

Professional Responsibility and the Protection of Human Subjects of Research in Canada

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Introduction

Protection of human subjects of research involves governments, research funding agencies, professional organizations, institutions, individual researchers and research participants.¹ This paper reviews the responsibilities and roles of professionals and their organizations, including the development of appropriate assurance mechanisms for such protection.

What Does it Mean to Be a Professional?

A profession is more than “an occupation, especially one that involves prolonged training and a formal qualification.”² An important omission in that definition is the contract with society on which professionalism is based. That contract requires public trust, which in turn depends upon the integrity of individual professionals and their organizations.

Fundamental principles that characterize medicine’s social contract are primacy of the patient’s welfare, patient autonomy and social justice.³ Professions become *de facto* trustees of the public interest if those principles are maintained in the face of pressures from the state or the marketplace. Professions must protect not only vulnerable persons but also vulnerable social values. If professions do not meet their responsibility, public criticism ensues and, in the case of

medicine, characterizes physicians as servants of the state or tools of business.

Self-Regulation

Self-regulation is a responsibility and privilege permitted professions through legislation. An important component of self-regulation is defining and organizing educational and standard-setting processes for current and future members of the profession. Professional organizations do much to ensure quality assurance by establishing standards and confirming their implementation by accreditation, certification and continuing education. For example, the Québec Professional Code lists five elements to be considered when designating a professional order, including, “the special gravity of the prejudice that might be sustained by those who have recourse to the services of such persons because their competence or integrity was not supervised by the order.”⁴

The setting for self-regulation involves legislation, regulation, accreditation, certification and licensure; they are complementary mechanisms, each has strengths and limitations.

Legislation is the law, considered collectively. Laws are the system of values that, in a particular country or community, regulate the actions of its members and which may be enforced by the imposition of penalties. Elected representatives pass laws in a democracy.

Regulations are the rules or directives made and maintained by an authority. They are the mechanism by which govern-



ment bureaucracy implements legislation. For example, *The Canadian Food and Drug Act* provides regulations with regard to the safety and marketing of drugs. Regulations may cite guidelines produced by non-governmental organizations.

Accreditation is a non-governmental, self-assessment and external peer assessment process used by professional organizations to accurately assess levels of performance in relation to established standards and to implement ways to continuously improve.⁵ It is neither an audit nor an inspection. Existing federal and provincial regulations and policies may be used as a starting point in developing the purpose and scope of accreditation standards but accreditation moves beyond the minimal standards set by regulations. Accreditation is a more flexible process than regulation. It is a process that can be applied internationally.

A successful accreditation program is voluntary (a frequently misunderstood and underestimated element), involves peers, incorporates lay persons, is educational, rigorously evaluative, has buy-in by major stakeholders and is accountable to the public and adheres to internationally agreed methods of accreditation. It is done by an organization at arm's length from the program/organization being accredited.

An important benefit of accreditation is the synergy created among stakeholders in the process of developing standards. It contrasts with the top-down process of government regulators who lack a tradition of interaction with professionals in the field. Accreditation bodies adhere to internationally agreed upon methods of accreditation.

Critics of accreditation⁶ appear not to appreciate the value of stakeholder involvement in the development of standards, the ongoing identification with accreditation by professionals, its powerful educational component, authority, and the significant implications of losing accreditation.

Nation-wide accreditation standards avoid federal-provincial jurisdictional issues in Canada. For example, provincial governments make effective use of the national standards of

the Royal College of Physicians and Surgeons of Canada (RCPSC). Certification by the RCPSC of a physician trained in an RCPSC accredited program is accepted by provincial colleges as a standard for licensure.

Certification is the process that attests to a level of achievement defined by the certifying organization. Maintenance of certification is a process of continuing education designed to ensure engagement in personal professional development; it provides standard documentation demonstrating such engagement for purposes of licensure or privileges to practice.

Licensure is the provision of a permit from a licensing authority to carry on a profession. The licensing authorities for physicians in Canada are the territorial regulatory agencies and provincial colleges of physicians and surgeons. They are granted their authority by provincial or territorial law.

Governments view efficiency, effectiveness and measured outcomes as the best way to judge the services of professions. A common government reaction when perceiving problems with professionals is to establish more legislation, regulations and monitoring. Regulatory agendas in such circumstances may reflect politics, history and even chance and ignore priorities identified by professionals. A balance must be maintained between internal and external accountability.

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Professional Stewardship of the Ethical Review of Research in Humans: a Brief Review of Recent Events in Canada

A. Canada

1. Non-Governmental

National Council on Ethics in Human Research (NCEHR): *“Reflections on Monitoring Ethics Review of Research with Human Subjects in Canada”* was published by NCEHR in



1996.⁷ That report describes the strengths and weaknesses of different models of oversight including informal visits (conducted by NCEHR since 1992), visits within a formal framework, accreditation and investigation. The report was intended to stimulate discussion among stakeholder professional organizations in Canada.

The continuing absence of professional interest in Canada in developing an oversight mechanism to review the work of REBs prompted NCEHR to create the *Task Force to Study Models of Accreditation for Research Ethics Boards in Canada* in November 1999. The Task Force heard invited presentations from the RCPSC, Canadian Psychological Association, Canadian Institutes for Health Research, Canadian Council on Animal Care, the US Office for Human Research Protections and chairs of REBs. The task force report, approved by NCEHR council in 2002⁸, made the following recommendations:

1. that NCEHR affirm the need for a nation-wide oversight process for the ethics review of research in humans based on standards;
2. that such oversight take the form of an accreditation program to be conducted by an arm's length, non-governmental organization, and
3. that NCEHR facilitate discussion with organizations that would be stakeholders or observers in a new Program of Accreditation for Human Research Protection Programs.

The NCEHR reports were distributed to organizations with responsibilities in research with humans in Canada including the Association of Universities and Colleges of Canada (AUCC), the Association of Canadian Medical Colleges (ACMC), RCPSC, the three federal research funding agencies (MRC, NSERC, SSHRC), Health Canada and the Quebec Ministry of Health and Social Services.

Due to the continuing absence of meaningful interest by Canadian stakeholder professional organizations, NCEHR established yet a third task force in November 2003. It is charged with "developing a system of accreditation for human research protection programs in consultation with stakeholders."

Federal Research Funding Agencies (CIHR, SSHRC, NSERC): An important development in the ethical review of research in humans (RIH) in Canada was the publication by the three major federal research funding agencies of the *Tri-Council Policy Statement: Ethical Conduct of Research*

in Humans (TCPS) in 1998.⁹ TCPS provides standards for ethical review for both biomedical and behavioural research; it does not comment on means to ensure or monitor their application.

The Standing Committee on Ethics of MRC endorsed the development by NCEHR of models for the accreditation of REBs in 1999. The members of the NCEHR Co-ordinating Committee (the presidents of CIHR, NSERC and SSHRC, the deputy minister of Health Canada and the executive director of RCPSC) agreed at their last meeting (Nov. 2000) that Health Canada would take the lead in developing a process of oversight. SSHRC later indicated that it considered an accreditation system to be premature and advocated a Public Assurance System (PAS) governed by the Tri-Council Panel on Research Ethics (PRE). PAS would use annual reports and site visits.

Law Commission of Canada: The Law Commission of Canada published "*The Governance of Health Research Involving Human Subjects*" in May 2000.¹⁰ That report found that ethical governance in Canada required greater involvement by major actors and innovation in experimentation with alternative forms of governance. It commented on "...how substantial the gaps were between the ideals expressed in policy and the ground arrangements for accountability, effectiveness and the other criteria for good governance."

The Royal College of Physicians and Surgeons of Canada (RCPSC): RCPSC is responsible for accreditation of residency training programs, certifying physician specialists and setting standards for maintaining competence. RCPSC council received and approved the report of a Task Force on Clinical Research in May 2003.¹¹ The report noted the rapidly increasing number of clinical trials supervised by specialists, especially in community settings. It recommended development by RCPSC of educational standards for specialists in research methodology and ethics of research in humans. It also recommended "that RCPSC, in view of its expertise in accreditation, and with the co-operation of other interested organizations, facilitate the development of an arm's length, non-governmental governance of research involving humans in Canada, and take such initiatives as necessary to maintain appropriate professional involvement, particularly as it relates to patient care."

Canadian Medical Association: The CMA Code of Ethics states that the duty of Canadian physicians is to submit research involving humans to REBs "that meet current stan-



dards of practice.”¹² There is no reference to methods to ensure that standards are met. The CMA Code has been adopted by its provincial affiliates, however, physicians are left to their own devices to access REBs.

Provincial Colleges of Physicians and Surgeons: Provincial colleges are the regulatory bodies governing the practice of medicine. They licence physicians and investigate complaints about physicians. The Alberta College established a Research Ethics Review Committee (RERC) in 1998.¹³ Physicians in Alberta involved in research with humans must obtain approval from one of the recognised university ethics review boards or the RERC. It is the only provincial college that has established an RERC.

Association of Canadian Medical Colleges: The Research Committee of ACMC developed a position paper in support of a national human research ethics accreditation program. ACMC has not taken further action.

Association of Universities and Colleges of Canada: AUCC received the NCEHR reports. An invited representative of AUCC at a meeting of NCEHR Council in March 2004 reported that mechanisms for the oversight of the ethics of research in humans had not been an agenda item at AUCC, that situation may be changing.

2. Federal Government

Health Canada: The Health Policy and Communications Branch (HPC) of Health Canada produced a working document on human research governance in February 2001 followed by a series of meetings across Canada in 2002. The Speech from the throne in October 2002 stated that the federal government would work with the provinces to implement a national system for governance of research involving humans, including national research ethics and standards.

A Health Sciences Policy Division was established at HPC with responsibility for policy concerning governance for the ethical conduct of RIH. An Advisory Committee on the Governance of Research in Humans was formed to provide advice for Health Canada’s consideration concerning a

national system of governance for research involving humans. The committee met in 2003 but did not move beyond identifying the development of assurance mechanisms in health research as a key priority.

House of Commons: Standing Committee on Health: “*Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*” was tabled by the committee in April 2004.¹⁴ The initial section dealt with clinical trials. The first recommendation in the report includes the statement, “The committee strongly supports the development of accreditation for research boards responsible for assessing clinical trials.”

3. Québec

The Province of Quebec has been active with regard to research participant protection. The 1998 *Plan d’action ministeriel en Ethique de la recherche et en integrite scientifique*, prepared in parallel with the TCPS, describes the

composition, jurisdiction, accountability and mechanisms for compliance of REBs.¹⁵ The Civil Code was amended; Article 21 requires any research project involving minors or incompetent adults to be submitted to an REB designated by the Minister of Health. This led to a centralized oversight program that decides on applications for such designation. Inspections of REBs can be carried out for cause. Discussions about the suitability of initiating a program of accreditation are underway.

B. The United States

While disparate professional groups in Canada worked in isolation or ignored the matter of oversight of ethical review of RIH, the American scene is characterised by tangible developments.

The American Association of Universities (AAU) published the report of the Task Force on Research Accountability in June 2000.¹⁶ That report was in response to lax supervision and well-publicised isolated cases with tragic consequences at a number of academic institutions engaging in RIH. The AAU report stated that human subject research on campuses should be addressed as a whole, including medical research and social science research: “While there are clear differ-

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ences between the two, the overall human subjects rules apply campus-wide, which is the frame of reference for AAU presidents and chancellors.” The report said that an additional public accountability mechanism was necessary and recommended establishing effective accreditation programs.

American Association of Medical Colleges: David Korn, senior vice-president of AAMC, led the initiative resulting in the incorporation of a non-profit organization known as the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in April 2001. Founding members included: AAU, AAMC, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, the National Association of State Universities and Land Grant Colleges, and the National Health Council. AAHRPP developed standards and began offering accreditation in February 2002.

The Department of Veterans Affairs: requires that the National Committee for Quality Assurance (NCQA) accredit all VA centres. NCQA recently partnered with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to form the partnership for Human Research Protection (PHRP).

Comment

RIH is an important reason for advances in health care and expanding understanding in the social and behavioural sciences. It also requires professionals, universities and hospitals to meet the highest ethical standards to maintain the privilege of conducting RIH.

Universities and professional organizations in the United States responded to tragic events in RIH by providing unambiguous reports about their responsibilities across all academic disciplines. They provided moral and financial support enabling the creation of AAHRPP. In spite of tragic incidents, investigative reports documenting serious laxity in RIH ethical procedures¹⁷ and recommendations by NCEHR for stakeholder organizations to commence discussions to develop a program of accreditation for human research participants protection programs. Canadian academic institutions and professional organizations have reacted, so far, with indifference or defensive comments about cost and interdisciplinary issues.

The overriding purpose of professional accreditation is to assure the protection of human participants in research within the context of laws, regulations and accepted guidelines. Those responsible for setting professional standards in Canada should heed Korn’s admonition that “Those boundaries, however, are not fixed, but contingent on the diligence of the academic community in meeting the responsibilities that accompany its fiercely defended claim to the privilege of self-governance and academic freedom.”¹⁸ We have yet to see in Canada the professional leadership and commitment required to develop meaningful RIH assurance mechanisms.

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