

How Well Protected Are Canadian Research Participants: Who Knows?

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The human research enterprise in Canada is large and growing. It spans a wide range of fields that includes political science, sociology, anthropology, education, social work, nursing, epidemiology and medicine, among others. Funding comes from many different sources, including the charitable research foundations such as the Heart & Stroke Foundation and the Canadian Cancer Society, hospital foundations, the three national funding councils – the Canadian Institutes of Health Research (CIHR), the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council (NSERC) – and the major provincial funding organizations in Nova Scotia, Quebec, Alberta and British Columbia among many others. Not all research is funded. This is particularly true of the humanities and student research across all disciplines. In Canada, all research on human subjects must be approved by a research ethics board (REB). The major funding bodies will not release funds until an REB has

approved the study. In Canada, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) (Medical Research Council of Canada 1998) dictates research ethics. It was developed over the 1990s by the Tri-Council Working Group under the auspices of the three national funding councils (the Medical Research Council preceded CIHR as the health research council signatory) and was finally adopted in 1998. By December of that year, all institutions that conducted research were expected to be in compliance with its tenets, or be in the process of becoming so. Since that time, many organizations have invested significant dollars in staff and in information technology to enhance their capacity to undertake credible reviews. Research ethics offices in universities and hospitals, in particular, have grown in size and expertise to respond to the increase in studies that have to be reviewed and to demonstrate the increased expectations of accountability.

So, is there a problem, and if there is, what is it? The answer is, we don't know, and the existing system does not make it possible for us to know. The current state of research participant protection in Canada has evolved over time and in response to the numerous policies and expectations set by Canadian and international research funding bodies and other authorities. These policies are not necessarily congruent, and it is virtually impossible to be in compliance with all of them. In fact, the TCPS pertains only to research conducted through funding from the three national research councils, although most organizations stretch that to apply to most of the research coming to their REBs. There are no standards for education in research ethics for investigators, graduate students undertaking research, REB members and chairs, or research participants; for example, some REBs have no members with expertise in law, privacy legislation or qualitative research, yet are reviewing proposals that require some or all of these competencies. There are no standards for the operation of research ethics offices in terms of resources, compensation for or acknowledgement of REB members' work, and length of terms for REB members. Proportionate review is still a thorny issue, particularly for researchers in the social sciences and humanities, who believe, with some justification, that the TCPS is biased towards medical or health sciences research. They contend that the level of risk to participants in most of their research studies is much lower than that of medical research in which participants' health and well-being may

be jeopardized, and their studies do not require the same scrutiny accorded medical research. The TCPS addresses this and calls for risk to be judged appropriately to the circumstances of the research, but REBs are left to develop their own standards on this issue. Researchers proposing studies that involve collecting data in several (and sometimes dozens) of sites face a requirement for their research proposals to be approved by an REB in each site; this can take months and even years.

On the other hand, while there are gaps in policies, concerns about under- and overzealous application of policies that do exist, and angst about multiple REB approvals, Canada has not seen the major breaches in research ethics that have arisen and cost lives in other jurisdictions. In the United States, some universities have had their entire medical research program shut down and all federal funding withdrawn because of grievous breaches of research ethics. However, there is the shared view that “the governance of research in Canada is fragmented and uneven – many players overseeing many other players through the use of many instruments” (Experts Committee 2008: 23) and, at the same time, no way of knowing how well research participants in Canada are protected.

Various groups have been and currently are trying to address these issues. The Interagency Advisory Panel on Research Ethics (PRE) was created in 2001 by the three federal funding councils to continue to elaborate the TCPS policies. The PRE has been working for several years on revising the TCPS, including the section on proportionate review, and is supposed to release its revisions for consultation before the end of 2008. Unfortunately, work from the PRE has been slow in developing, and the panel must live with the fact that its sponsors are in conflict of interest when it comes to developing policies to cover research that they fund. This requires an arms-length relationship. NCEHR, the National Council on Ethics in Human Research, is a voluntary organization of individuals with an interest in promoting research ethics and protecting research participants. It is funded by CIHR, Health Canada, the PRE and the Royal College of Physicians and Surgeons of Canada (RCPSC). NCEHR, which has been on the scene since 1989, has developed well-regarded educational programs and a site-visit program for organizations to assist in improving their participant protection

programs. Additionally, in 2003 NCEHR proposed an accreditation program that it would operate. However, NCEHR has not been able to secure funding for the proposed program, is frequently limited in its reach by lack of funding, and faces the same problem as the PRE in that its funds come in part from the body that funds research, reducing its arms-length status. SSHRC proposed a type of oversight program, called a public assurance system, as a way of dealing with its constituency's problems with the TCPS. This program was never embraced because it was seen as having "no teeth."

In frustration, after a meeting called by NCEHR in June 2005 to review the penultimate draft of its report describing its proposed accreditation program, the Royal College of Physicians and Surgeons convened a meeting to try to deal with the lack of progress in developing an oversight program for research ethics. It invited Health Canada, the three funding councils, the Association of Universities and Colleges of Canada (AUCC) and subsequently eight other organizations including the Association of Faculties of Medicine of Canada to form a coalition of sorts, called the Sponsors' Table. The main *raison d'être* was to establish an expert committee to look into a range of governance models for the oversight of ethics in human research and to explore issues including implementation and funding (Experts Committee 2008:15). The Experts Committee (of which I was a member) had among its members scientists from the humanities, social and health sciences, including those who investigated research ethics as their area of scholarship, research ethics program administrators and legal experts, and was chaired by the late Arthur Kroeger, a highly respected former federal deputy minister (Experts Committee 2008). The committee's mandate was to provide advice on developing a system for human subject research participant protection in Canada that would address the issues of concern. After nine months of meeting and consulting, the committee prepared a draft report, circulated it for consultation, revised it and submitted the final report, *Moving Ahead*, to the Sponsors' Table at the end of March. A sad note is that Arthur Kroeger died shortly after the report was completed.

The Expert Committee acknowledged both the strengths and weaknesses in the Canadian system but reached the conclusion that a new, independent organization was required that would take responsibility for the oversight

of research ethics programs, including policy development, the establishment of educational standards, and the development and operation of an accreditation program for participant protection programs in Canada. These three functions were seen as interdependent, with one influencing the other. It was proposed that the Canadian Council for the Protection of Human Research Participants be established under the *Canada Corporations Act* so that it would be at arm's length from all funding bodies. Because of fiscal realities, it was further proposed that the implementation of the Council be staged, with accreditation coming first, then policy, then education.

The Sponsors' Table has acted on some of these recommendations; it has established working groups on policy, education and accreditation and has secured funding to support them. It has not embraced the recommendation of the independent Council at this time, but neither has it rejected it, noting that a number of operational issues must be resolved first. It is not clear under whose auspices an accreditation program would operate or how the most concerning aspects of conflict of interest related to policy and accreditation would be resolved. In the view of the Experts' Committee, it is appropriate for the Sponsors' Table to further the development of an oversight system but it is inappropriate for it to operate such a system. It does not have broad representation of organizations and it perpetuates the problem of conflict of interest because the funding councils are among its members.

Nursing has not been a major player in this national drama. Nursing organizations are not represented at the Sponsors' Table, whereas organizations representing physicians are, and the Royal College of Physicians and Surgeons has played a leadership role. This is not acceptable. Nurses are now major participants in the research enterprise in this country. Nurse executives are responsible for knowing that the REBs under their auspices are staffed appropriately, have the requisite expertise among the members and are conducting appropriate proportional reviews. Deans and directors of graduate programs need to ensure that their students acquire the knowledge of research ethics that will allow them to conduct ethical studies as students, and as investigators following graduation. Nurse researchers use and are dependent on robust and highly ethical participant protection programs to review and approve their research proposals. All of us – research-

ers, nurse clinicians, nurse administrators and nurse citizens – need to have confidence in these same research participant protection programs. We cannot at this time. It is essential that nursing get involved, first by securing representation on the Sponsors' Table. At least one (but it could be more) of the national nursing organizations needs to take the lead on this, with a representative that is knowledgeable about issues related to research participant protection programs. Let's step up to the plate on behalf of all those individuals who contribute to nursing and all other types of research.

References

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