, time slice of the research process, namely, review of the research proposal (usually) before research is

initiated. The REB is typically unaware of the research activities that go on both before and after the REB performs its gatekeeper function.

Consider what happens before the REB receives a research proposal. Researchers have made decisions about which areas to investigate and how. Their decisions are contingent on many other decisions, including the decisions of research institutions about who to hire and where to conduct research, research training institutions' decisions about education and credentialing, sponsors making funding decisions, and investors and policy makers deciding whether and where to spend public or private sector dollars on health research. Many of these pre-REB review decisions raise major ethical issues, e.g., the under-investment in research on issues relevant to the health of women. This under-investment is due in part to the intentional or unintentional adoption of criteria on the part of the research community and/or sponsors that exclude women from participation as research subjects in clinical trials. But I would suggest that the REB is not a very good place for setting right gender inequities in health research and only has a small (though important) part to play in the remedial process. Rather, action needs to be taken by those who set the research agenda - sponsors, leading scientists, social activists, and the like.(22)

Just as REBs do not look back to the time prior to the submission of the research protocol, they also do not look forward to the post-approval process of research, publication and production.(23) Aside from annual reports (if any)(24) and adverse incident reports, REBs generally receive little information about what happens to the human subjects in research projects that had earlier received REB approval.(25) In the numerous interviews conducted for our study, our interviewers found only one site that had provision for a random audit of on-going research. However, the random audit only involved a paper audit and an interview with the researcher. Indeed, in this case, the interviewee seemed surprised at our interviewer's suggestion that it might be worthwhile to interview research subjects about their experiences.(26) In general, we found no evidence of significant outreach to research subjects. Beyond the process of informed consent, current Canadian practices with respect to interactions with research subjects are passive and reactive - based on responding to complaints rather than routinely using research subjects as sources of vital information about the ethical quality of on-going research.(27)

In general, the Canadian system for dealing with the ethics of human subjects research lacks learning systems. This is surprising and indeed even shocking given that REBs are in the business of predicting what will happen to human subjects in particular research projects. Hence, to determine whether a given research project may be morally acceptable, the REB examines a research protocol and on that basis predicts what will likely happen to prospective subjects.(28)

The REBs' predictive judgments involve making assessments about informed consent (e.g., whether with the information provided, subjects would be able to make an informed choice about participation in research) and about the potential benefits and harms of research (e.g., whether the amount and kind of risk imposed would likely be morally acceptable).

Given the central role of predictive judgements in the REB's deliberations, it is astounding then that research institutions do not have in place mechanisms to attempt to verify REB predictions. No regulator insists across the board that research institutions have in place monitoring mechanisms,(29) and no one checks to see whether, for example, the research proceeded according to the research proposal, whether there was genuinely uncoerced and informed consent, or if the benefit/harm ratio actually was within ethical parameters.(30) So we have a system that puts all its energies into making predictions but then takes no steps to verify those predictions. If no one keeps track of what happens, how can REBs and, even more importantly, researchers learn from the ethical failures and successes that occur? There is a lack of what I describe in our study as "virtuous learning loops."

D. Bureaucratic Reductionism

So far I have said that we have in our institutional practices reduced governance for the ethical treatment of health research subjects to the narrow time period in which REBs review research proposals. We ignore both past and future - even though past events frame the narrow now examined by the REB and future events verify or falsify the REB's predictions. But even with respect to the narrow now examined by the REB there are major flaws. Thus, it has become almost a commonplace remark amongst those who study this area (though nonetheless a remark that bears

repeating) that REBs and researchers are too fixated on issues of informed consent with the result that issues of harm and benefit are under-examined. A rather simplistic ethics of autonomy and informed consent drives the REB process and through it the expectations of researchers, research sponsors and research institutions. The actual moral lives of research subjects (as well as researchers) are much more rich and complex. So all too often, we start on the wrong moral foot - focussing narrowly on the process of informed consent. To put this another way, our current system starts with only one tool in its moral tool kit. Faced with a surface that needs sanding or a screw that needs tightening, it is unsurprising that the tool used will be a hammer.

Moreover, informed consent is all too often reified into a paper form. Those of us who work in health law and bioethics know well the situation in which we are invited to join a health research project, whether in genetics, cardiology or immunology, where the first question put to us is, "would you help us design the consent form?" It seems as if we have arrived at a situation in which the ethics of research with human subjects has been reduced to checking off two boxes. One box is marked "REB approval" and the second box is marked "signed consent forms." As soon as both boxes are ticked, everyone can relax, forget about ethics and get on with the important business of research. By "everyone" I mean research sponsors, research funders, research institutions, professional bodies, and research regulators. From a governance perspective, ethical oversight has been reduced to ensuring that the two boxes are ticked. We have then what I would describe as a serious case of bureaucratic reductionism and the trivialisation of major ethical concerns.

Let me complete this observation by saying that in the areas where REBs have a very important role--research approval and oversight for monitoring--they are woefully under-resourced. I am filled with admiration for the dedication and energy that volunteer members of REBs and the National Council on the Ethics of Human Research (NCEHR) put into their work. But they lack the resources to do their jobs well. My own university has in the past prided itself on keeping overhead costs at zero for its REB. This means that there have been no resources dedicated to research ethics education for REB members and researchers, no time-release for REB members, and no professional bioethics support. This situation is repeated across the country. At the national level, twice as much is spent on overseeing research involving animals as is spent on research involving humans. And I would say from my experience in the area of animal welfare (as a current member of Canadian Council on Animal Care and as a former member of UBC's Animal Care Committee) the difference in investment and in mandate between the animal and human areas is painfully obvious. Mice in Canadian laboratories are much better looked after in governance terms than are human subjects.

Part II: What Would Ethical Governance Look Like?

I have used the metaphor of a net with major holes in it. So far I have spoken of the net, as it exists now. In this part of my paper, my aim is to describe a mended net, that is, to offer a general description of what is needed to ensure ethical governance for health research involving human subjects. I have argued that our current governance system treats the ethics of this area in a very reductionist way - reifying ethics in the REB process and the informed consent form. I have also said that we are in a complex and highly competitive environment in health care research. There are multiple actors with a multiplicity of commercial, political, intellectual and other agendas. In designing an adequate governance net we need to be anti-reductionist in our approach to ethical oversight and realistic about the real life forces at work in contemporary research.

Here, my colleagues and I argued that appropriate governance has two key aspects - a formal side involving the design of institutional arrangements and an informal side involving the reshaping of the culture of research. The formal and informal sides should be complementary so that institutionalized accountabilities and responsibilities take root in a culture that is appropriately accountable and responsive. This is not of course to say that the aim should be to do away with all tensions between institutional structures and cultural norms. Such tensions are at the root of many useful social reforms and so ought not to be seen as inherently problematic. But there needs to be a fair degree of congruity for the sake of effectiveness and stability.(31)

On the formal institutional side, we saw a need for a significant investment of interest and resources in more adequate structures of accountability. Clearly, it is a mistake to put all our ethics eggs in the REB review basket. The

REB basket cannot bear the full weight of legitimate expectations with respect to the ethical conduct of research. Our governance arrangements must cover the full time span from the genesis of research projects through to their completion and even beyond in their effects upon general health and well-being. For example, it is essential to have fair and effective processes for scrutinizing public investment in research and more broadly public policy for research (e.g., taxation policies) that take into account a wide range of ethical objectives, such as ensuring that research serves the needs of all Canadians - including women, First Nations people, the poor, and others.

When research is completed, there is a role for other kinds of oversight. A major part of the justification for research involving human and animal subjects is utilitarian. That is, researchers, research institutions, research sponsors and REBs justify their use of subjects on the basis that it is an intelligent social investment - an investment that produces net benefit, be it in terms of increased knowledge, better health, or profits. In general, the greater the potential differential risks to subjects, the more certain should be the odds in favour of success and the greater the potential payoffs. But how often does anyone do the retrospective analysis with respect to high-risk research to say whether or not this was a smart social investment decision? If such analysis is not systematically done and fed back into the research design, investment, approval and conduct process, how can we as a health research community justify what we are doing? This needs to be done in a systemic way for various areas of research where research involving human subjects is conducted. It is not enough to rely on anecdotal reports or to assert that in general overall health research has proven beneficial to society. This, I will argue below, requires an evidence-based approach to research ethics.

In parallel with this, my colleagues and I saw the need for a significant investment in the REB process and in appropriate national oversight.⁽³²⁾ REBs are notoriously under-resourced; so is their oversight at a national level. Beyond this there is the need for investment in the creation and maintenance of ethical research communities. In public and private sector research institutions, a great deal of time and effort is invested in terms of effective and accountable governance to ensure high quality research. For instance, research institutions use peer review processes to evaluate the quality of research. They want to know what the outcomes of research are in terms of publications, products, and other socially beneficial effects. Research institutions are also very careful about who they employ as researchers and use as peer reviewers. In other words, those who fund, house, conduct, and promote health research pride themselves on the rigour of the governance processes they use to promote quality research. In general then, our societal approach to the production of quality research is both interventionist and activist.

But when it comes to ensuring the production of research that is ethical, what do we see? Aside from the REB process and the actions of isolated groups of individual researchers, we see an anti-interventionist and passive approach. While research sponsors and institutions verbally espouse a commitment to principles of ethical research, they rarely take any effective steps to disseminate, evaluate, implement and internalize these principles. My diagnosis is that the research community has come to view the REB process as a bureaucratic surrogate for an intelligent and concerted approach to the challenges of governance in this area. Aside from the REB, Canadian research institutions, professional bodies, research sponsors and regulators cross their fingers and hope for the best. Perhaps this is due to the misconception that beyond childhood there is little one can do about the ethical choices that people make. Or it may be that we have as a society so privatized the domain of values that we deny the possibility of there being shared defining values for public life. Such misconceptions rationalize a passive role on the part of research institutions and researchers alike. The attitude might be described as "good science is hard and takes effort, but no one can do anything about good ethics."

There are two further issues that I wish to touch upon here. The first is the general failure to deal with conflicts of interest in the governance of research and the correlative need for arm's-length independence. The second is that of accountability to research subjects. In both respects, our current system is severely wanting. With respect to the conflicts of interest, I think there is a good deal of public awareness of the latent and not so latent conflicts of interest that dog private and public sector health research. In the research community, though, I see major blind spots. In universities, for example, social scientists and humanists are quick to view with suspicion industry-funded research.

However, as a community they seem singularly unaware of the conflicts that lie in public sector research funding (research sponsors and institutions have their own agendas) and in the members of their own community who are as much driven by the desire for prestige and power as their colleagues in the natural and applied sciences. Institutionally we have a situation in which university REBs generally report to the offices that promote research. At the federal level, the three councils that provide a significant degree of public funding for health and other types of research involving humans determine policy with respect to the ethical treatment of human subjects through the TCPS. With respect to private sector research involving humans, there is outside Quebec little in the way of public oversight.(33) Now I have no problems with public and private sector sponsors of research wanting a voice in governance arrangements for research involving human subjects, but it is essential to public trust that they not have a controlling role and that there be accountability to independent public responsible agencies.

The final desideratum for effective and ethical governance is the active involvement of the general public and particularly research participants in governance - not only in its implementation of policy but also in its design. By involvement, I mean more than token lay participation on REBs. I have already argued that effective REBs are at best only a part of a good governance system. There is a need for monitoring, evaluation, education, accreditation, and the like, areas in which research subjects could play important roles. As well, research subjects should be considerable sources of wisdom for the formation of policy. I would note that in our governance arrangements for research involving animals a much better job has been done than on the human side for including the perspectives of advocates for human research subjects.(34)

Part III: Key Aspects of Good Governance

In the final part of this paper, I will address two central questions that reveal important aspects of good governance for the ethical conduct of research involving humans:

- (1) How would an evidence-based approach to the ethics of research involving humans improve governance?
- (2) How in principle do we determine whether the kinds and amount of governance are appropriate?

A. Evidence-based Ethics

The notion of an evidence-based ethics of research is implicit in many of the major conclusions in our Law Commission sponsored study. However, we did not develop it explicitly other than in the notion of virtuous learning loops where we made the following points:

- (1) Good governance requires virtuous learning loops so all the actors can learn from their successes and failures.
- (2) Virtuous learning loops should be based on evidence-based standards.
- (3) Thus, there is an urgent need for research on what happens to human subjects in research.
- (4) Such research requires resources from sponsors and research institutions; it also requires a commitment to use the research results in improving governance.
- (5) Failure to establish evidence-based learning loops represents a serious failure in governance for which research institutions, sponsors and standard-setters should be held accountable.(35)

In this paper, I want to say more about an evidence-based approach to the governance of health research involving human subjects. Above, in criticizing the current regime for health research governance in Canada, I said that REBs focus on a narrow time slice in the research process. The REB functions much like customs inspectors at a border point who, after a few perfunctory questions about the citizenship and destination of the vehicle's occupants and maybe a peek in the car's trunk, send the travellers on their way. But much is missed at the border crossing: what happened before and what will happen after the travellers cross the research ethics check point. In particular, I have said that not only is there a dearth of useful information about what happens to research subjects in the conduct of research, but also a general failure to systematically and rigorously seek such information.

Moreover, if one also believes that effective and appropriate governance for research involving human subjects is about more than REB review and must include other forms of institutional oversight as well as address the many cultures of research, then I would suggest that we need the evidence to make such interventions effective and ethical.(36) For example, it would be worth conducting research on such questions as:

- Are there significant divergences in terms of risk predictions by REBs, researchers, and research subjects?

- What are the key factors in such divergences, e.g., are they mainly factual or evaluative?
- What sorts of ethics training make a positive impact on the behaviour of researchers?
- How can we create an ethically appropriate culture for health research involving humans?
- How effective are community and subject representatives in various research governance functions, e.g., membership in an REB or research policy committee?
- How are the families, friends and acquaintances of research subjects affected by particular types of research, such as research on predictive genetic testing, research into chronic alcoholism, or research into patterns of HIV transmission?
- What are the actual (as opposed to official) criteria used by given REBs in evaluating research protocols?

I have used the term "evidence-based research ethics" to draw a parallel with evidence-based medicine particularly with regard to the need for higher standards of knowledge than the simply anecdotal.⁽³⁷⁾ An evidence-based approach aims at developing systematic and comprehensive understandings or interpretations of the phenomena in question. It involves a search not only for the most significant variables, but also for those factors that tend to confound our practical judgements. An evidence-based approach requires that we identify the criteria for evidence and develop ways of applying these criteria. Because we are in the area of ethics, the criteria for evidence-based ethics will generally be wider than in medical and scientific areas because of the greater prominence of normative elements.⁽³⁸⁾ In an evidence-based approach to research ethics, this mixture of normative and causal elements requires an interdisciplinary research effort that spans several fields: the health sciences, social sciences and the normative sciences of health ethics and health law. For this to happen, a serious commitment of resources is needed on the part of research sponsors. Part of what I hope our report will generate is an impetus from within the research community and without for such research.

I want to emphasize that the notion of an evidence-based ethics of research that I am espousing is not one that precludes debate about standards and modes of governance and about permissible and impermissible types of research. Rather it should inform debate and move it to a higher level. I offer as an example the contentious area of research involving collectivities, which was a major target of opponents of the 1997 draft Code proposed by Tri-Council Working Group on Ethics. Led by the Canadian Association of University Teachers, these opponents were successful in securing the deletion of the section on research involving collectivities and its replacement by a section limited to research involving Aboriginal peoples.⁽³⁹⁾ While there are deep differences of principle here, in particular regarding the responsibility of researchers for dealing with third-party harms caused by research, there are also important empirical and conceptual issues as to the type and degree of such harms. That is, it is possible to investigate whether research involving collectivities causes harms to such groups: for example, whether publishing research on sexual abuse in a particular ethno-culturally defined group causes social stigmatization. Such investigations would inform debates about whether such harms are wrongful, and if so, who is to blame: for example, if there is stigmatization, whether to blame the researcher for publishing the data in a form that identifies the group or to blame miscreants in the subject population for such harms.⁽⁴⁰⁾ In our Law Commission study, Burgess and Brunger's paper provides important insights for reconceptualising research involving collectivities in ways that open the door for relevant empirical research.⁽⁴¹⁾

Sometimes evidence will settle disputes, for example, that a particular type of health research actually had or failed to have the long-term benefits predicted when it was first proposed. In other cases, there will be disagreement because the evidence is mixed or, in philosophically more interesting situations, because there is disagreement about the criteria for evidence, for example, whether in evaluating prospective research REBs ought to take a narrower medicalized conception of harms and benefits or a wider conception that includes psychological and sociological factors. In my opinion, these are important debates that are essential for the policy and practice of research ethics. That sometimes, despite the evidence, there will be reasonable disagreement should not be seen as a defect peculiar to evidence-based ethics, for we also find such disagreements in evidence-based science, for instance when the evidence available fits rival theories.

Here my main point is that we are much more likely to make better decisions about policy and practice if decisions

are made on the basis of evidence grounded on a body of well-conducted research. The lack of evidence (e.g. from monitoring or from relevant research) may in the short run lead to a superficial and likely short-lived agreement, but this is scarcely the sort of agreement on which to build social policy. Evidence by itself will not settle all the important ethical issues in the area, but it should deepen our confidence in areas where there is consensus and narrow (though also sharpen and make more precise) areas in which there is deep disagreement. So I would conclude that an evidence-based approach to the ethics of research should enable rather than preclude informed debate for policy and governance issues with respect to human subjects research.

I would also like to address the fear that evidence-based ethics would lead to governance by ethics experts. While ethicists and health lawyers have important roles in generating an evidence-based ethics of research, our opinions are not the final word. Our expertise can only be as good as the evidence available. But securing good evidence requires making use of the expertise of sociologists, anthropologists, clinical specialists and other researchers in the life and social sciences. Ultimately, some of the most important evidence would likely come from those most affected by research--namely, research subjects, their families and communities. That is, an evidence-based approach should in my view also be a subject-centred approach--taking the lives and testimony of research subjects as central.

I would also hope that an evidence-based approach would encourage experimentation with different forms of governance. Around the time of the adoption of the Tri-Council Policy Statement, there were many disputes, particularly between health scientists and social scientists. While health scientists were generally comfortable with the REB review process, many social scientists were not and indeed were quite suspicious of it. It is worth asking what lies behind these divergent reactions. Perhaps it is the longer familiarity of health scientists with REB review, that the health sciences are more professionalized, or that there is much less consensus about research methodologies in the social sciences than in the health sciences. We should be asking if governance or educational processes could be altered to deal more creatively and effectively with such differences.

Another crucial area for experimentation is that of monitoring and retrospective evaluation. In the interviews we did with REB members at several major Canadian universities, we found considerable apprehensiveness about monitoring. While there seems to be growing recognition that monitoring is essential, I do not think that we have very well grounded ideas about how best to conduct meaningful monitoring and retrospective analysis. We risk then turning monitoring into a bureaucratic exercise of somewhat dubious value. This suggests the need for research on and experimentation with forms of monitoring. We need to look at significant variables, for example type and size of study, degree of risk, subject involvement, and the like. If experimentation is to be possible in this sensitive area of research ethics, care needs to be taken not to put at risk central values. So there is a need for regulators, like Health Canada and the Tri-Council, to make possible and encourage judicious research and experimentation in these areas.

B. Governance and Goldilocks

I have fancifully entitled this part of my paper "governance and Goldilocks" for I believe that at the heart of good governance are "just right" solutions that are neither too intrusive nor too lax; these are solutions that fit the mode of governance to the moral realities of the situation. Governance involves oversight, but it should not be oversight for the sake of oversight (or simply as a make-work project for would-be bureaucrats and executives). Earlier I described governance in terms of second-order oversight. In some cases, only minimal oversight is required because the first order functions well pretty much on its own. This may be due in some cases to natural propensities, general moral goodness or (as Adam Smith argued with regard to economics and John Stuart Mill with respect to freedom of thought and enquiry) because of the self-correcting processes created by competitive markets, or simply because the potential risks of malfunctioning are quite minimal. In other cases, oversight is worth its costs and may well be essential to an institution's fulfilment of its moral mandate. Thus, as admirable as we think the great majority of our academic colleagues are in institutions of higher learning, we still need to have controls over expense accounts for research, travel and the like and to have rigorous processes for hiring, tenure and promotions. In our study, I emphasized that the test of good governance is not whether things happen to be going well on the

ground or at the first level. Institutions with poor governance can sometimes "get lucky" and do well almost accidentally. Similarly, a well-governed institution is still vulnerable to error, fraud and deceit. A system of governance that was utterly foolproof in these regards would likely be repressive and much too risk averse, devoting too much to oversight and not enough to its mainline activities.

My own sense is that in Canada today we do not face serious risks of over-governance in the general area of research involving humans.(42) Our problems at this stage are of inadequate, ineffective and missing governance at all levels from the local to the national. We have a serious problem of missing "accountabilities" both within institutions and inter-institutionally. Key institutional actors in the Canadian research enterprise--public and private sector research institutions, sponsors and funders--are unable to give a proper evidence-based systematic accounting for their activities with respect to the use of human subjects in research. The best they can do is say that some (most?) research went through an REB(43) and that probably consent forms were signed. Beyond the institutional level, there are parallel issues at the inter-institutional level, where, as I have said, there is a lack of clarity as to who is responsible for what, and in which accountability relations are absent or seriously lacking. Good governance, particularly in terms of appropriate accountability and effective oversight, is essential to trust. For instance, it is fundamental for a corporation building trust relationships with customers, stockholders, employees, and suppliers. In constitutional democracies, good governance is basic to the trust of the governed in those who govern. With respect to building trust relationships, it is essential to get the directionality of accountability and trust right. In the case of research involving human subjects, the trust of those subjects and the general public in the research enterprise is based on the research community's accountability to them. There are some who have this backwards - they think that the main concern in setting regulations is to win the trust of researchers.(44) While we must protect the important values of freedom of enquiry and advocacy in research institutions, we must never forget that it is we as a research community who stand in a fiduciary relation to research subjects. This fiduciary relation requires more than a first-order, unsupervised commitment to ethical research practices; it requires appropriate institutional and inter-institutional governance arrangements to ensure ethical performance and accountability.

Conclusions

At the end of this paper, I would draw two fairly stark conclusions:

- (1) The current state of governance for Canadian health research involving humans is ethically untenable.
- (2) Major changes in Canadian governance for health research involving human subjects are required structurally and culturally in the research community.

Nevertheless, I do not wish to close on a pessimistic note. While there is much wanting with regard to how the health research store is being minded, it is a store well worth minding. There are significant needs for health research, nationally and internationally. We have dedicated researchers in the multiple areas of health research. In health research institutions, I certainly do see dedicated people committed to good ethical practices in health research involving humans. While I by no means underestimate the serious bureaucratic, structural and cultural obstacles to major reforms in governance, I believe that this is an enterprise worth fighting for. But we will need the wisdom and help of those in health law, ethics, the health sciences, positions of responsibility and most of all those with the most to gain or lose, the communities from whom research subjects are drawn and the general public.

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(2) The substance of this paper was presented as the Picard Lecture in Health Law at the Faculty of Law, University of Alberta, 31 January 2001.

(3) In this paper and its title, I have used the term "human subject" rather than "research participant." I recognize that

this is a sensitive issue for some working in the area. There are moral reasons for preferring the latter to the former, especially since it looks at the involvement of individuals in research as an active, as opposed to passive manner. In fact on these and related grounds, the Tri-Council Working Group ultimately recommended the use of the term "research participant" rather than "research subject." (The three research councils however rejected this suggestion and used the term "research subject" in the 1998 Tri-Council Policy Statement.) Nonetheless, there are reasons in favour of using the term "subject," for example, the contrast of "subjects" with "objects" and the notion of personal perspective found in the idea of subjectivity. But the main reason for my using the term "subject" is simply its general familiarity to readers.

(4) M. McDonald, *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000).

(5) *Ibid.*

(6) *Ibid.* at 7.

(7) Methodological issues are discussed in *ibid.*, section A-1.

(8) In talking about "collective moral intentions," I am assuming that the intentions are reasonably well-informed morally speaking. That is the intentions must meet appropriate moral standards. Having morally appropriate intentions is not then a matter of arbitrarily labelling an intention as "moral" or seeing it as the product of a vague wish to do good.

(9) There are other aspects of putting collective intentions into practice, for example the appointment of trustworthy agents.

(10) Centre on Governance, University of Ottawa, *Governance of the Ethical Process for Research Involving Humans* (Ottawa: Centre on Governance, University of Ottawa, 2000).

(11) McDonald, *supra* note 3 at 30-31.

(12) Allen Buchanan explores the notion of agency risk in a very perceptive paper, "Toward a Theory of the Ethics of Bureaucratic Organizations" (1996) 6:4 *Business Ethics Q.* 419. My account of governance in terms of second-order oversight of an institution's first-order operations is based on Buchanan's account of a theory of the ethics of bureaucratic organizations in terms of first- and second-order agency risks.

(13) "The Governance of Health Research Involving Human Subjects: Reflections on Ethical Policy for Scientific Research," to appear in a forthcoming issue of the Royal Society's journal *Transactions*.

(14) T. Hobbes, *Leviathan*, ed. C.B. Macpherson (Harmondsworth, UK: Penguin, 1968) at 192. I owe this idea to a very important paper on moral obligation published by my mentor Kurt Baier in 1966. K. Baier, "Moral Obligation" (1968) 3:2 *Am. Philosophical Q.* 210.

(15) International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, ICH, *Good Clinical Practice: Consolidated Guidelines. ICH Harmonised Tripartite Guideline* (Ottawa: Minister of Health, 1997); Medical Research Council of Canada (MRC), National Sciences and Engineering Research Council of Canada (NSERC) & Social Sciences and Humanities Research Council of Canada (SSHRC), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Medical Research Council of Canada, 1998) [hereinafter TCPS]. The three federal research councils require as a condition of continued funding that research institutions review all research involving human subjects under the TCPS. In turn, research institutions explicitly or implicitly make adherence to TCPS on the part of their employees conducting research a condition of employment.

(16) B.M. Knoppers, "Ethics and Human Research: Complexity or Confusion?" in McDonald, *supra* note 3, 109.

(17) B.M. Dickens, "Governance Relations in Biomedical Research" in McDonald, *ibid.*, 93.

(18) This is detailed by T. Douglas Kinsella in his contribution to the governance study: "Research Involving Humans: Current Regulatory Status of the Canadian Medical Profession," in McDonald, *ibid.*, 165. The reference to "private offices" is important in that research conducted by physicians in institutions receiving funding from CIHR would fall under the TCPS and be reviewed by the university or hospital REB. The problem area then is mainly industry-sponsored research that would have no arm's-length review.

(19) Ibid.

(20) These boards are variously labelled as REB in Canada, institutional review board or IRB in the U.S., research ethics committee, REC in the U.K. and Australia, etc.

(21) See B.A. Brody, *The Ethics of Biomedical Research: An International Perspective* (New York: Oxford University Press, 1998) at 303.

(22) This is a point the Tri-Council Working Group on Ethics, of which I was a member and Deputy Chair, made in the 1997 draft Code of Ethical Conduct for Research Involving Humans (Ottawa: Medical Research Council of Canada, 1997) with respect to the involvement of women and other excluded groups as research participants. In the relevant section of the draft Code there was an explicit discussion of the complexity of setting a fair and inclusive research agenda. The Working Group's aim was to have the three Research Councils commit themselves to a comprehensive approach to issues particularly concerning the health of women and children. A good example would be the U.S. requirements for encouraging clinical research on women's health. National Institutes of Health, "NIH Guidelines on the Inclusion of Women and Minorities as Subjects of Clinical Research" (1994) 59:28 Federal Registrar 14508. The Working Group did not believe that an equitable approach to research involving the health of women could be limited to tinkering with the REB process. As Baylis, Downie and Sherwin note, the Councils completely gutted this section of the Code: F. Baylis, J. Downie, and S. Sherwin, "Women and Health Research: From Theory, to Practice, to Policy" in A. Donchin & L. Purdy, eds., *Embodying Bioethics: Recent Feminist Advances* (Lanham: Rowman & Littlefield, 1999) 253. So we have in the final version of the TCPS only the most tepid of statements in regard to the just distribution of the benefits of health research to men and women.

(23) An additional problem here is that not all human subjects research actually goes before the REB. Joly offers an interesting example of such a case with public health enquiries into specific disease situations that as a by-product produce publishable research. J. Joly, "Public Health Research and Public Health Non-Research: Or Who Governs What?" in McDonald, *supra* note 3, 153.

(24) Practices are not uniform at Canadian research institutions (even those under the TCPS) with respect to annual reporting. It should be stressed that annual and other reports required by TCPS are only self-reports with no mandated system for verification.

(25) Many of those interviewed in our study complained of the flood of adverse incident reports sent out for clinical trials. They complained that the sheer amount of unfiltered and unevaluated information was overwhelming and of doubtful utility. They saw this as a case of research sponsors trying to off-load potential liability onto REBs and research institutions.

(26) McDonald, *supra* note 3 at 192-93.

(27) Ibid. at 302-303.

(28) In addition to the research protocol, REBs typically look at the consent form and, in some cases, the research budget.

(29) See the discussion below on monitoring.

(30) A further major problem with the fixation on research protocol approval is that there can be considerable variance between the research proposal and the actual conduct of research.

(31) See the philosopher John Rawls' notion of overlapping consensus. J. Rawls, "The Idea of an Overlapping Consensus" (1987) 7:1 *Oxford J. Leg. Stud.* 1.

(32) In my view, appropriate national oversight would involve arm's-length accreditation of REBs and of relevant research oversight processes (such as monitoring) adopted by research institutions. McDonald, *supra* note 3 at 310.

(33) The federal government has raised the possibility of regulations for clinical trials in terms of official accreditation for REBs. See Department of Health, *Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials)*, 22 January 2000, C. Gaz. 2000.I.227.

(34) Many Animal Care Committees, the equivalent of REBs for research using animals, have animal welfare advocates as members. More importantly, the Canadian Federation of Humane Societies has guaranteed

representation on the Canadian Council on Animal Care (CCAC). Unlike its equivalent for research using human subjects, NCEHR, the CCAC determines policy for ethical research and has the power (through withdrawal of accreditation) to stop CIHR and NSERC funding to research institutions.

(35) McDonald, *supra* note 3 at 301.

(36) It is important to realize that there are important ethical considerations in governance relations. Governance, for example, may be too intrusive and disrespectful of the autonomy of the governed. Or governance measures may be used as a veneer to provide only the appearance of accountability; that is, it may inappropriately serve the interests of agents at the expense of principals and beneficiaries of fiduciary relationships.

(37) In making this parallel with evidence-based medicine, I want to caution against assuming that the traditional scientific models for medical investigation, such as double blind testing, are necessarily appropriate for the types of questions raised in this section. My sense is that qualitative methods are likely to be far more helpful than quantitative methods at least in the initial stages. This of course raises difficult questions about generalizability that I cannot address in this paper.

(38) Of course, normative elements are also present in medical and scientific areas.

(39) This section is in abeyance pending "discussions with representatives of the affected peoples or groups, or with the various organizations or researchers involved." TCPS, *supra* note 14, s. 6. My understanding is that there was significant concern in the federal government that this section dealt with issues involving aboriginal rights and so could not be unilaterally imposed. As a member of the Working Group that prepared the 1996 and 1997 draft Codes, I should say that we refused to limit concerns about research involving collectivities to Aboriginal peoples on the grounds (a) that as non-Aboriginals we could not speak for Aboriginal peoples; (b) that the ethical bases for concern about research involving Aboriginals were not *sui generis* but applied to other groups (particularly, vulnerable groups); and (c) that, representing researchers, we could propose essentially a self-regulatory model for research involving humans, including humans in community or collectivities.

(40) This based on the familiar legal and moral belief that not all harms are wrongfully caused.

(41) M. Burgess & F. Brunger, "Negotiating Collective Acceptability of Health Research" in McDonald, *supra* note 3, 117.

(42) Thus, Allen Buchanan, the distinguished American philosopher and advisor to the Presidential Commission on the Human Radiation Experiments, has noted that in health research involving humans there are stunning examples of poor governance. Buchanan, *supra* note 11 at p. 433.

(43) There is a lack of data on the amount of research involving humans that escapes REB review. Anecdotally, we know that such research occurs in a variety of situations. One type of situation is that in which a non-research intervention (e.g., a public health investigation or a clinical intervention) produces publishable data. Sometimes in these cases, the authors of the research seek retrospective REB approval. In other cases, researchers deliberately or inadvertently fail to seek REB approval.

(44) See our remarks on the University of Ottawa study, McDonald, *supra* note 3 at 306, n. 213.

DETAILS

Subject: Research; Human subjects; Medical research; Ethics

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