

Research Governance, Bio-politics and Political Will: Recent Lessons from Newfoundland and Labrador

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Introduction

For the past several years the province of Newfoundland and Labrador has been taking halting steps to introduce the legislative mechanisms necessary to establish a Provincial Health Research Ethics Board (PHREB). If and when that legislation is in place the PHREB will be responsible for the governance of all health research involving human subjects conducted in the province. However, the process has not been without its difficulties. In what follows I summarize briefly some of the circumstances that led to this provincial initiative, some of the steps and missteps that have occurred so far, and identify some lessons learned as we continue to struggle forward in this regard. Before embarking on this brief review, however, it is worth pausing for a moment to reflect on some reasons as to why lessons learned in Newfoundland and Labrador might be important to the rest of the country.

Why Newfoundland and Labrador?

Several reasons can be given as to why a Newfoundland and Labrador case study might prove instructive. First, if the PHREB initiative is successful, Newfoundland and Labrador will be the first jurisdiction in Canada to establish in law a comprehensive governance structure for all health research involving human subjects. The precedent setting nature of this initiative makes it interesting in and of itself.

Second, Newfoundland and Labrador can serve as a microcosm of the systemic problems that might be encountered in other Canadian jurisdictions. The population of Newfoundland and Labrador is small (just over 500,000), the majority of health researchers in the province are located in the province's single university, and the amount of health research conducted in the province is relatively small. On the face of it then, it would seem that efforts to establish a comprehensive governance structure should be less onerous in Newfoundland and Labrador than might be experienced in jurisdictions that include more institutions, more research, and a greater number of competing interests. Indeed, there has been broad general support for the PHREB initiative in all quarters. Nevertheless, we are still without legislation in spite of four years of concerted effort. The reasons for this failure may prove instructive. Finally, Newfoundland and Labrador might serve as a test case for the country with regard to research governance, similar to the manner in which Saskatchewan was a test case with regard to comprehensive health insurance. When Saskatchewan demonstrated that comprehensive health insurance was a realistic possibility the federal government came on board and other jurisdictions followed suit. If Newfoundland and Labrador can demonstrate that a comprehensive, effective, and efficient system of governance for health research is possible, similar results at the national level may ensue. Conversely, if the practical problems of implementation are insurmountable here, it does not bode well for a larger national initiative.



Background Circumstances

Memorial University of Newfoundland is the only university in the province. With a Faculty of Medicine, a large Faculty of Arts, and Schools of Nursing, Pharmacy, and Social Work, among others, this institution houses the vast majority of investigators involved in health related research in the province. However, it wasn't the activities of university based researchers or even those of other non-affiliated researchers in the province that served as the impetus to establish the PHREB. Rather, it was concern about the activities of outside researchers who have been visiting the province to conduct their studies. Occasionally these investigators have collaborated with local researchers either formally or informally. However, in some cases they visited communities to collect biological samples, health records and related data, and returned to their home institutions.¹ At times it was only when research results were published or when the national media reported an interesting study that had been conducted in the province, that local researchers and health officials learned of the existence or nature of this research.²

Things came to a head in the late 1990s when local geneticists and clinicians were frustrated in their attempts to gain access to health information and research results that had been collected in Newfoundland over several years by researchers from Baylor University in Texas.³ Local geneticists and clinicians believed this information was important to the continuing management of patients who suffered from a particularly lethal cardiomyopathy. However their overtures to the Baylor researchers were largely ignored.⁴ At about the same time a local dermatologist contracted with a biotech company in California to do research related to psoriasis. The physician agreed to provide genetic samples to the company in California with the understanding that the samples would be returned when appropriate storage and research facilities were available locally. However, when the physician tried to retrieve the samples the California company claimed them as their intellectual property.⁵ It was cases of genetic misadventure such as these that served as the initial impetus to establish a stricter regulatory regime in order both to track research occurring in the province (especially as it related to genetics), and to ensure that the health and economic interests of Newfoundlanders and Labradorians were properly served.

Steps and Missteps

Two distinct but related initiatives were implemented in the fall of 1999 with the intent of addressing the problems related to the oversight of genetic research in the province. First, inasmuch as it was clear that geneticists from outside the province relied on local physicians to gain access to local subjects, it was thought initially that the problem would be best addressed through the Newfoundland Medical Board. To that end an "Ad hoc Committee on Practice Guidelines for Genetic Research in Newfoundland and Labrador" was established. The second initiative came out of the provincial Department of Health and Community Services (DHCS) which commissioned Dr. Verna Skanes, a medical researcher and former Assistant Dean of Research in the Faculty of Medicine, to prepare a report on issues arising from the commercialization of human genetics research.

Of these two initiatives the second proved to be the more significant. Although the Ad hoc Committee met briefly in the fall of 1999 and drafted practice guidelines for genetic research that were to apply to all physicians in the province, it was decided early on that without the force of legislation to require compliance such guidelines would serve little practical purpose. This misstep is instructive for it points to potential difficulties if professional bodies are seen as a key element in a program of research governance. Without the force of law to back them, such bodies may be viewed as paper tigers.

Dr. Skanes' initial mandate from the DHCS had been to address issues related only to the commercialization of genetic research. However, her consultations convinced her of the need to expand that mandate. Thus her report to the provincial government raised the issue of legislative oversight and recommended that the DHCS take leadership in establishing a provincial research ethics board responsible for the oversight of all health research involving human subjects. The report was recommended for release in May 2000 by the Honourable Roger Grimes, then Minister of Health and Community Services.⁶

Following the release of the Skanes Report the DHCS took steps to move the PHREB initiative forward. Two working committees were established in the fall of 2000, one to draft Terms of Reference for the proposed PHREB, and the other to draft guidelines specific to the conduct of genetic research. I served as co-chair of the genetic guidelines sub-committee, and have continued to work with the PHREB oversight committee as the legislative process has



moved forward. Both sub-committees included significant representation from the Faculty of Medicine, and in particular from those affiliated with the Human Investigation Committee (HIC), the research ethics board (REB) housed in the faculty. The HIC is responsible for reviewing the vast majority of health related research studies conducted at Memorial University. Inasmuch as the PHREB initiative was coordinated out of the DHCS, such an inordinate weighting of membership from the Faculty of Medicine was understandable. First of all, members of this faculty work closely with the DHCS on a regular basis. Furthermore, although there is another REB on the Memorial campus that focuses primarily on social science research, the vast majority of health research projects conducted at the university (and in the province for that matter), involve investigators affiliated with the Faculty of Medicine. Also, since the initial concerns regarding the oversight of health research had been related to genetic research, and inasmuch as those concerns were still to be addressed, a sub-committee to look specifically at those matters seemed appropriate.

The foregoing points notwithstanding, the composition and subsequent focus of these sub-committees became the source of some concern. Echoing some of the concerns raised following the introduction of the Tri-Council Policy Statement, social scientists and humanists were worried that ethics review of their research would be co-opted by medical researchers. In particular there was anxiety that a medical model of health research would be imposed on non-medical research. Social scientists and humanists utilize different methodologies from the medical sciences, and hence they are understandably concerned when it appears that any research they do that is construed as “health research” will be vetted by a committee that might be largely unfamiliar with their methodologies. External to the university, REBs elsewhere in the province raised concerns that a board situated in St. John’s might be insensitive to local issues regarding specific projects.

Such concerns point to two issues—one conceptual and the other practical—that will require careful attention and sensi-

tive management wherever regulatory reforms are proposed. The conceptual issue concerns the definition of “health research” and what is or is not included under that umbrella. The practical issue points to the fact that the majority of health research is medically based, and includes projects that incur the greatest risk to subjects. It is likely then that medically based researchers will take the lead in moving governance issues forward. In so doing, however, non-medically based health researchers will have legitimate concerns that their methodologies, research contexts, and

unique ethical issues may be poorly understood. Hence it is important to have all affected groups at the table early in the process, and to concentrate on open communication throughout. Despite the awareness of the need for stakeholder involvement from the outset, the manner in which our process evolved from a narrow focus on genetic research to include all health related research, resulted in some missteps early on with regard to the communication process. Steps have now been taken to address

these issues as the process has continued to unfold, including scheduled meetings with other REBs to apprise them of continuing developments and to solicit their input.

In the summer of 2001, as part of a public consultation process, the DHCS invited three nationally recognized experts—Dr. Michael McDonald, Professor Timothy Caulfield and Dr. Douglas Kinsella—to visit the province to meet with various stakeholders and to prepare recommendations. The public meetings were well attended. The consultants were supportive of our efforts, and were particularly impressed that the province was leading an initiative that appeared to have broad support. The establishment of an arms-length oversight body for all health research conducted in the province was considered to be a particular strength. While the consultants made a number of specific recommendations regarding the details of the proposal, the most significant was that the province should move forward expeditiously with enabling legislation to establish the PHREB.

Before legislation could be drafted, however, several technical matters needed to be addressed. First, the relationship

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between the existing HIC and the proposed PHREB needed to be clarified. The Human Investigations Committee (HIC) is a university based REB, while the PHREB would be a provincial board. If and when the PHREB is established, the HIC will become the *de facto* REB for the province with an expanded mandate for oversight of all health research including that conducted by researchers not affiliated with the university. In order to facilitate this arrangement it was necessary to establish a Memorandum of Understanding (MOU) between DHCS and Memorial University.

The first draft of an MOU appeared in the fall of 2001. However, there were a number of technical points that caused some concern. For example, the definition of “health research” contained in the MOU was different from that proposed by the working committees. Part of the difficulty here was that those responsible for drafting the MOU for the government and the university respectively were not the same individuals who had been at the table over the previous eighteen months. A similar problem occurred when draft legislation finally appeared in the fall of 2003. The key lesson here is that establishing a comprehensive governance structure involves

multiple institutions, and multiple levels of bureaucracy within those institutions. We are fortunate in Newfoundland and Labrador that representatives from these various organizations and bureaucratic levels can maintain communication and ensure that documentation is reviewed in a timely manner. Thus potential problems can be identified and addressed as the process unfolds. However, this is a demanding and time consuming exercise involving individuals with numerous responsibilities. Unless the task of moving such an initiative forward is designated as the primary responsibility for a particular individual or body, bureaucratic misadventure and potential derailment of the process is likely. Subsequent developments in this process bear this out.

An initial draft of legislation to establish the PHREB was finally prepared in the fall of 2003. In the eighteen months

between the drafting of the MOU and the drafting of this legislation, there had been much discussion about how the proposed PHREB would be financed. The province was committed to the project in principle, but only if it could be accomplished in a revenue neutral manner. There were numerous meetings to discuss if and how this would be possible. In the meantime other political events intervened to slow the process. Brian Tobin stepped down as premiere of the province and Roger Grimes took over. The newly appointed Minister of Health and Community Services had

to be brought up to speed on the PHREB. There was some reshuffling of the government bureaucracy. The Assistant Deputy Minister of Health who had championed the PHREB for almost three years left her government post to take another position. The Deputy Minister of Health then served as the champion of the PHREB for a period of time and was instrumental in moving the draft legislation forward. However, a subsequent change of government in the fall of 2003 resulted in the Deputy Minister being moved to another position. Without a champion at the government level to keep such an initiative on track, the chances for success diminish significantly. Given the time frames

involved the potential for a change in government is high as such a process unfolds. Hence it is best that the champion of such an initiative be a high placed public servant who is likely to survive a change in government.

When draft legislation was finally proposed the issue of how the PHREB would be financed was still unresolved. In addition, there were other concerns about how the administrative activities of the proposed corporation would be separated from the actual ethics review process. Part of the difficulty here is that government really doesn’t understand how REBs work, and academics do not really understand corporate structure and governance. One proposed solution was to drop the idea of a separate provincially legislated board, and instead introduce legislation that simply required that all research conducted in the province be reviewed by a duly constituted board in the province.⁷ Although this gambit

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would avoid both the financial and administration challenges of the PHREB, it would do so at the expense of arm's length review. Furthermore, the *University Act* would need to be amended if the HIC was to take on responsibility for oversight of non-university related research in the province. Finally, this model would leave open the question of who would bear ultimate responsibility for oversight and monitoring of health research. Would it be the university, the province, or other organizations who conducted research? In the end it was decided to stick with the original plan.

At this point we have a piece of draft legislation that is still undergoing revisions, and talks continue as to how to finance the proposed PHREB. Although we lost our champion in government when the Deputy Minister moved to a new post, he is now in another senior position in which he may be able to exert some influence. We hope that this legislation will be introduced in the spring of 2005.

Concluding Observations

Although all agree that ethics oversight of health research is important, the reality is that this issue is generally not a vote-getter, and hence it is not a hot button issue for government. It is interesting to note, for example, that throughout this process there has generally been greater interest on the government side when economic issues related to research were at the forefront, rather than issues of ethics oversight. Recall that the initial Skanes Report was intended to address the narrow issue of commercialization of genetic research, and not research ethics more broadly. Indeed, during the time in which the PHREB process has been unfolding the provincial government commissioned another report on the regulation of commercial genetic research. That project was funded primarily out of the DHCS, but the Department of Industry, Trade and Rural Development also contributed

some funding. Although the final report was never released government took a clear interest in its recommendations, especially as they pertain to potential economic opportunities and the question of benefit sharing. Perhaps this is simply another example of the tail wagging the dog, but it seems that reform in the area of governance of health research is more likely to come about if government is convinced of its necessity in order to encourage continued economic development, rather than simply because it is the right thing to do to ensure adequate protection of human subjects.

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1. Carolyn Abraham, "A World Gene Hunt Targets Canada" *The Globe and Mail* (28 November, 1998) A1.
2. Charles Gillis, "Doomed Newfoundlanders Opt to Eat, Drink and be Merry" *National Post* (12 April, 1999).
3. Sarah Staples, "Bio-Piracy or Bio-Cure?" *The Ottawa Citizen* (4 July, 2002).
4. Alliance for Human Research Protection, "3 Physicians Suspended from Baylor Clinical Research for 5 years", online: <<http://groups.yahoo.com/group/Bioethics/message/4813>>.
5. Moira Baird, "Group Wants DNA Returned" *The Telegram* [St. John's] (22 March, 2001).
6. Access information online: <<http://www.gov.nf.ca/releases/2000/health/0502n03.htm>>.
7. "Duly constituted" here means as per the Tri-Council Policy Statement (TCPS) or any document that supersedes it. If and when this legislation is passed it will be the first time that the TCPS is mentioned explicitly in a piece of legislation.

