

Contrasting Modes of Governance for the Protection of Humans and Animals in Canada: Lessons for Reform

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“The cover of a recent edition of *Time* magazine features a research subject in a cage with the caption ‘human guinea pigs,’ signifying perhaps that human subjects are no more protected from research abuses than are laboratory animals.”¹ However, as Barnes and Florencio state: “Ironically, in certain respects, animal research is more stringently regulated than is human subjects research” and note how this is the case in the U.S.² In this article, our argument will be that the governance of research involving animals in Canada is not only more stringent but better, in other respects, than the governance of research involving humans. This analysis offers insight and suggests a rationale for reforming the governance of research involving humans.

There are many similarities between the two governance systems, including:

- Similar histories and many common ethical concerns centring on the tension between the social benefits of research and the interests of the research subjects;
- Use of local review committees to assess research proposals as part of the process of research approval; and
- National guidelines enforced by conditional research funding.

Yet we find major features of the governance system in animal research that are either absent or underdeveloped in human research. These include:

- At the national level, arm’s length, independent, and transparent oversight of research;
- A national system of quality assurance and accreditation/certification for local systems of protection;
- Systematically gathered and publicly available information on the volume and type of research;
- A national curriculum of education mandated for those conducting or involved in research using animals.

Below we describe in more detail these similarities and differences. We begin with a brief description of research involving animals and the connections it has to research involving humans and why the two systems might learn from each other. After making comparisons in six key areas of governance (compliance, independence, transparency, accountability, quality assurance and education), we offer some hypotheses about the reasons for significant differences between these areas of governance and draw some lessons for the reform of research involving humans. Given that this article is part of a special issue on Canadian governance for research involving humans, we assume that readers will be more familiar with human research than animal research, and so go into more detail about the latter.

Background

There are many reasons why the governance system of research animals is applicable to the system for humans. In



biomedical research, animal and human studies are inextricably linked. Much knowledge and many assumptions about human biology have their basis in animal models. In fact, the history of using animal models dates back to 300 A.D.³ Currently, when pharmaceutical products or new procedures demonstrate promise for human use, testing for safety and efficacy in animals is required before testing may begin in humans.⁴ Many of the fundamental ethical issues and principles in research involving animals are similar to those for research involving humans. Both recognize the importance of research that benefits humans or animals, or that advances our knowledge, as long as this is achieved in an ethically appropriate manner, including meeting substantive standards related to potential harm, benefit, and social value, as well as procedural standards, such as independent ethical review.⁵

Some of the basic principles differ (for example, respect for human dignity versus maintaining animals “in a manner that provides for their physical comfort and psychological well-being”⁶) but they both provide a rationale for the protection of research subjects. Clearly such principles as free and informed consent and respect for privacy and confidentiality do not apply to animals. In fact, the animal protection system is entirely dependent on humans acting on behalf of animal welfare. Yet it is worth noting that a significant portion of research involving humans deals with persons who lack in whole or in part the capacity for free and informed consent. Also, even when research participants have the capacity for free and informed consent, a variety of problems relating to the consent process may occur such that more reliance needs to be placed on the ethical elements identified above that are common to both human and animal research protection.⁷ On the whole, we believe that there are sufficient similarities to provide a basis for comparing the two systems.

History

Historically both types of research have been and remain controversial. In Canada, several examples of misconduct have raised concerns about appropriate protection of human

research subjects. For example, brainwashing experiments using LSD were conducted by Dr. Cameron and colleagues at McGill University in the 1950s⁸ without patient consent. Two legal cases, *Halushka v. University of Saskatchewan*⁹ in 1965 and *Weiss v. Solomon*¹⁰ in 1989, involved drug trials where a research subject was harmed but researchers failed to fully disclose risks. Perhaps more well known, were cases of research involving humans in the U.S. (Tuskegee, Willowbrook, etc.). These events generated several waves of concern leading to major reforms in the governance of research involving humans.¹¹

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On the animal side, there have also been repeated waves of concerns dating back to a very active anti-vivisectionist movement in the 1800s and even earlier.¹² In Britain in the late 1800s, scientific experiments on living animals were the targets of some of the greatest protests involving both the public and scientists.¹³ In 1876 the *Cruelty to Animals Act* was passed by the British government, becoming the world’s first national law regulating animal welfare and animal experimentation.¹⁴ Despite the effectiveness of the antivivisection movement, public support for the use of animals in experiments began to grow in the first half of the 19th century as a result of the growing successes of experimental medicine and the gradually accumulating weight of evidence of the utility of animal models for human research. However, the late 1950s and early 1960s saw a resurgence of widespread public attention and concern over the use of research animals in Europe and North America.¹⁵ Over the next 30 years, many developed countries introduced or revised practices for the protection of research animals.

In Canada, the scientific community began formalizing the protection of research animals in 1961. In part this was a reaction to information from the Minister of Justice that his office had been requested to consider legislation concerning the use of research animals in Canada.¹⁶ Recognizing that use of research animals was a sensitive area and that improving the care and treatment of these animals increased the scientific validity of research, the Canadian Federation of Biological Societies established a committee to develop guiding principles on the care of research animals.¹⁷ In 1963



the Medical Research Council (MRC) requested that the National Research Council (NRC) establish a committee to further investigate the care and use of research animals in Canada. *The Report of the Special Committee on the Care of Experimental Animals* recommended the creation of an outside advisory body “to ensure the uniform application of the guiding principles at the national level and to assist local committees in the effective implementation of these principles for the procurement, facilities, care, and use of laboratory animals.”¹⁸ The idea was well supported by scientific and animal protection communities (as determined by a feasibility study¹⁹), and thus the Canadian Council on Animal Care (CCAC) was created in 1968. The council membership included representatives of researchers involved in the use of animals such as the Canadian Council of Departments of Psychology and the National Cancer Institute of Canada, research institutions such as the Association of Universities and Colleges of Canada (AUCC), and later, other academic societies such as the Canadian Bioethics Society (in 1995). The animal welfare movement was also represented amongst the founding members through the Canadian Federation of Humane Societies (CFHS). The CCAC was financed by MRC and NRC and operated as a sub-committee of the AUCC, until it was incorporated as a non-profit, autonomous and independent body in 1982.

The CCAC mandate is “to work for the improvement of animal care and use on a Canada-wide basis.”²⁰ The mandate is achieved through an institutional assessment program, educational workshops, publications, presentations, production of guidelines for the care and use of animals, and through local voluntary oversight by Animal Care Committees (ACC). In fact, Canada was the leading country internationally to establish local committees to supervise animal research.²¹ It should be noted that CCAC guidelines have been distributed widely internationally in both official languages as well as Spanish (at the request of users in Spanish-speaking countries). We note too that CCAC standards are recognized by the American Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) as equivalent to American standards, thereby reducing administrative requirements for Canadian research institutions’ eligibility to U.S. Public Health Service funding and to the American College of Laboratory Animal Medicine (ACLAM) accredited programs, and administrative requirements for ACCs. In short CCAC and its standards have a substantial international profile.

Procedural and structural requirements for REBs and ACCs are quite similar. For both committees, membership varies

depending upon the needs of each institution but usually includes a selection of members drawn from scientists and/or teachers experienced in research involving human or animal subjects and people representing community interests. CCAC specifies that ACCs must also include a veterinarian and an institutional non-animal-user member and recommends membership of animal technicians. Tri-Council Policy Statement (TCPS) specifies that REBs should have members with legal (for biomedical REBs) and ethics expertise. REBs are required and ACCs are encouraged to meet regularly for face-to-face meetings to review protocols. Decisions are based on a proportionate harm-benefit analysis and a process of expedited review exists for protocols of no more than minimal risk (referred to as lower categories of invasiveness for animals).

Comparison of Governance Systems

We turn now to six areas (compliance, independence, transparency, accountability, quality assurance, and education) for comparison of governance for animal and human research. These areas were chosen because they typically represent key conditions of a good governance system for research subject protection. These areas also highlight where human systems of governance may learn from animal systems of governance. The Institute of Medicine report *Responsible Research: A Systems Approach to Protecting Research Participants* suggests that an effective protection program for human research subjects requires accountability, transparency, ethics education programs, and adequate resources.²² Accountability is necessary for assuring quality and performance of a system. This includes a need for compliance with standards and the need for universal protection of research subjects. Transparency is considered necessary in order to maintain public trust in the integrity of the research and research ethics and “mechanisms used to protect participants from undue harm and to respect their rights and welfare must be apparent to everyone involved.”²³ Education of research personnel and committee members is “necessary to carry out their obligations to conduct or oversee ethically sound research.”²⁴ Finally with regards to independence, it has been argued that in order to maintain public trust “it is essential that there be an appropriate distance between the arms of government that promote research and those that protect human subjects. Moreover, the arm that protects human subjects must be in a position to verify the effectiveness of its efforts.”²⁵



(1) Compliance and Universality

For research involving either animal or human research subjects, receipt of federal research funds from one or more agencies of the Tri-Council²⁶ – Canadian Institutes of Health Research (CIHR), National Sciences and Engineering Research Council (NSERC) and Social Sciences and Humanities Research Council (SSHRC) – is contingent upon compliance with research ethics guidelines. In 2002, the three research Councils signed with universities or other bodies receiving and administering funds The Tri-Agency Memorandum of Understanding (MOU), which requires compliance with CCAC standards or TCPS for all research conducted at the institution, whether or not it is funded by the Tri-Councils.²⁷ With the CCAC, a similar agreement was reached as early as 1986.²⁸ CCAC is required to notify the funding agency of any non-compliance, which the agency follows up with a set procedure.²⁹

Although there is no federal legislation specific to either animal or human research, various other pieces of legislation are occasionally relevant. Included here, for example, is the Criminal Code with respect to cruelty to animals³⁰ or assault and battery for humans.³¹ Several provinces have legislation that is relevant to animal research (Alberta, Manitoba, New Brunswick, Nova Scotia and Prince Edward Island incorporate CCAC standards in their regulations and Ontario incorporates similar standards to CCAC)³² or to humans used in research.³³

Recognizing the complexity of the Canadian federal and provincial structure, the CCAC has developed a multi-pronged strategy aimed at achieving universal compliance with CCAC standards and oversight for all animal use in research, testing and teaching (post-secondary).³⁴ The strategy involves changing policies and practices in existing government departments (e.g., requiring CCAC compliance in safety testing of drugs regulated by Health Canada), enhancing existing legislation (e.g., *Migratory Bird Act*) or introducing new legislation. The CCAC has actively lobbied provincial and territorial legislatures to incorporate reference to CCAC standards in enacted provisions pertaining to the use of animals for experimental or other scientific purposes in their statutes or regulations.³⁵ Similarly, the CCAC has been promoting the incorporation of reference to CCAC standards in ongoing amendments to the Criminal Code (Bill C-22).³⁶

Using a different approach, the CCAC has also developed publicly recognized trademarks, Certificates of GAP-Good Animal Practice® and Bonnes pratiques animales (BPA^{MD})

which are awarded to any institution, whether private or public, that meet CCAC standards as determined by site assessment visits. As of 2004, a total of 187 institutions participate in the CCAC program (105 academic institutions, 40 government departments and 42 private or industry participants).³⁷ Currently, all universities, research hospitals, and federal government agencies involved in animal research participate in CCAC programs. Participation rates in industry are increasing as a result of interest in the Certificate of GAP-Good Animal Practice®.

There has been a less systematic approach to achieving universal compliance in human research. There is no mandatory system of site inspections for institutions receiving Tri-Council funding to ensure compliance. There have been no publicly known instances where funding has been withdrawn or even threatened to be withdrawn.³⁸ A few agencies require compliance with TCPS – Alberta College of Physicians, Canadian Blood Services and Health Canada for internal research – but there is no available evidence for compliance by private industry. Compared to animal research, rates of participation are likely lower in comparable programs aimed at improving voluntary compliance with TCPS by organizations and individuals who are not recipients of Tri-Council funding. Moreover, there appears to be no organized strategy on the part of the Panel on Research Ethics or other federal bodies to extend TCPS to research involving humans outside the current Tri-Council range, e.g., extending TCPS to industry.

With respect to pre-clinical and clinical trials for testing and marketing drugs intended for humans, all Canadian researchers, whether public or private sector, are required by Health Canada regulations to follow the International Convention on Harmonization of Good Clinical Practice (ICH-GCP).³⁹ The incentive for complying is to prevent any delay or denial of drug approval, rather than loss of funding. Some Canadian researchers may also have to comply with other standards. For example, Quebec has specific provincial legislation for research involving humans.⁴⁰ As well, Canadian researchers who receive funding from foreign research agencies, most notably the U.S. National Institutes of Health (NIH) are required to follow U.S. regulations. Multiple potentially conflicting standards raise compliance costs and complicate human research protection.⁴¹

(2) Independence

The CCAC has some degree of independence from the interests of research promotion. First, the CCAC comprises



twenty-four member organizations including representatives from the humane movement (3 out of 28 voting seats). Animal advocates are nominated by Canadian humane movement organizations and not by the research Councils. Other members include scientists, educators, members of industry, veterinarians, and animal technicians. NSERC, CIHR, and NRC have one voting seat each. Second, the very active participation in the CCAC and local ACCs by animal advocates also helps to provide a degree of independence from the immediate interests of researchers and their institutions. Third, the research councils have taken some care to assure functional independence for CCAC with respect to funding. The CCAC is currently co-funded by the CIHR and NSERC (together, 93% of funding) and financial support from additional voluntary, public and private sector participants. Every three years, CCAC applies for renewed funding and an external expert panel chosen by CIHR and NSERC reviews this request as well as past performance and offers its advice to CIHR and NSERC. Finally, from its start, the CCAC has set, revised and administered its own guidelines, which have not been subject to review or approval by the research Councils. These guidelines are developed through consultation with relevant stakeholders and are the property of the CCAC and its constituents. In effect the CCAC provides arms length research ethics standards and enforcement to the funding Councils.

This contrasts starkly with the role of the Councils for research involving humans. The Councils face a major conflict between their primary role as promoters and sponsors of research and their secondary role as protectors of research subjects. As research promoters, Councils are formally mandated to advance Canadian industrial and social objectives. Informally they act as advocates for their constituents – researchers and research institutions. From the MRC (1975) and SSHRC (1979) Guidelines through to the TCPS, the Councils have set and administered the policies for ethical research involving humans. In addition, the members of the Panel on Research Ethics, which is charged with “the development, evolution, interpretation, and implementation of the TCPS,”⁴² are appointed by and report directly to the Presidents of CIHR, NSERC and SSHRC. Thus, the Coun-

cils cannot be seen as independent protectors. At best they are “interested” or “invested” protectors who perforce have to balance the objectives of research promotion with human subject protection. In 2002 the Governing Council of CIHR expressed its concerns about this “systemic conflict of interest.”⁴³ In the supporting documentation for that motion⁴⁴, two examples of appropriate arm’s length independent governance were given: the CCAC and the U.S. Office for Human Research Protections (OHRP). OHRP’s functions related to the oversight and compliance with U.S. regulations, had been previously located in NIH, where it was known as the Office for Protection from Research Risks (OPRR). OPRR reported to the NIH deputy director. The OHRP offices have been moved from the NIH campus and the agency’s director reports directly to the Office of the Secretary of Department of Health and Human Services, as do other agencies such as NIH, Centers for Disease Control and Prevention, and Food and Drug Administration.

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(3) Accountability and Quality Assurance

The CCAC governance system has developed a variety of mechanisms for monitoring and assessing the effectiveness of their system ranging from assessments by CCAC to ongoing monitoring of research by institutional veterinarians who work closely with animal care technicians. Also, ACC members are mandated by CCAC to do regular site visits to animal facilities at their home institutions. Larger institutions have a staff veterinarian who advises the ACC and also oversees the proper care and use of animals on a daily basis. Animal care technicians are also encouraged to report any concerns to the ACC or institutional veterinarian. In effect then, veterinarians and animal care technicians provide quality control at the local level.

The CCAC conducts assessment visits to each participating institution at least every three years, and follow-up visits are also carried out, often unannounced. The site assessment panel is made up of individuals external to the assessed institution with special knowledge of various aspects of animal experimentation and care as well as one member from the humane movement. All members volunteer without remuneration.



neration. The goals of these visits are to evaluate the effectiveness of ACCs and assess the animal care and use program. The visits include meetings with ACC members and senior administrative staff, examination of protocols and ACC minutes, inspections of all facilities where animals are held and procedures take place, and interviews with investigators. Any major deficiencies (e.g., when an animal's health is at risk) must be addressed immediately. A report is written with recommendations and the institution has six months to explain how it will implement the recommendations. A unique aspect of animal research is that much of it takes place within an institution where research subjects are maintained so that monitoring can occur more easily. Wildlife research taking place in field conditions is generally not monitored in the same way, although institutional ACCs must review and approve protocols before their implementation with additional feedback required for ACCs to ensure minimization of numbers and pain and distress and to educate ACC members.

TCPS calls for monitoring and annual review of ongoing research projects, but this mostly focuses on documentation such as annual reports. Only a few institutions have started to do in depth annual review and monitoring.⁴⁵ The National Council on Ethics in Human Research (NCEHR) site assessment visits focus mostly on the ethical review process: on assisting institutions in reviewing strengths and weaknesses of their current system of ethics review, to enable REBs and NCEHR to learn from each other, to foster dialogue and understanding of the utility and limits of national ethical guidelines and to develop a national database on findings from the site-visit process.⁴⁶ Confidential summary reports are also written for each institution. For such site visits, it might be useful for NCEHR to ensure that they are able to interview a sample of past and current research subjects and also to interview those individuals who work directly with subjects, such as clinical nurses. Hence, in sharp contrast to animal research, monitoring, review, accreditation, and assessment for human research is in the very early stages in Canada.

Institutions under the purview of the CCAC must also provide information on their use of animals in research. In 1996, the CCAC introduced the Animal Use Data Form (AUDF) in order to refine and standardize the annual collection of data. The following information is reported:

- 1) the purpose of animal use (fundamental research, medical research, regulatory testing of products,

development of medical products, education and training of students in post-secondary institutions),

- 2) the total number of animals approved by the ACC and actually used per project,
- 3) the animal species used, (if cats and dogs, from where these animals were acquired),
- 4) the number of animals exposed to each of 4 categories of pain, distress or suffering (based on the "Categories of Invasiveness,"⁴⁷ a well respected international category system developed by the CCAC),
- 5) identification of ethically contentious issues according to a predefined list (for example, the use of genetically modified (GM) animals).

Data have been collected by the CCAC since 1975 and the majority of this information is available to the public. In addition, national animal use statistics are published annually. Information on investigators, animal care personnel, space allocation, location of animals, and description of protocols are collected by the institution through the review of protocols. Other countries such as the UK, the Netherlands and Switzerland, compile similar national information. A benefit of collecting such information is that it highlights important trends in animal use. For example, the numbers of GM animals has been increasing recently which raises particular welfare concerns (e.g., unpredictable adverse effects resulting from the random integration of the transgene and from gene expression) and which is resulting in efforts to address these concerns.⁴⁸ These statistics can highlight where improvements are needed and permit comparisons with other countries. Such information is also used to assess progress toward ethical goals, such as the reduction of the number of animals used and the invasiveness of research – both are widely accepted utilitarian rules of thumb for minimizing suffering of research animals.⁴⁹

In contrast, we have very little information about the participation of humans in research in Canada. Some information is collected by Health Canada for clinical trials but it is not publicly available – though it is worth noting that CIHR will soon require registration of the clinical trials it funds.⁵⁰ Valuable data could be collected that would be similar to that collected for animals. For example, it would be valuable to know how many studies are proceeding and how many human subjects are involved in different areas (clinical drug trials, basic research, behavioural and social science research, student projects, teaching, emergency health research, epidemiological research, human genetic research, biobanking) or using different research methodologies (qualitative, quantitative, deception) or different groups of



individuals (Aboriginal, subjects unable to give consent, patients versus non-patients), or prevalence of adverse events or different types of harms that were reported during and after studies. Studies could also be classified according to a predetermined set of ethically contentious categories, reflecting areas of concern highlighted in TCPS. Similarly, research could also be classified according to risk, minimal versus more than minimal.

Similar to data collection for animals involved in research, this information could be used for quality assurance measures, to help identify how effective our system of governance is, and where improvements are warranted. Public reporting of this information would also provide transparency. We have outlined a few possibilities of data, but in all cases, consideration should be given to the ease of collecting this information, as well as the relevance of the data to the substantive goals of national guidelines such as TCPS. As one example, although both systems try to minimize the number of research subjects that are exposed to potential harm, some reasons for counting human populations (e.g., ethnicity, race, or sex) involved in research would be different than reasons for counting animals. For example, in animal research, an ethical goal has been to provide greater protection for and to reduce the numbers of animals of “higher order” species. Even with different reasons, understanding the scale of use of different populations of humans in particular types of research in Canada might help to provide data on which to base policy decisions, and at the institution level, such data could help inform resource allocation decisions for REB administrative support or training opportunities. From a political perspective, knowing the number of human subjects involved in research – particularly higher risk research – could prove important for raising the profile of human research protection and increasing the resources devoted to it. Costs of collecting such data may only be marginal because information is already being tracked through the REB protocol review process. As is done for animal research, protocol applications outline desired sample size for their studies and report actual sample sizes in annual and end of study reports. The animal governance system has a system of collecting information that works well. For the human system, synthesizing data at a national level cannot be done unless a national agency, such as the NCEHR, is given the mandate along with resources and support to accomplish this task. Naturally, a lack of universal compliance with TCPS *or* CCAC standards will limit the comprehensiveness of national data collection.

(4) Transparency

In addition to the important data that are published annually, CCAC makes a variety of information publicly available or available to the council. CCAC Certificates of GAP-Good Animal Practice® are published on the CCAC website with permission from each institution. Institutions may distribute copies of assessment reports to those they wish. CCAC produces annual reports, available to the public, with information about the number of institutions that are compliant, conditionally compliant or on probation. There is no equivalent public reporting for research involving humans; instead the Tri-Agency MOU requires institutions receiving federal research funds to assure the three federal research sponsors compliance with Tri-Council policies. Unlike research involving animals, there is no independent mode of verification available to sponsors or recipient institutions for adherence to standards. Although site visits may be conducted by NCEHR, these are purely voluntary. Finally, a further striking contrast between the two systems has been the very active participation of subject-advocates in the governance of research involving animals from animal welfare groups and community representatives with no real equivalent in research involving humans.

(5) Education

Since 2003, the CCAC has developed a National Institutional Animal User Training (NIAUT)⁵¹ for all individuals who use animals in research. The goals are to foster a philosophy of compassion and respect for research animals and an understanding of the ethical issues of using animals in science, and to ensure that researchers and animal technicians have the knowledge and technical skills necessary to conduct quality science based on appropriate animal use. Web-based training modules are available to all institutions and these include modules on CCAC guidelines, ethics, animal care, assessment of pain and distress, and so on. Training for specialized skills is designed by each institution. This is a mandatory program and each ACC must ensure that all animal users in their institution have obtained certification. There is no equivalent training program for research staff that work with humans. In addition, the training modules were developed by CCAC and a wide variety of volunteer experts from institutions across the country. This bottom up approach may result in greater buy-in by individual users.

In the area of training ethics committee members, the two systems are similar. There is no systematic training set up for ACC members but the CCAC offers publications and



annual workshops across Canada for ACC members and researchers. Similarly, NCEHR also offers regular workshops on issues such as informed consent, as well as a Listserv for REB members to discuss issues. The Panel on Research Ethics also offers an electronic training module for REB members that centres on knowledge of TCPS.⁵²

Conclusion

This examination of the system for the governance of animals used in research has shown that in six areas, the animal system appears to be better developed than that for humans, except perhaps in the area of training ethics committee members. This raises the compelling question of why. Since we are arguing from an anthropocentric view, in principle, the protection of humans involved in research should be of even greater importance to Canadians. Without doing a detailed historical analysis, we can hypothesize that animal rights activists have had a galvanizing effect on the Canadian public's concern for animal welfare. There have been effective advocates for animal research subjects in the Canadian humane movement, which we have not seen for human subjects, unlike in the US, where human subject protection has become a prominent public concern, including vigorous interventions by prominent members of Congress.⁵³ Also, contributing to the establishment of an earlier protection system was that researchers, their institutions, and sponsors saw that it was in their mutual best interests to work together to build a régime that had public credibility. In contrast, the politics of human research ethics in Canada have moved from significant lack of concern on the part of the research community manifest in the pre-TCPS period to the over-politicized concerns in the TCPS period.

The existing governance system for research animals offers important insights and experiences that seem directly relevant to the improvement of Canadian governance of human research protection. Perhaps the possibility even exists for cooperation or sharing efforts to advance protection for both animal and human research subjects simultaneously. Of course we are not saying that the CCAC model is ideal, but along the dimensions that we have discussed it has several advantages: it is an example of a Canadian model of governance that tries to work across both federal/provincial, and public/private jurisdictions. The model is moderately independent from research and sponsor interests; it monitors and assesses effectiveness of the system and compliance with standards; it collects and publishes information about the effectiveness of the system as well as research trends; and it

has a national education program. Hence it is more transparent and accountable, and it provides quality assurance. Moreover, the absence of a system of accreditation for Canadian human research protection and the lack of information about the system as a whole makes it impossible to reassure Canadians that they are adequately protected as research subjects.⁵⁴ We would conclude that a comparison of the two Canadian régimes provides a disquieting picture of Canadian protection for human subjects.

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21. Brody, *supra* note 11 at 23.
22. Institute of Medicine. *Responsible Research: A Systems Approach to Protecting Research Participants* Daniel.D. Federman, Kathi E. Hanna & Laura Lyman Rodriguez eds., (Washington DC: The National Academies Press, 2003) at 7.
23. *Ibid.* note 21 at 64.
24. *Ibid.* note 21 at 52.
25. Michael McDonald *et al.* *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000) at 11, Section F, Conclusions and Recommendations, online: <<http://www.lcc.gc.ca/en/themes/gr/hrish/macdonald/macdonald.pdf>>.
26. Since 2002, the accurate term used to describe the three federal Granting Councils is Granting Agencies (see note 27) but since TCPS refers to them as Tri-Councils we choose to use the latter terminology.
27. NSERC, *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards (MOU)* (2002), online: <http://www.nserc.gc.ca/institution/mou_e.htm>. [NSERC, "MOU"]
28. Harry C. Rowsell, "Regulation of Animal Experimentation: Canada's Program of Voluntary Control" (1986) 554 *Acta Physiologica Scandinavica* (Suppl.) 95.
29. NSERC, MOU, *supra* note 27, *Schedule 8: Investigation and Resolution of Breaches of Agency Policies*.
30. R.S.C. 1985, c. C-46, Part XI Willful and Forbidden Acts in Respect of Certain Property, ss. 446 and 447 Cruelty to Animals.
31. R.S.C. 1985, c. C-46, Part VIII Offences Against the Person and Reputation, Section Assaults.
32. CCAC Module 1, *Guidelines, Legislation, and Regulations* (2004) <<http://www.ccac.ca/english/educat/Module01E/module01-11.html>>.



33. Kathleen C. Glass & Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy* 2nd ed. (Toronto: Butterworths, 2002) 459.
34. CCAC, *Towards a Strategy for Obtaining Universal Application of the CCAC's Programs* (Ottawa: CCAC, 1996).
35. For example, see CCAC, *Annual Report 2000-2001*, online: <<http://www.ccac.ca/english/publicat/annualre/annual01.htm>>.
36. Bill C-22, *An Act to Amend the Criminal Code (Cruelty to Animals)* 3rd Sess., 37th Parl., 2004.
37. Personal communication with Executive Director of the CCAC (2004).
38. Michael McDonald & Eric M. Meslin, "Research Ethics as Social Policy: Some lessons from Experiences in Canada and the United States" (2003) XXIV *The Tocqueville Review* 61.
39. ICH, *Consolidated Guidelines supra* note 4.
40. Quebec Civil Code Arts. 20-25
41. 41. James Lavery, Eric M. Meslin & Michael McDonald, "Research Ethics Across the 49th Parallel: The potential value of Pilot Testing 'equivalent protections' in Canadian Research Institutions" (2005) 13 2 & 3 *Health Law Review*.
42. 42. Interagency Panel on Research Ethics, *Terms of Reference: Part II Role and Constitution of the New Governance Structure* (2002), online: <<http://www.pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#intermandate>>.
43. 43. CIHR "18th meeting of the Governing Council" (Meeting Minutes, 20-21 November, 2002), online: <<http://www.cihr-irsc.gc.ca/e/13135.html>>. The following is an excerpt:
- "Through motions from the SCE [Standing Committee on Ethics], Governing Council has been apprised of the problem of systemic conflict of interest for CIHR in its dual role of promoting and sponsoring researchers, and ensuring compliance to protect research participants. The November 7th motion of the SCE on this issue: "The CIHR Standing Committee on Ethics supports the concerns raised at both meetings of the Institute Advisory Board Ethics Designates with respect to the perceived systemic conflict of interest within the governance structure of the Tri-Council Policy Statement. The Standing Committee on Ethics is of the view that there is a systemic conflict of interest in the dual role of the federal funding councils - CIHR, SSHRC, and NSERC - to both promote research and regulate its ethical conduct. The Standing Committee on Ethics urges Governing Council to explore with the two others federal agencies the problem of systemic conflict of interest with a view of making structural changes to avoid such conflict of interest", was presented to and accepted by the Governing Council."
44. CIHR, "3rd Meeting of Standing Committee on Ethics" (Meeting Minutes, Conference Call 7 November, 2002), online: <<http://www.cihr-irsc.gc.ca/e/16778.html>>.
45. Robert Bortolussi & Diane Nicholson, "Auditing of Clinical Research Ethics in a Children's and Women's Academic Hospital" (2002) 25 *Clinical and Investigative Medicine* 83.
46. National Council on Bioethics in Human Research, "Protecting and Promoting the Human Research Subject: a Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine" (1995) 6 *NCBHR Communiqué* 3.
47. CCAC, *Experimental Animals, supra* note 5.
48. Catherine Schuppli, David Fraser & Michael McDonald, "Expanding the Three Rs to Meet New Challenges in Humane Animal Experimentation" (2004) 32 *Alternatives to Laboratory Animals* 525.
49. William M.S Russell & Rex L Burch, *The Principles of Humane Experimental Technique* (London: Methuen, 1959).
50. David Moher & Alan Bernstein, "Registering CIHR-Funded Randomized Controlled Trials: a Global Public Good" (2004) 171 *Canadian Medical Association Journal* 750.
51. CCAC, *National Institutional Animal User Training Program* (2003), online: <<http://www.ccac.ca/english/educat/edframe.htm>>.
52. Interagency Advisory Panel on Research Ethics, *Introductory Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*, online: <<http://www.pre.ethics.gc.ca/english/tutorial/>>.
53. Rebecca Dresser, *When Science Offers Salvation: Patient Advocacy and Research Ethics* (New York: Oxford University Press, 2001).
54. See the papers by Dinsdale on accreditation and Beagan and McDonald on evidence-based research ethics elsewhere in this issue.

