# THE REGULATION OF BIOMEDICAL RESEARCH EXPERIMENTATION IN CANADA: DEVELOPING AN EFFECTIVE APPARATUS FOR THE IMPLEMENTATION OF ETHICAL PRINCIPLES IN A SCIENTIFIC MILIEU

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*Bien qu'un consensus international semble se développer quant à la nature des principes éthiques de base qui devraient servir de guide a la conduite d'expériences biomédicales, il existe un débat par rapport a la quesion cruciale, a savoir exactement comment ces principes devraient être mis à exécution dans la pratique. Parmi les inquiétudes principales de ce débat figure la question a savoir si l'expérimentation biomédicale devrait être réglementée en tout ou en partie, en vertu de lois, ou si le contrôle de l'entreprise de recherche devrait être laissé entre les mains des institutions, des universités, de la profession médicale et des checheures et chercheurs par voie d'un processus d'auto-réglementation.*

*Cet article traite la question fondamentale suivante : comment faut-il réglementer les expériences biomédicales dans le contexte canadien? Les auteurs discutent du contrôle social de l'expérimentation biomédicale dans le contexte de l'éventail des solutions de rechange en fait de mécanismes régulateurs, de la structure actuelle de révision de la recherche et du rôle central que joue le*

*Although there appears to be an emerging international consensus as to the general nature of the basic ethical principles that should guide the conduct of biomedical experimentation with human subjects, a debate exists in relation to the critical question of exactly how these principles should be implemented in practice. Among the key concerns of this debate are whether biomedical experimentation should be regulated, in whole or in part, by legislation or whether control of the research enterprise should be left primarily in the hands of the granting agencies, universities, the medical profession and researchers themselves through a process of self-regulation.*

*This article addresses the fundamental question of how biomedical experimentation should be regulated in the Canadian context. The authors discuss the social control of biomedical experimentation in the context of the range of alternative regulatory mechanisms, the existing structure of research review, and the central role of the Research Ethics Board (REB) in the United States, the United Kingdom and Canada, with a*

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*Conseil d'éthique de recherche (CER) aux États-Unis, au Royaume-Uni et au Canada, en mettant l'accent sur la réforme du système règlementaire canadien.*

*Les auteurs recommandent que les provinces et territoires du Canada promulguent des lois établissant sans équivoque l'autorité des CER pour revoir tous les protocoles de recherche traitant d'expériences biomédicale avec des sujets humains. Ces lois devraient indiquer que le fait de mener des expériences sans l'approbation préalable d'un CER est une infraction, et prévoir des règles générales régissant la conduites des scientifiques.*

*focus on reforming the regulatory system in Canada.*

*The authors recommend that the various provinces and territories of Canada enact legislation that unequivocally establishes the authority of REB's to review all research protocols involving biomedical experimentation with human beings. Such legislation should emphasize that it is an offence to conduct experimentation without the prior approval of a local REB, and should articulate general rules governing the conduct of researchers.*

TABLE OF CONTENTS

## I. INTRODUCTION

The regulation of biomedical experimentation became an urgent issue after the horrors of the Nazi atrocities, committed upon prisoners during World War II, became widely known in the world community. Such regulation became necessary because it emerged that these outrages were not perpetrated solely by brutal guards or rogue members of the military machine; indeed, it was manifest that *medical researchers themselves* had participated in experiments that shocked the conscience of the world. Significantly, the hellish vision that the Nazis sought to bring to fruition was not developed by a few demented leaders acting in total isolation from the rest of contemporary German society; rather, it reflected many of the dominant themes that were current in the medical theory and practice of the time and gave them a brutal twist. As Dumont has pointed out,

> [w]hat we see as horrifying in retrospect, in the use of human beings as guinea pigs, the mass sterilization of unwanted people, the racist eugenics and all the rest, was the mere flowering of much more commonplace and perennial preoccupation with biological determinism, scientific authority and medical hegemony. Indeed, the entire Nazi era with its culmination in the Final Solution was not so much the result of the "politicization of medicine" as the "medicalization of politics." The very gas chambers ultimately used to destroy millions of Jews, Gypsies, Communists and homosexuals were originally designed by psychiatrists for mental hospitals. It was not, we now know, that a reluctantly compliant medical profession was conscripted by the Nazis, but that the very definition of Nazi policies was based on, and would not have been possible without, the enthusiastic leadership of doctors.[1]

The immediate outcome of the World War II atrocities was the articulation of ethical and legal codes that were designed to regulate the process of biomedical experimentation with human beings. The first, and undoubtedly most famous, of these codes was the so-called *Nuremberg Code* that emerged from the trial of the defendants involved in the Nazi experiments.[2] Foremost among the principles established by the *Nuremberg Code* was the fundamental prerequisite of informed and free consent on the part of those who participate as subjects in biomedical experimentation.[3] Subsequently, at an international level, the most significant codes of ethics that have been widely embraced are the World Medical Association's *Declaration of Helsinki* (first adopted in 1964 and revised on a number of occasions between 1975 and 1989)[4] and the Council

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[1] M.P. Dumont, "Book Review: *The Nazi Doctors and the Nuremberg Code*, by George J. Annas & Michael A. Grodin" (1993) 36 Social Sciences & Medicine 1519 at 1519-1520.

[2] *U.S.* v. *Karl Brandt et al., Trials of War Criminals Before the Nuremberg Military Tribunal Under Control Council Law No. 10.* (October 1946-April 1949).

[3] See G.J. Annas, L.H. Glantz & B.F. Katz, *Informed Consent to Human Experimentation: The Subject's Dilemma* (Cambridge, Mass.: Ballinger Publishing, 1977) at 6-19.

[4] World Medical Association, *Declaration of Helsink*

Adopted at the 18th World Medical Assembly in Helsinki in June 1964. Amended at the 29th World Medical Assembly in Tokyo in October 1975; at the 35th World Medical Assembly in Venice in October 1983; and at the 41st World Medical Assembly in Hong Kong in September 1989. [Reprinted in (1991) 19 Law, Medicine & Health Care 264]. In 1974, the World Medical Association also adopted the *Declaration of Tokyo* that prohibited physicians from involvement in any form of torture or cruel, inhuman or degrading treatment of prisoners or political detainees.

of International Organizations of Medical Sciences' *International Guidelines for Biomedical Research Involving Human Subjects* (promulgated in 1993).[5]

In addition to the emergence of international legal and ethical codes, there have been parallel developments at the national level. In the United States, for example, federal regulations, embodied primarily in the *Federal Policy for the Protection of Human Subjects*, establish the basic requirements for biomedical experimentation, although these regulations are supplemented by state legislation and the requirements of local institutions.[6] In Canada, with the exception of Québec, there is no comparable legislation. However, the Medical Research Council of Canada issued a set of ethical guidelines in 1987 that are applied to all research projects funded by the Council[7] and, in 1996, a Working Group of the three national councils that fund research involving human subjects prepared a draft *Code of Conduct for Research Involving Humans* that, if ultimately adopted, will set the ethical rules for all such research in Canada.[8]

While there appears to be an emerging international consensus as to the general nature of the basic ethical principles that should guide the conduct of biomedical experimentation with human subjects, there has nevertheless been a keen debate in relation to the critical question of exactly how these principles should be implemented in practice. Should biomedical experimentation be regulated, in whole or in part, by *legislation* or whether control of the research enterprise should be left primarily in the hands of the granting agencies, universities, the medical professions and researchers themselves through a process of *self-regulation*? At present in Canada, only Québec has followed the legislative route; elsewhere, a pattern of self-regulation continues to hold sway.

This article addresses the fundamental question of how biomedical experimentation should be regulated in the Canadian context. The range of regulatory alternatives is discussed and the experiences of the United States and the United Kingdom in this arena are considered, with a view to informing the debate as to the nature of the appropriate regulatory policies that should be adopted in Canada. The central role played by research ethics boards (or committees) in the regulation of biomedical experimentation in Canada, the United Kingdom and the United States is examined and recommendations are made as to the nature and direction of reforms to the existing system. One of the most important goals of any regulatory process must be to protect

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[5] Council for International Oganizations of Medical Sciences, in collaboration with the World Health Organization, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 1993) [hereinafter *CIOMS Guidelines*]. The Steering Committee on Bioethics of the Council of Europe has recently (June 1996) adopted a *Convention on Human Rights and Biomedicine*. If the Convention is approved by the Council of Ministers and is signed by member states, it is expected that it will be followed by, *inter alia*, a specific protocol concerning research with human subjects. See B. Starkman, "Models for Regulating Research: The Council of Europe and International Trends" [unpublished manuscript].

[6] See 45 C.F.R. 46 (1991).

[7] Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Minister of Supply and Services Canada, 1987).

[8] Tri-Council Working Group, *Draft Document: Code of Conduct for Research Involving Humans* (Ottawa: Minister of Supply and Services Canada, 1996). The three funding councils are the Medical Research Council of Canada (MRC), The Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC).

human subjects (particularly those who are members of vulnerable groups) from the very real dangers of unethical research. However, such a process must also operate so as to ensure that ethically sound experimentation with human beings is facilitated and encouraged because, without such research, sorely needed advances in medicine may well not be accomplished.

## II. THE SOCIAL CONTROL OF BIOMEDICAL EXPERIMENTATION: THE RANGE OF ALTERNATIVE REGULATORY MECHANISMS

There is a marked diversity of mechanisms that are potentially available to assert regulatory control over the conduct of biomedical experimentation. These mechanisms include (i) *intraprofessional controls* based on medical licensing and disciplinary proceedings administered by the appropriate professional bodies; (ii) *judicial controls* based either on the law of torts and criminal law or on specific legislation dealing with experimentation; and (iii) *independent boards of review* that administer ethical rules that have been officially sanctioned in one form or another.

In the United States and an increasing number of other countries, there has been a dramatic departure, over the past several decades, from reliance on primarily intraprofessional methods of regulation that are based on broad ethical codes emerging from within the confines of the medical community itself. Instead, as Benson points out, there has been a determined shift towards adoption of a system of controls that is administered by bureaucratically organized boards of review that are, on the face of it, external to the medical professions themselves.[9] Indeed, most countries have adopted the system of research ethics boards (or committees)[10] and it has been given the seal of approval by such international agreements as the *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* promulgated by the Council for International Organizations of Medical Sciences (CIOMS) in 1993.[11] As McNeill notes,

> The predominant model of research regulation is that any researcher, before embarking on any research involving human participants, seek and gain approval for that research from a committee. The committee, specially constituted to consider the ethics of research, has the power to recommend modifications to the proposed research, reject the application outright, or approve of the research ...The setting for the committee is different in different countries, but with few exceptions, committees are based in an institution, usually a research institute within which the research is conducted, or are established within a regional authority, such as an area health board.[12]

Why have ethical review boards assumed such a central role in the regulation of biomedical experimentation in so many countries? To some extent, their very

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[9] R. Benson, "The Social Control of Human Biomedical Research: An Overview and Review of the Literature" (1989) 29 Social Sciences & Medicine 1 at 1. See also P.R. Benson & L.H. Roth, "Trends in the Social Control of Medical and Psychiatric Research" in D.N. Weisstub, ed. *Law and Mental Health: International Perspectives, Volume 4* (New York: Pergamon Press, 1988) 1 at 3-4.

[10] See P.M. McNeill, "International Trends in Research Regulation: Science as Negotiation" in (1996) [unpublished manuscript].

[11] See *CIOMS Guidelines, supra* note 5.

[12] See McNeill, *supra* note 10.

dominance in this field reflects the failure of other regulatory mechanisms to establish themselves as viable alternatives. For example, the general view seems to be that intraprofessional controls are not very effective as a means of controlling abuses in biomedical experimentation. In this respect, Benson has indicated that such factors as medical education, peer influence, codes of ethics and disciplinary procedures are not *per se* adequate to prevent unethical research practices.[13] Similarly, Goldner makes the point that it is scarcely surprising that there have been very few reported disciplinary cases in which questions have been raised concerning the propriety of physicians conducting biomedical experiments because, in general, the available research suggests that disciplinary actions taken by licensing boards are of dubious efficacy and, in any event, disciplinary actions based on allegations of incompetence are rare.[14]

Social control of biomedical experimentation may also be achieved through litigation before the courts. In particular, a civil action may be brought by a research subject who alleges a cause of action recognized by the law of torts. In the context of biomedical experimentation, the most likely action is one based on alleged negligence.[15] In theory, the very existence of the tort system is supposed to act as a deterrent to negligent conduct or unethical conduct on the part of biomedical researchers.[16] However, there has been a marked paucity of court cases that have arisen in the specific context of biomedical experimentation and the few cases that have been brought to trial have focussed on the issue of informed consent.[17] They have not dealt with any of the issues that arise from biomedical experimentation with subjects whose capacity to consent is in doubt nor have they come to grips with the thorny problem of how one balances risk to the subject against the potential benefits to society that may flow from such experimentation.[18] While there is some evidence that this may be an area in which the courts may, in the future, become more involved as a regulatory mechanism,[19] it is

[13] Benson, *supra* note 9 at 2-4.

[14] J.A. Goldner, "An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously" (1993) 38 Saint Louis University Law Journal 63 at 68-69.

[15] Goldner, *ibid* at 70-88; Benson, *supra* note 9 at 6-7; Benson & Roth, *supra* note 9 at 12-15; P.M. McNeill, *The Ethics and Politics of Human Experimentation* (Cambridge: Cambridge University Press, 1993) at 121-138.

[16] Goldner, *supra* note 14 at 70.

[17] See, for example, P.M. McNeill, *supra* note 15 at 122. For cases in Canada, see *Halushka* v. *University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask.C.A.); *Weiss* v. *Solomon*, [1989] R.J.Q. 731 (S.C.). For cases in the United States, see, for example, *Kaimowitz* v. *Michigan Department of Mental Health*, Civil Action No. 73-19434-AW (Wayne County, Michigan Cir. Ct. 1973) in A.D. Brooks, *Law, Psychiatry and the Mental Health System* (Boston: Little Brown, 1974) at 902 ff.; *Blanton* v. *United States*, 428 F. Supp. 360 (D.C. 1977); *Burton* v. *Brooklyn Doctors Hospital*, 452 N.Y.S. 2d. 875 (N.Y. 1982); *Begay* v. *The United States*, 768 F. 2d 1059 (4th Cir. 1985), and *Moore* v. *Regents of the University of California*, 793 P. 2d (Cal. 1990), cert. denied, 499 U.S. 936 (1991).

[18] However, in *Muir* v. *Alberta*, [1996] 4 W.W.R. 177 (Alta. Q.B.), damages were awarded against the Government of Alberta for the wrongful sterilization of a woman who had been in the care of the Province.

[19] *Supra* note 9 at 6, Benson notes that, "Despite the general paucity of case law concerning human experimentation, court cases dealing with research have increased in recent years. Rising court involvement suggests that judicial social control may play a more prominent role in the future regulation of human subjects research than it has in the past." Predictions about the

clear that, to date, the role of the civil courts has been relatively minor.

The criminal law has generally not been used as a means of regulating biomedical experimentation. In Canada, for example, there is a number of provisions in the *Criminal Code* that might be relevant to experimental abuses, particularly those provisions relating to assault.[20] However, in practice, the criminal law is not resorted to for this purpose. The Law Reform Commission of Canada made the following observations about the role of the criminal law in medical treatment and, in many respects, they are equally applicable to the field of biomedical experimentation:

> The impact of criminal law on the administration of treatment is largely overlooked in the Canadian context. Potential criminal liability is rarely considered by doctors or hospitals when seeking consent to or waiver of treatment. The handful of prosecutions in the last fifty years, as compared with the increasing frequency of civil litigation suggests to some that the Criminal Code is ineffective in this area because the type of harm contemplated in the administration of treatment is not of the degree to warrant the intervention of the criminal law. Indeed, the risk of criminal liability has been said to be more the "product of a fertile legal mind than a realistic possibility."[21]

What has been the role of legislation as a means of regulating biomedical experimentation? In the United States, the elaborate institutional review board structure has been established by regulations that have been issued by federal agencies such as the DHHS and FDA and have been codified in the Code of Federal Regulations.[22] Furthermore, a number of individual states have, since the 1970's, enacted legislation regulating various aspects of human experimentation,[23] with the most detailed and comprehensive statutory framework being established in the State of California, where the legislators included an "experimental subjects' bill of rights."[24]

However, to date, countries such as Canada, New Zealand, and the United Kingdom have made very little use of legislation as a means of regulating biomedical experimentation, although there have recently been a number of calls to give some form of legislative backing to the system of ethics review in those jurisdictions.[25] In Canada, while the Medical Research Council of Canada's *Guidelines on Research Involving Human Subjects*[26] are applied by most ethics review boards that scrutinize the conduct

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direction case law in this area may take, however, are premature.

[20] See, for example, *Criminal Code*, R.S.C. 1985, c. C-46 [hereinafter *Criminal Code*], sections 266 (assault); 267 (assault causing bodily harm); 268 (aggravated assault); 269 (unlawfully causing bodily harm). For discussion of the issue of consent in the context of assault, see *R.* v. *Jobidon* (1991), 66 C.C.C. (3d) 454 (S.C.C.) and *R.* v. *Welch* (1995), 101 C.C.C. (3d) 216 (Ont. C.A.).

[21] Law Reform Commission of Canada, *Working Paper 26: Medical Treatment and the Criminal Law* (Ottawa: Minister of Supply and Services Canada, 1980) at 1.

[22] See 45 C.F.R. 46 (1991) Note also *Federal Policy for the Protection of Human Subjects: Notices and Rules*, 56 Federal Register 117 (18 June 1991).

[23] Benson, *supra* note 9 at 7.

[24] California Laws 1987, Chap. 1.3, codified as California Health and Safety Code, ss. 24170-24179.5.

[25] McNeill, *supra* note 15 at 136-137. Legislative intervention in the area of medical ethics did occur in Australia: see *National Health and Medical Research Council Act, 1992*, 1992 Austl. Acts 225, ss. 35-36.

[26] *MRC Guidelines*, *supra* note 7. For a critical review of these *Guidelines*, see B. Hoffmaster, "The Medical Research Council's New *Guidelines on Research Involving Human Subjects*: Too Much Law, Too Little Ethics" (1990) 10 Health Law in Canada 146.

of biomedical experimentation, they do not have any independent legal force. Significantly, the Law Reform Commission of Canada has recommended the introduction of legislative controls, at the federal level, through amendments to the *Criminal Code* and a general federal statute on experimentation.[27] To date, no action has been taken on these recommendations. However, there is now one provincial legislature that has enacted statutory provisions that deal explicitly with biomedical experimentation, namely the National Assembly of Québec. These provisions, the content of which will be addressed later, were enacted as amendments to the *Civil Code of Québec*.[28] As is the case in the United States, the Québec legislation articulates basic principles concerning the conduct of biomedical experimentation and establishes a legislative framework to underpin a system of regulation by research ethics boards.

Although a number of alternative regulatory mechanisms are available, there is little doubt that the most important component in the contemporary apparatus for the control of biomedical experimentation in many countries around the world is the research ethics board. In some jurisdictions, there is a legislative framework that supports the work of these boards while, elsewhere, they operate in the context of a non-statutory system of self-regulation administered by the granting agencies, universities, the medical profession and biomedical researchers themselves. It is to the nature and functions of the research ethics boards that the focus of inquiry will now turn.

## III. THE EXISTING STRUCTURE OF RESEARCH REVIEW: THE CENTRAL ROLE OF THE RESEARCH ETHICS BOARD

Institutional research ethics boards (or "committees") have become well-entrenched in a number of countries, with 140 in Australia, 240 in England and Wales, over 100 in Canada, and over 5000 in the United States.[29] The evolution of such quasi-legal decision-making mechanisms may be traced back to the 1960's but it acquired its most significant degree of momentum in the late 1970's with the promulgation of the revised *Declaration of Helsinki* in Tokyo in 1975.[30] Significantly, as Benson and Roth note,

> Although ethics review committees (IRBs) often differ to some degree in developed Western nations, the overall purposes, organization, and functioning of these committees have largely evolved in similar ways.[31]

Specifically, research ethics boards (known, in the United States, as institutional review boards or IRBs) have evolved in a context in which biomedical research is carried out through "public or quasi-public medical research funding agencies, generally

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[27] Law Reform Commission of Canada, *Working Paper 61: Biomedical Experimentation with Human Beings* (Ottawa: Law Reform Commission of Canada, 1989) at 61-63.

[28] L.Q. 1991, c. 64, as amended by *An Act respecting the implementation of the reform of the Civil Code*, L.Q. 1992, c. 57. See articles 20 to 25. See S.N. Verdun-Jones & D.N. Weisstub, "Consent to Human Experimentation in Québec: The Application of the Civil Law Principle of Personal Inviolability to Protect Special Populations" (1995) 18 International Journal of Law & Psychiatry 163.

[29] National Council on Bioethics in Human Research, "Protecting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine" (1995) 6 NCBHR Communiqué 3 at 5.

[30] See Benson & Roth, *supra* note 9 at 34.

[31] *Ibid.* at 34-35.

termed National Research Councils (NRCs)."[32] NRC research funds are generally disbursed through a system of competition-based grants and most NRCs stipulate that all governmentally funded research must undergo an ethical review before it may proceed. Unlike many other countries, in the United States, this process of ethical review is unequivocally required by legislation. In those countries where there is no such legislation underpinning the system of ethics review, the exact legal status of the ethics review boards is somewhat unclear. It may well turn out that the only effective sanction that may be imposed on a researcher who does not comply with the requirement of ethical review is the denial of government funding.[33]

> The current Canadian system for regulating biomedical experimentation reflects a model of ethics review that is undoubtedly predicated on the pivotal role of review committees The model consists of three general components: (1) a requirement or duty that medical studies involving human research pass before a local institutional research ethics committee; (2) national research ethics guidelines, principles or criteria, which are to apply to the evaluation of individual medical research proposals; and (3) broadly articulated goals or purposes to guide the functions of local research ethics committees.[34]Before turning to a detailed examination of the operation of the nature and functions of research ethics committees in Canada, we shall establish a more general context in which to anchor this discussion by considering the development of the ethics review board in the United States, the trailblazer for this particular mechanism for the regulation of human experimentation, and in the United Kingdom, where the system of regulating biomedical research closely resembles that which exists in Canada.

### A. *Evolution Of The Review Board System In The United States*

According to Benson and Roth, it was "the paucity of internally imposed controls by researchers themselves, as well as the general absence of statutory or case law" that precipitated the enactment by the federal government of detailed regulations concerning the control of biomedical experimentation in the United States.[35]

In retrospect, the need for such regulation became readily apparent during World War II, when the exigencies of war were used as a justification for subjecting human subjects to experiments that, it was argued, would assist the U.S. war effort even though today there would be little doubt that these experiments would be considered unethical. During this era, prison inmates were routinely used in the testing of new drugs that might assist members of the armed forces in combat and some were deliberately infected with malaria in order to test the efficacy of available treatments. There was little, if any, contemporary criticism of the unethical nature of these practices. Indeed, the participation of prisoners was clearly regarded by many as a 'patriotic' contribution to

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[32] *Ibid.* at 34.
[33] *Ibid.* at 34-35.
[34] See NCBHR, *supra* note 29 at 6
[35] See Benson & Roth, *supra* note 9 at 8.

the American war effort.[36] At the time, emphasis was placed on the utilitarian justification for such experiments and their potential contribution to the struggle against the enemy rather than on such profoundly ethical considerations as whether these prisoners gave a free and informed consent to such experiments.[37]

However, it was not these war-time experiments with prisoners that led to the intervention of the federal government. In the 1960's, a number of scandals, involving the abuse of human research subjects came to the attention of the public. For example, in 1966, Henry Beecher published an article in which he provided information about some 22 cases of unethical research involving human subjects.[38] Such reports contributed towards an emerging consensus that there should be legislative intervention to control the enterprise of biomedical experimentation in the United States. It took the discovery of one particular example of unethical experimentation for the U.S. Congress to build on this consensus and to implement a régime of legislated regulations.

The immediate spur to Congressional action was intense criticism of the so-called Tuskegee Study, which commenced in the early 1930's but did not come to the attention of the American public until 1972. This study involved a study of syphilis that was inaugurated by the United States Public Health Service (Venereal Disease Division). The study was designed to investigate the effects of untreated syphilis on the human body (assessed on the basis of autopsies). Approximately 600 black males, from Tuskegee, Alabama, were observed for an extended period in order to determine the natural progression of the disease: 400 of these men had the disease and 200 (the control group) did not. The major ethical issue that arose centred on the fact that, by the mid-1940's, penicillin had become readily available and was considered to be an unequivocally effective cure for syphilis. Nevertheless, subjects continued to be observed by the researchers without the administration of penicillin. The Department of Health, Education and Welfare finally called a halt to the study in 1972 and the whole sorry episode became the centre of Congressional hearings in 1973.[39]

The outcome of these hearings and the public furor that surrounded them was the enactment, in 1974, of the *National Research Act*, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was given the mandate to review the "the problems and practices associated with protection of the rights and welfare of human subjects

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[36] See K Schroeder, "A Recommendation to the F.D.A. Concerning Drug Research on Prisoners" (1983) 56 Southern California Law Review 969 at 971 and C.M. McCarthy, "Experimentation on Prisoners" (1989) 15 New England Journal on Criminal and Civil Confinement 55.

[37] See D.J. Rothman, "Ethics and Human Experimentation: Henry Beecher Revisited" (1987) 317 The New England Law Journal of Medicine 1195. The fact that these issues are still relevant in the contemporary world is illustrated by the contention that, in 1990, the F.D.A. and the Department of Defence of the United States Government permitted the use of experimental drugs and vaccines on U.S. troops involved in the Gulf War without the soldiers' consent; see G.J. Annas & M.A. Grodin, "Treating the Troops: Commentary" (1991) 21 Hastings Center Report 24.

[38] H. Beecher, "Ethics and Clinical Research" (1966) 274 New England Journal of Medicine 1354.

[39] See J.H. Jones, *Bad Blood* (New York: Free Press, 1981).

involved in various forms of biomedical and behavioral research."[40] Over a period of four years, the Commission produced nine, separate reports that addressed a variety of topics including research involving prisoners, the "institutionalized mentally infirm" and children; the nature of informed consent; the selection of human research subjects; psychosurgery; and sterilization.[41]

On the basis of the recommendations made by the National Commission, the U.S. Department of Health, Education and Welfare ultimately prepared regulations for the conduct of biomedical experimentation with human subjects that were enacted in 1981. These have regulations have since been amended, most significantly in 1991. The June 1991 revision encompassed the adoption of the *Federal Policy for the Protection of Human Subjects*, promulgated by the sixteen federal agencies that conduct, support, or are otherwise involved in the regulation of research with human subjects.[42] Adoption of this policy resulted in a uniform system for protecting human subjects in all relevant federal agencies and departments.[43] Indeed, as Starkman points out, the "achievement of the common Federal Policy in 1991 was to provide substantial uniformity and thus to make the legal regulations more user-friendly."[44] The federal regulations serve as the bedrock upon which the system for regulating biomedical experimentation with human beings is constructed; however, they have been modified and extended by legislative action in certain states and by the specific requirements of individual institutions that conduct research.[45]

At the heart of the regulatory system in the United States is the Institutional Review Board. The IRB in any given institution has the "authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified both by the federal regulations and local institutional policy."[46] As far as jurisdiction is concerned, it is clear that the regulations apply to "all research involving human subjects conducted, supported, or otherwise subject to regulation" by any federal department or agency that has adopted the human subjects regulations.[47]

Each institution involved in research covered by the regulations must give a written "assurance" to the federal department or agency concerned that it will comply with the requirements of the *Federal Policy for the Protection of Human Subjects*. Without this assurance and the prior approval of individual protocols by an IRB, the relevant department or agency will not conduct or support any research in the institution

[40] See J.V. Brady & A.R. Jonsen, "The Evolution of Regulatory Influences on Research with Human Subjects" in R.A. Greenwald, M.K. Ryan & J.E. Mulvihill, eds. *Human Subjects Research: A Handbook for Institutional Review Boards* (New York: Plenum Press, 1982) 3

[41] The most influential of the reports was the so-called Belmont Report. See National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles for the Protection of Human Subjects of Research* (Washington, D.C.: U.S. Government Printing Office, 1978).

[42] See 45 C.F.R. 46 (1991)

[43] See Office for Protection from Research Risks, National Institutes of Health, *Protecting Human Subjects: Institutional Review Board Guidebook* (Washington, D.C.: U.S. Government Printing Office, 1993) at xix.

[44] See Starkman, *supra* note 5.

[45] See Benson, *supra* note 9 at 7.

[46] See *OPRR Guidebook*, *supra* note 43 at 1-1.

[47] See 45 C.F.R. 46 (1991) § 46.101 (a)

concerned.[48] The assurance must include: (i) a statement of the general ethical principles that will govern the institution in discharging its duty to protect the rights and welfare of human subjects in research; (ii) designation of at least one IRB which will apply these principles and which will meet the federal requirements for a diverse membership base; (iii) written procedures which the IRB will follow in reviewing research protocols and which require that any significant changes in a research activity will be promptly reported to the IRB; and (iv) written procedures for reporting any unanticipated problems involving risk to subjects or any incidents of serious or continuing non-compliance to the Federal Government.[49]

It has been suggested that, apart from this process of negotiating an assurance with the Federal Government and the included requirements for reporting incidents of non-compliance, "there is no other formal mechanism whereby the activities of IRBs are in any way monitored by the federal government."[50] Effectively, enforcement of the regulations is left to the institutions themselves, because they stand to lose federal funding if the regulatory requirements are not met. Goldner notes that,

> ...most institutions generally make compliance with its policies on human research a condition of employment, or part of the faculty manual or contract so that the institution would be able to pursue disciplinary actions against an employee who failed to follow their policies.[51]

One major problem with the localized nature of the IRB system is that the boards themselves do not engage in general reflection about the nature of the broad ethical principles that should guide research in the United States. Katz, among others, has suggested that a need exists for a national approach to develop such broad principles. In particular, he has recommended the establishment of a National Human Investigation Board to formulate broad research policies and promulgate procedures that IRBs should use in implementing them:

> The policy questions underlying the tensions between the inviolability of subjects of research and advancing the frontiers of knowledge require more careful articulation and resolution than can be gleaned from the federal regulations so far enacted. The concerns I have raised and the recommendations I have made need to be examined, debated and decided by a national regulatory body to which the IRBs can also turn for advice and guidance on difficult problems that require resolution.[52]

The National Board would not only publicize decisions made by both itself and local IRBs but also function as a source of advice and guidance for IRBs. Local decisions tend to have low visibility, which prevents valuable experience from being made known and shared among those concerned with implementing ethical standards. Furthermore, this excludes members of the public from the opportunity to express their views on the practices followed in the course of biomedical experimentation. Indeed,

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[48] *Ibid.* § 46.122.

[49] *Ibid.* § 46.103.

[50] See Goldner, *supra* note 14 at 99-100.

[51] *Ibid.* at 103.

[52] See J. Katz, "Human Experimentation and Human Rights" (1993) 38 Saint Louis University Law Journal 7 at 39.

Katz suggests that there is some truth to the contention that IRBs might currently be constituted to protect the institution and its researchers rather than the human subjects, because the majority of the members are on the faculty of the institutions to which the researchers belong.[53]

Each IRB is required to have at least five members, with "varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution." It must also be "sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." Where the IRB regularly reviews protocols involving "a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects." Every effort must be made to ensure that no IRB consists only of men or women, or of members of only one profession. Each board must include at least one member whose primary expertise is in the field of science and one member whose primary concerns are non-scientific areas. In addition, each IRB must include at least one member who is not affiliated with the institution. The board may seek specialized assistance where necessary but an expert who is invited to assist in this way may not participate in any vote.[54]

In spite of the apparent intent of the regulations governing membership of IRBs, most commentators have emphasized that, in practice, they are dominated by biomedical and behavioral researchers. As Goldner notes, "this dominance occurs both numerically, in terms of the composition of the typical board, and in terms of how the boards themselves usually function"[55] and the consequence of this dominance is a systematic bias in favour of conducting research. Indeed, Annas has contended that the IRB's have effectively "betrayed the research subjects that they are charged to protect."[56]

Goldner suggests that greater participation by non-scientists and persons not affiliated with the institutions actually conducting research would best be achieved by establishing a dual-committee system. A committee of professionals would first determine whether a research protocol is scientifically valid, and a second committee, consisting primarily of community-based members, would subsequently address the issue of ethical permissibility in light of community values, particularly those held in relation to the risk-to-benefit ratio presented in any protocol.[57] Goldner also asserts that increasing the lay membership of the IRBs would be beneficial, because it would help to render the process of obtaining informed consent relevant to the needs of the particular subject group that is being approached. Lay members are more likely to understand the average subject and to know what information is really important to him or her and whether the information will be presented by the researcher in a form that

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[53] *Ibid.* at 40-41.

[54] See 45 C.F.R.46 (1991) § 46.107.

[55] See Goldner, *supra* note 14 at 106.

[56] G.J. Annas, "Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research," (1996) 12:24 Journal of Contemporary Health Law and Policy 297 at 324.

[57] See Goldner, *supra* note 14 at 107-108.

would be readily understood by such a subject.[58]

The criteria for IRB approval of research protocols are set out in the regulations:

> (1) that risks to subjects are minimized;
> (2) that risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result;
> (3) that selection of subjects is equitable;
> (4) that informed consent will be sought from each subject or the subject's legally authorized representative;
> (5) that informed consent will be appropriately documented;
> (6) that, where appropriate, the protocol makes adequate provision for monitoring;
> (7) that, where appropriate, there are adequate provisions to protect the privacy of the subjects and the confidentiality of the data.[59]

Significantly, there are additional safeguards in the regulations where "some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons."[60]

It is certainly worth asking whether the highly detailed nature of the U.S. regulations has stripped the local IRBs of the flexibility they need to deal with local conditions and with ever-changing medical technology? Significantly, American commentators do not appear to believe this to be the case. In Benson's view, for example, it is readily apparent that the system of IRBs is designed to leave considerable discretion in the hands of local institutions, based on the theory that local boards are manifestly in the best position to evaluate the ethical permissibility of research undertaken in their own communities. Essentially, he sees the system as a decentralized one in which the local institutions, within the framework of the general rules established by the federal government, retain a considerable degree of discretion over "the structure, make-up, policies, and operations of individual IRBs."[61]

In October 1995, in the wake of a report on human radiation experiments carried out prior to 1975, President Clinton ordered a review of the regulation by federal agencies of research involving human subjects and established a National Bioethics Advisory Commission to oversee this review.[62] It is, no doubt, possible that this review will result in significant changes to the current regulatory system in the United States.

### B. *The Role of Research Ethics Committees in the United Kingdom*

Research ethics committees in the United Kingdom (RECs) date back to the mid-1960's when they were established partly in response to the establishment of the system of IRBs in the United States and partly in response to disturbing revelations of scandalous experiments. In 1967, a committee of the Royal College of Physicians,

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[58] *Ibid.* at 108.

[59] See 45 C.F.R. 46 (1991) § 46.111 (a).

[60] *Ibid.* § 46.111 (b).

[61] See Benson, *supra* note 9 at 5.

[62] See D.L. Wheeler, "Making Amends to Radiation Victims: Report on Controversial Cold War Experiments Calls for Tighter Ethical Standards for Research" (October 13, 1995) The Chronicle of Higher Education A10.

referring to U.S. experience, recommended that every institution in which biomedical research was conducted should form a group of doctors which would "satisfy itself of the ethics of a proposed investigation."[63] In the very same year, Pappworth published an influential study that exposed serious incidents of unethical clinical research in the U.K. Pappworth recommended that RECs should be created in every region, and that at least one lay member should serve on each committee.[64] Pappworth also recommended that the RECs should be made legally responsible to the General Medical Council (the body that is responsible for licensing physicians); significantly, this counsel has never been accepted in the United Kingdom.[65]

In recent years, RECs have been guided in their work by a series of guidelines issued by both the Royal College of Physicians (RCP) and the Department of Health (DoH). The RCP guidelines are contained in two publications that were most recently revised in 1990: *Research Involving Patients* and *Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects*. The most recent revision of the DoH guidelines are contained in a 1991 volume, entitled *Local Research Ethics Committees*. In a more recent development, the Medical Research Council published and endorsed the reports of two of its working parties: *The Ethical Conduct of Research on Children* and *The Ethical Conduct of Research on the Mentally Incapacitated*. The guidelines contained in the MRC reports, published in December 1991, also have a role in governing the decision-making of the RECs. The responsibility for establishing RECs rests on the District Health Authorities. Although some attempts have been made to place the DoH guidelines on a statutory basis, they remain purely advisory in nature.[66]

With the sole exception of research concerning human embryos,[67] regulation of biomedical research in England and Wales operates without any formal legislative sanction or legal requirements.[68] This approach persists in spite of the attempt by the Committee of Ministers of the Council of Europe to encourage member states to give formal legal status to the principles that guide the conduct of such research.[69] However,

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[63] J. Neuberger, *Ethics and Health Care: The Role of Research Ethics Committees in the United Kingdom* (London: King's Fund Institute, 1992) at 9.

[64] M.H. Pappworth, *Human Guinea Pigs: Experimentation on Man* (London: Routledge & Kegan Paul, 1967).

[65] Neuberger, *supra* note 63 at 9.

[66] *Ibid.* at 12.

[67] See *Human Fertilisation and Embryology Act 1990*, (U.K.) 1990. c. 37.

[68] See Starkman, *supra*, note 5 at 10. Significantly, the Law Commission recommended, in 1995, that Parliament should enact legislation to establish a Research Committee to approve all research protocols involving participants who are mentally incapacitated. Among other considerations, an important reason for this recommendation was the perceived need to create a régime that would ensure that the approval of a protocol would render a researcher's actions lawful, if they were carried out in accordance with its stipulations. See Law Commission, *Mental Incapacity* (London: HMSO, 1995) at 99.

[69] Council of Europe, Committee of Ministers, Rec. No. R(90)3 (1990). This recommendation included a set of principles designed to "protect the human rights and health of persons undergoing research, as well as to establish clear legal rules on the duties of research workers and promoters of medical research." The Recommendation itself falls short of requiring legislation but calls on member states to "adopt legislation in conformity with the principles appended to this recommendation, or to take any other measures in order to ensure their implementation." The "explanatory memorandum" attached to the Recommendation indicates

in the absence of a basic legislated framework to direct the activities of RECs, there has been a perceived lack of uniformity in their nature and functioning and in the application of ethical standards across the country. For example, Nicholson's 1982-83 findings highlighted the marked discrepancies in the practices and composition of RECs and the lack of agreement as to their role.[70] Similar findings were published in 1989 by Gilbert, Fulford and Parker.[71]

Apart from providing valuable experience that illuminates the policy question of whether RECs should be placed within a legislated framework of some kind, it is clear that many of the basic issues surrounding their functioning within the United Kingdom are of equal concern to those concerned with the operation of their counterparts in Canada. For this reason, it would be particularly appropriate to refer to a major study of the nature and role of RECs in the United Kingdom which was published by Neuberger in 1992.[72]

This study was based on a postal survey of REC members in England and Wales and site visits to twenty-five RECs. As in many countries, a critical issue is the optimal size of such committees. The study found that RECs varied considerably in size and were often larger than the suggested maximum of twelve members.[73] Neuberger also found that the committees were "medically dominated"[74] in that more than half of the total membership of the RECs studied consisted of hospital doctors.[75] This finding reflects the situation elsewhere (e.g. in the United States).

Significantly, the Department of Health Guidelines for RECs require that membership should consist of both men and women; should be drawn from a wide range of age groups; and should include hospital medical staff, nurses, general practitioners, and two or more lay persons. The Royal College of Physicians' Guidelines make similar suggestions for membership, although they place more emphasis on the role of scientists and on the need for the physicians and nurses to work directly with patients.[76] In theory, these guidelines should ensure that all RECs have a reasonably well-balanced and representative membership. However, Neuberger found

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that the Recommendation asks the member states "to adopt legislation in conformity with the Principles or to take any other measures thus giving the Principles legal status at national level" (Paragraph 14). The memorandum does not share in the authority of the Recommendation but it does suggest an intention to ensure that the Principles are accorded legal status in the member states. The Steering Committee on Bioethics of the Council of Europe has recently (June 1996) adopted a *Convention on Human Rights and Biomedicine.* If the Convention is approved by the Council of Ministers and is signed by member states, it is expected that it will be followed by, *inter alia,* a specific protocol concerning research with human subjects. See Starkman, *supra,* note 5 at 22-23.

[70] See R.H. Nicholson, ed. *Medical Research with Children: Ethics, Law and Practice* (Oxford: Oxford University Press, 1986).

[71] C. Gilbert, K.W.M. Fulford & C. Parker, "Diversity in the Practice of District Ethics Committees" (1989) 299 British Medical Journal 1437.

[72] See Neuberger, *supra* note 63.

[73] The recommended size is from 8 to 12 members. See Department of Health, *Local Research Ethics Committees* (London: HMSO, 1991).

[74] See Neuberger, *supra* note 63 at 7.

[75] *Ibid.* at 17.

[76] *Ibid.* at 16. Citing Royal College of Physicians of London, *Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects*, 2d. ed. (London: RCP, 1990).

that, while a majority of the RECs did meet the requirements of these Guidelines, a substantial minority did not — "by having too many or too few members, or by having no GP member, no nurse, or insufficient lay members."[77] Furthermore, in 28% of the committees women constituted less than 20% of the total membership, and in only 7% were they either equally represented or in a majority.[78] Equally surprising was the finding that 44% of the RECs did not include either a pharmacist or a clinical pharmacologist in their membership, even though many of the research protocols involved testing drugs.[79]

Those who wish to make ethics review committees more reflective of the values of the community will be particularly concerned with the involvement of lay members. In this respect, Neuberger discovered that one third of the RECs had fewer than the minimum two lay members required by the guidelines, and only 18% had more than two. In half of the RECs studied, the lay members made up less than 20% of the total.[80]

A perennial difficulty for research ethics committees appears to be establishing effective procedures for the appointment of lay members. The Community Health Councils (and their equivalents in Scotland and Northern Ireland), which have been created to represent the interests of patients within the National Health Service, provide one source for lay members. In fact, the Department of Health Guidelines stipulate that lay members should be selected in consultation with the local Council. However, only half of the RECs had lay members who were also members of a Community Health Council.[81] In any event, the tactic of approaching such bodies as representative patient groups as a means of recruiting credible lay members could well serve as an invaluable precedent for other countries, such as Canada.

Insofar as lay representation is concerned, the Guidelines now require that either the chairperson or the vice-chairperson should be a lay person and, by 1992, nine of the twenty-eight RECs that Neuberger visited had lay chairpersons.[82] Again, this could establish a serviceable model to be embraced by ethics review committees both in Canada and other countries.

As elsewhere, there has been an extended debate in the United Kingdom as to whether RECs should combine the roles of reviewing the scientific quality and the ethical permissibility of research protocols. Neuberger states that,

> For the technically complex scientific and medical research there is also an argument for a separate research methods committee, as exists in many US institutions and is under active discussion at a few UK institutions as well, to ensure that the research is vetted properly for its scientific validity before the REC sees it. Alternatively, members could be co-opted to the REC as necessity arose to discuss the complex issues, though lengthy technical discussion of very specialist issues might be difficult for lay and other non-specialist members.[83]

Once again, this is a process that has been put forward as a feasible option for

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77 See Neuberger, *ibid.* at 16-17.
78 *Ibid.* at 17
79 *Ibid.* at 18.
80 *Ibid.* at 19-20.
81 *Ibid.* at 20.
82 *Ibid.* at 21.
83 *Ibid.* at 28.

implementation in the United States and should seriously be considered within the Canadian context as well.

Neuberger also addressed the problem of multi-centre trials and pointed out increasing support for a national committee to deal with the special problems they raise. She suggested that a national committee could give conditional approval to a multi-centre proposal but that each local REC would have the opportunity to approve or reject it (but not to modify it).[84] This would avoid the situation in which a multi-centre study would potentially be hampered because each local ethics committee might request different, and even conflicting, modifications. While a national committee may be the appropriate body to undertake this function in the unitary state of England and Wales, it may well be the case that, in the Canadian context, it should be carried out by a provincial Board.

Finally, English and Welsh experience with sanctions may well provide valuable lessons for Canada. Significantly, Neuberger states that the RECs in England and Wales do not have the power to impose sanctions against researchers who ignore their advice and that they generally do not see themselves as fulfilling a monitoring role. The Guidelines merely require that researchers notify the RECs of any significant changes to their protocols or any unusual difficulties in recruiting subjects.

As far as active monitoring of research is concerned, the study found that only one of the RECs had ever conducted a 'spot-check' in relation to an ongoing project and only one had a computerized system for checking on the status of projects that were required to submit reports on a six-month or annual basis.[85] As presently constituted, the RECs in England and Wales have only an advisory role to their respective District Health Authorities and other appointing authorities and they are apparently very loath to assume a policing or monitoring role. Commenting on this critical aspect of the role of the RECs in the regulation of biomedical experimentation, Neuberger states that,

> However hard they work, however thorough their examination of research protocols on a case-by-case basis, however much better constituted and trained, and however well supported they may be administratively, unless they have the power to ensure that all research is submitted to them and to stop research that they regard as unethical, they will not be taken sufficiently seriously. For these reasons and others, this report.....recommends that there should be proper legislation.[86]

This call for the enactment of regulatory legislation and the establishment of an effective mechanism for enforcement of the RECs' decisions runs counter to the prevailing approach in England and Wales. However, the position advanced does reflect the views of an increasing number of commentators in this field and may be of particular relevance to other countries, such as Canada, which face similar problems of enforcement in the area of regulating biomedical research.

### C. *The Structure of Regulation in Canada*

In Canada, as in the United States and the United Kingdom, ethics review

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[84] *Ibid.* at 29.
[85] *Ibid.* at 34-35.
[86] *Ibid.* at 8.

committees, known as Research Ethics Boards (REBs), have been assigned the task of assuring the public that only ethically sound biomedical research is being conducted and that the process of obtaining informed consent for participation in such research is acceptable. The REBs are affiliated with the institutions in which the relevant research is to be conducted. One of the more significant aspects of the policy developed by the Medical Research Council of Canada (MRC), between 1978 and 1987, is the emergence of the REB as the primary locus of responsibility for the maintenance of ethical standards in medical research. In the words of the *MRC Guidelines*, "[e]valuation by an REB (Research Ethics Boards) of a research protocol is the major step through which the community can be certain that its values are respected."[87]

At present, while biomedical research is guided by the application of the *MRC Guidelines,* other research involving human subjects falls under the aegis of either the Natural Sciences and Engineering Research Council of Canada (NSERC) or the Social Sciences and Humanities Research Council of Canada (SSHRC). However, in March 1996, a Tri-Council Working Group involving the MRC, NSERC and SSHRC presented a proposed *Code of Conduct for Research Involving Humans* that would apply uniformly to the research falling within the jurisdiction of all three councils.[88] In the case of biomedical research, the implementation of such a Code would mean that the existing *MRC Guidelines* would be superseded.

In common law Canada, no legislative framework underpins the system of REBs. In making their decisions, they apply the *MRC Guidelines*, U.S. regulations (if funding is sought from the National Institutes of Health), and other ethical codes (such as the *Nuremberg Code* and the *Declaration of Helsinki*). The REBs have no independent power to require that research protocols involving human subjects be submitted to them for prior approval. However, the MRC requires that all biomedical research that it funds receive prior approval by a REB and, in practice, most institutions stipulate that such approval be obtained for all research protocols involving human subjects, regardless of the source of funding.[89]

In Québec, however, the system of REBs does have a clear basis in legislation and formal legal rules have been articulated in relation to the general circumstances in which biomedical experimentation may be conducted in the province. For example, article 21 of the *Civil Code of Québec* sets out the limited circumstances in which children and incompetent adults may participate in biomedical experimentation. In general, they may participate if the appropriate substitute decision-maker gives their consent (the mandatory, tutor or curator, as the case may be) and there is an "absence of serious risk" to their health. However, Article 21 of the Civil Code also stipulates that,

> An experiment on a group of minor persons or incapable persons of full age shall be carried out within the framework of a research project approved by the Minister of Health and Social Services, upon the advice of an ethics committee created by him for that purpose: in addition, such an experiment may be carried out only if a benefit to the

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[87] See *MRC Guidelines*, *supra* note 7 at 46.

[88] See Tri-Council Working Group, *supra* note 8.

[89] See NCBHR (1995), *supra* note 29 at 9. See e.g. the definition of the jurisdiction of REBs associated with the Faculty of Medicine at McGill University: McGill University, *McGill University Ethical and Legal Aspects of Research Involving Human Subjects Conducted in the Faculty of Medicine and Affiliated Hospitals: Policies and Procedures* (Montréal: Faculty of Medicine, McGill University, 1994) at 8.

> health of persons of the same age group and having the same illness or handicap as the persons submitted to the experiment may be expected.

Clearly, Article 21 not only mandates the involvement of an ethics committee but also requires the further approval of the Minister before any such biomedical experimentation may proceed. No such legislation exists in the other Canadian provinces and territories.

A precedent for legislated regulation of biomedical experimentation in Canada as a whole may well arise in the area of "New Reproductive and Genetic Technologies." In June, 1996, for example, the Minister of Health introduced a bill in the Canadian Parliament that would prohibit certain uses of these technologies[90] and also indicated that there was an intent to establish a system of regulation at some stage in the future.[91] Nevertheless, for the present, the universal mechanism of regulating experimentation in Canada is the local research ethics board that (except in Québec) operates without legislative sanction.

The Tri-Council Working Group's proposed *Code of Conduct* devotes considerable attention to the nature and function of the REB and its analysis is useful as a means of identifying the mission of the REB in contemporary Canadian society. The REB is described by the Working Group as "an institution's administrative and educative body established to ensure that the ethical principles developed in the philosophical approach and ethical framework of this Code are applied in an ethical manner in research involving human subjects."[92] The mission of the REB is considered to be "to ensure that research involving the participation of humans as research subjects is ethical." It will carry out this mission by:

- reviewing research protocols;
- respecting the rights and integrity of those who participate as research subjects;
- attracting an interdisciplinary membership with commitment to exemplary ethical and scientific research.;
- consulting with and advising institutions, its members, and the public on matters related to research ethics; and
- promoting ethics education within all communities involved in the research enterprise.[93]

According to the proposed *Code of Conduct*, REBs should give an affirmative answer to each of three "categorical questions" before giving ethical approval to any research protocol:

- Is the research scientifically valid?
- Does the research have sufficient overall value?
- Are research subjects treated with dignity and respect?
- A negative answer or "No" to any of these questions means the research cannot be

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[90] Bill C-47, *An Act Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction.* See also The Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Government Services, 1993).

[91] See Starkman, *supra*, note 5 at 23-24.

[92] See Tri-Council Working Group, *supra* note 8 at 3-1.

[93] *Ibid.* at 3-1.

ethically justified[94]

Having identified the functions that the REBs are supposed to perform in terms of their general mandate, it is now necessary to examine the available empirical data that paint a picture of how they operate in practice. Fortunately, comprehensive information concerning the nature, structure and functioning of REBs in Canada has become available through a report issued, in 1995, by The National Council on Bioethics in Human Research (NCBHR).[95] The report follows an ambitious three-year study of the functioning of REBs in the Faculties of Medicine at 16 Canadian Universities from 1990 to 1993. In addition to the data generated by questionnaires and site-visits, the report contains a number of recommendations by the Council to improve the current system.

One important finding of the study was the extent to which there may be multiple REBs associated with one institution in Canada. There were some 100 REBs affiliated with the 16 medical schools surveyed. In most cases, they operated within a hospital and were ultimately responsible to its president. There were varying degrees of communication between the different REBs affiliated with the same university; however, it is disconcerting that, in some cases, it was reported that such communication was "often random or absent."[96]

In submitting this potentially confusing situation to further analysis, the NCBHR suggested that there were generally two lines of authority and reporting responsibilities in Canadian universities. In the first, a university committee receives its mandate from the University President or Senate, usually through a senior member of the administration. This committee may fulfill a number of different functions, including serving as a review committee for a broad range of research activities or functioning as a review committee for non-medical human research only. In the second, a hospital committee reports to the president or board of trustees of the hospital, "usually through a medical advisory committee, although sometimes through a board bioethics committee or a quality assurance committee." Most of these hospital committees conduct ethical reviews, although a minority of them consider their role to be restricted to the review of resource-related issues.[97] To ensure co-ordination among multiple REBs, the NCBHR made the following recommendation:

> University REBs should consider taking responsibility for co-ordinating REB activities, especially when multiple hospital REBs exist. Such co-ordination should focus on providing policy direction, on considering difficult or generic problems, and on training and educational activities for REB members.[98]

The proposed *Code of Conduct for Research Involving Humans,* prepared by the Tri-Council Working Group, specifically endorsed this recommendation.[99]

A critical issue concerns the extent to which REBs exercise regulatory control over the whole range of biomedical experimentation in Canada. Significantly, the NCBHR report states that more than 90 per cent of the REBs indicated that no research could be

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[94] *Ibid* at 2-4.
[95] See NCBHR (1995), *supra* note 29.
[96] *Ibid.* at 9.
[97] *Ibid.* at 17.
[98] *Ibid.* at 18.
[99] Tri-Council Working Group, *supra* note 8 at 3-2.

undertaken at their institution without prior board approval.[100] This finding suggests that almost all biomedical experimentation is receiving prior ethical approval regardless of the source of funding. The Tri-Council Working Group later emphasized the need to render this requirement explicit and recommended that "each REB must be invested by its affiliated institutions with the authority to approve or reject all research protocols involving the participation of humans as research subjects within the institution's jurisdiction.."[101] Where research is conducted outside of those institutions that receive funding from one or more of the national research councils, the Working Group suggests that there should be a Community, Professional or Commercial Research Ethics Board (CPC-REB) that would determine the acceptability of research protocols involving human subjects.[102] The Group stipulates that the CPC-REB's should have the same terms of reference, membership, procedures, etc. as the institutional REB's. Although research conducted outside of institutions receiving funding from the national research councils is not required to follow the precepts of the proposed *Code of Conduct,* the Working Group states that, unless there is a "minimal level of harmonization with the Code of Conduct, editors, journals and researchers should not accept the decisions of an CPC-REB" since to "do so risks jeopardizing public trust and confidence in research."[103]

What ethical principles are applied by REBs in Canada? According to the NCBHR report, the vast majority (93%) of REBs indicated that they used the *MRC Guidelines* as the basis for their review of research protocols, although they also relied on other sets of guidelines, where appropriate (e.g. U.S. Federal regulations when funding was provided by the National Institutes of Health).[104] However, a number of REBs criticized the *MRC Guidelines* for being ambiguous; the NCBHR report suggests that "the perception that *MRC Guidelines* sometimes prove ambiguous and that they are flexible and not necessarily "binding" may also explain their less than universal use."[105]

The report recommends that the NCBHR itself should identify areas of consensus and controversy arising from the use of different sets of guidelines in Canada. Where disagreements exist, it recommends that the NCBHR identify the areas of disagreement, inform the REBs of the critical issues and notify the appropriate funding agency's ethics committee (e.g. the Standing Committee on Ethics of the MRC) of these issues, and make recommendations to them as to how these problems might be resolved by clarifying or modifying existing guidelines.[106] The Council also recommended that the MRC update its Guidelines in collaboration with the NCBHR with a view to reinforcing and facilitating the educational role of the Council. Of course, the problems raised by multiple sets of ethical guidelines would be considerably ameliorated if the proposed *Code of Conduct,* developed by the Tri-Council Working Group were to be adopted as the basis for the ethical review of all biomedical experimentation in Canada.

An important procedural question about the operation of REBs in Canada concerns

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[100] NCBHR (1995), *supra* note 29 at 9. 10% of the REBs indicated that research involving no patient contact (i.e. chart review) could be undertaken without a prior review.

[101] See Tri-Council Working Group, *supra* note at 3-2.

[102] *Ibid.* at 4.

[103] *Ibid.*

[104] *Ibid.* at 10. See also *OPRR Guidebook, supra* note 43 at I-1.

[105] NCBHR (1995), *supra* note 29 at 19.

[106] *Ibid.* at 18-19.

the extent to which there is any attempt to separate the function of determining the scientific validity of a research protocol from the function of reviewing its ethical permissibility. As we have seen, there have been determined calls, both in the United Kingdom and the United States, to introduce a bifurcated process of review in this respect. However, more than 80 per cent of the Canadian REBs indicated that they carry out their own scientific evaluation of research proposals, while the other boards stated that they referred this task to external experts to assess scientific quality.

The NCBHR report recommends that the REBs should continue to consider the scientific quality of research protocols, although it suggests that REBs should consider ways of confirming the scientific validity of a study before the ethical review takes place. It emphasizes that "adequate processes must be developed to enable competent scientific review to be performed in a fashion that does not detract from ethical consideration of the protocol, particularly as it relates to the benefits and harms to research subjects."[107]

It is not entirely clear what the Council intended. What was suggested appears to be a process that would screen protocols to assess their scientific validity, so that methodological and related problems could be addressed prior to a consideration of the ethical issues. Such an approach would apparently permit the REB to place greater emphasis on the specifically ethical aspects of any given research proposal. However, it would seem that the screening would probably be undertaken by the scientific experts on the REB, rather than by an entirely separate committee. This might represent a workable compromise, although it is clear that REBs will still need to increase the number of members who have expertise in ethics if they are to focus more of their attention on the application of ethical principles to biomedical experimentation.

The Tri-Council Working Group also addressed this issue in its draft *Code of Conduct for Research Involving Humans.* The *Code* suggests that there are many models that might be employed in the assessment of the scientific validity of a research protocol. For example, it suggests three models that might be adopted by an REB:

- The REB is completely responsible for the scientific and ethical review of the protocol. This presumes the REB has the necessary expertise to evaluate both the science and the ethics of the research proposal;
- In those cases where the REB lacks the necessary scientific expertise, it arranges for external review of the protocol's science; or
- As a variation of the preceding, the REB establishes a permanent science review committee that reports directly to the REB on the science of all protocols.[108]

The Working Group did not, however, favour any particular model, contenting itself with the comment that:

> Whatever model an REB develops, it always remains responsible for the overall review and retains final authority concerning approval or rejection of both the science and the

[107] *Ibid.* at 19. However, Meslin points out that the precise nature of the connection between scientific validity and ethical permissibility in REB review has not been clearly articulated. See E.M. Meslin, "Ethical Issues in the Substantive and Procedural Aspects of Research Ethics Review" (1993) 13 Health L. Can. 179 at 181.

[108] Tri-Council Working Group, *supra* note 8 at 3-3.

ethics of all research projects.[109]

As far as the nature and outcome of the review process are concerned, the NCBHR study found that more than 60 percent of the REBs met monthly. Most REBs indicated that they reached decisions by consensus and that the average time for the processing of an application was one month, a factor of considerable importance to researchers.[110] It appears that most protocols are approved with only minor modifications being requested, more specifically, responses indicated that: only three percent of proposals were rejected outright; 75 percent were approved with minor modifications; and 22 percent were approved as they were.[111] More than half of the REBs had an appeal process available to researchers.[112] Interestingly, the Tri-Council Working Group referred to the need to establish such an appeal process for all REBs throughout Canada. Indeed, it suggested that researchers be given the right to appeal decisions directly to the REB and it acknowledged the possibility of permanent appeal boards within the institutions. These appeal boards would be required to meet the *minimal* membership requirements for REBs, so as to ensure consistency in the application of scientific and ethical standards.[113] The Group also emphasized that no institution should have the right to overrule REB decisions that disallow a research protocol.[114]

As discussed previously, the most controversial aspect of ethics review boards, in whichever country they operate, is the extent to which their membership and operation reflect a genuine balance between the interests of researchers, on the one hand, and the interests of members of the public and potential research subjects, on the other hand. As far as the overall size of the membership of the REBs was concerned, the NCBHR report established that there was a considerable range, with membership varying between three and 21 on any given board. Almost half of the institutions surveyed indicated that their REBs had ten to 15 members and one-third of respondents indicated membership of between four to nine.[115] However, the critical question is which constituencies these members represented and whether they reflected a balance of interests and expertise.

In this respect, only ten percent of the REBs met all the compositional requirements set by the *MRC Guidelines*, which were intended to achieve some kind of balance in board membership. The Guidelines stipulate that REBs should contain: "members who can reflect community values," preferably not affiliated with the institution concerned; "at least one specialist in the relevant discipline of the research"; scientists with a broad knowledge of research methodology; and nurses (where clinical research is involved). The Guidelines also indicate that: a clinical psychologist or mental-health expert may "aid in assessing the subject's capacity to understand the protocol and exercise a free choice"; and that "[b]ioethicists, philosophers or theologians will also contribute greatly to the work of an REB."[116]

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[109] *Ibid.*

[110] NCBHR (1995), *supra* note 29 at 10.

[111] Tri-Council Working Group, *supra* note 29 at 3-6.

[112] *Ibid.*

[113] *Ibid.*

[114] *Ibid.* at 3-7.

[115] NCBHR (1995), *supra* note 29.

[116] *MRC Guidelines*, *supra* note 7 at 45-46.

According to the NCBHR report, very few REBs consisted exclusively of researchers (only six percent). The great majority of boards consisted of a mixed membership of some kind. Although there was some variation, the report concluded that the REBs were generally strong in scientific and medical expertise but varied in the depth of their ethical expertise. A few boards included ethics consultants, individuals in pastoral care, patient representatives, and lawyers competent in bioethics. However, the Council noted that other REBs had difficulty in recruiting members with such expertise:

> At least 7 REBs reported a lack of expertise in ethics as a specific deficit in their composition. Others noted deficiencies with respect to community members, lawyers, and mental-health experts; this indicated a broad concern about ensuring sufficient representation from competent and diverse individuals able to discuss ethics issues.[117]

Clearly, the lack of expertise in ethics raises many questions about the balance of interests struck among the various members of the REBs. As in many other jurisdictions, REBs appear to be dominated by scientists and researchers, even though the fundamental ethical issues facing the REBs cannot be resolved by applying an exclusively scientific or technological expertise.

On the critical issue of lay membership, the Council noted that, while a number of REBs had active lay members, some boards had found it difficult to find such representation, while others had not made this a priority. Overall, about half of the REBs had some type of lay representative (usually no more than one) who had no direct affiliation with the institution.[118] Significantly, no specific procedure was established for selecting this member; usually he or she was identified by the chair of the committee.[119] Indeed, the lack of any standard process for the nomination and appointment of any of the members to REBs is clearly perceived as being an ongoing problem of major proportions.[120] In this respect, the NCBHR stated very candidly that:

> REBs are having difficulty meeting some requirements of MRC and US OPRR guidelines, since only a minority of REBs described a composition that would meet the standards set by these bodies.[121]

Generally, these medical institutions require faculty, external and departmental representation on their REB. Others indicated a need for representation to include

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[117] NCBHR (1995), *supra* note 29 at 20.

[118] *Ibid.* at 20-21. In a National Workshop on Ethics Review, co-sponsored by the NCBHR and the MRC in April 1989, "[d]iscussants agreed that the lay member is a key part of the process....An ideal lay member was defined as a mature person not connected with the institution, who was not doctrinaire, and who was willing to invest time and work hard." See J.N. Miller, "Ethics Review in Canada: Highlights from a National Workshop: Part 2" (1990) 23 Annals RCPSC 29 at 30.

[119] NCBHR (1995), *supra* note 29 at 11.

[120] *Ibid.* at 21.

[121] NCBHR (1995), *supra* note 29. Since the U.S. Department of Health and Human Services funds a considerable number of the research projects carried out in Canadian settings, many REBs attempt to meet the requirements for membership specified by the U.S. Office for Protection from Research Risks (OPRR). See *e.g.* McGill University, *supra* note 89 at 10. The general requirements for IRB membership are set out at 45 C.F.R. § 46.107 (1991).

individuals with research expertise, members of the legal profession, and a member of the Board of Trustees. REBs, with few exceptions, seem *unable to ensure lay representation.*[122]

The record of Canadian REBs in adding lay people to their membership compares quite unfavourably with the RECs in England and Wales. An explanation for this deficiency may lie in the fact that considerably more attention appears to have been paid in England and Wales to identifying appropriate representative organizations to nominate community representatives to the RECs. This initiative might well be addressed within the Canadian context at a provincial level.

The NCBHR report recommended that the Council work with REBs to 'encourage' compliance with *MRC Guidelines* on composition of membership and to assist them in finding individuals with the necessary expertise. In particular, the study recommended that the NCBHR provide assistance in the area of recruiting lay representatives, who were seen as having "a primary role in assuring patient/subject protection."[123] It was also recommended that the National Council "assist REBs by defining the minimal ethics expertise that members should have for the adequate functioning of an REB."[124] This would presumably address the current paucity of ethicists on the REBs.

Whether the assistance of the NCBHR can resolve the long-standing membership problems of all the REBs that review biomedical research protocols in Canada remains to be seen. One of the only efficacious methods to achieve a more balanced membership on REBs may be to establish province-wide committees charged with assisting local REBs in finding suitable members, from both community groups and professionals with specific expertise in ethics. This is a theme that is further dealt with in the concluding section dealing with potential reforms to the system of REBs in Canada.

At present, however, many REBs are making a serious effort to meet the requirements of a diverse membership. For example, the McGill University *Guidelines for Ethical Review of Research Involving Human Subjects* address the issue of committee membership by stating that:

> The committee should include a community volunteer(s); a person from other non-medical disciplines, such as a bioethicist, a lawyer (preferably not the Institution's counsel), or a theologian; and a patient advocate. The latter is particularly important when an REB regularly reviews research that involves a vulnerable category of subjects (children, elderly people, mentally ill persons, among others). DHSS requires and the Faculty of Medicine recommends, that one member of the REB (including his/her immediate family) not be affiliated with the institution served by the REB. In the McGill setting a non-affiliated member might be a physician or scientist who is not in the employ of the University or Hospital to which the REB reports.[125]

This statement is particularly significant insofar as it contains an explicit recognition of the need for REBs to include in their membership a representative of potential research subjects, particularly where they may belong to one of the populations perceived as being particularly vulnerable (e.g., the mentally challenged, the developmentally challenged, prisoners, children, and the elderly).

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[122] NCBHR (1995), *supra* note 29 at 20.

[123] *Ibid.* at 21.

[124] *Ibid.*

[125] McGill University, *supra* note 89 at 10.

Another issue relating to public accountability concerns the extent to which members of the general public can gain access to information about the REBs. The NCBHR report did not make recommendations about making such information available, but did recommend that both investigators and research subjects be given ready access to the REBs, which should, in turn, "develop access mechanisms for all interested parties."[126] This recommendation would allow potential research subjects, who are affected in a direct way by biomedical experimentation, to have a voice in the one forum that is intended to balance their interests against those of the researchers. However, it is suggested that there should be a broader dissemination of information about the decisions made by the REBs, in order to allow for informed public debate about the nature of biomedical experimentation in Canada. Again, the task of collecting information about such decisions and disseminating them in an appropriate form might well be undertaken by a province-wide board.

One of the most vital issues is the process for the *monitoring* the ongoing research projects approved by an REB. Prior approval of a research protocol is only one step in a process intended to ensure the protection of human subjects through all phases of experimentation. There must also be measures to ensure that the protocol is followed in the actual conduct of the research. However, most REBs did not consider ongoing monitoring of research to be part of their mandate (and they lacked the time and resources for it),[127] even though the *MRC Guidelines* clearly recommend that REBs establish a process for the ongoing review and monitoring of research protocols.[128]

The NCBHR report assessed the situation pertaining to ongoing monitoring of research projects by REBs in the following manner:

> Statistically, our survey found that it is obligatory in 88 percent of institutions to report any change in protocol design, yet because of time and resource constraints 25 percent have no monitoring mechanisms. Some institutions rely on individual departments to review ongoing research, and a few institutions are reluctant to monitor because they believe it suggests a lack of trust in the researcher, who is expected to monitor voluntarily and review ongoing projects. Progress reports for all human research are required by 50 percent of institutions; others require reports in specific instances. End-of-protocol reports are required by 30 percent of institutions; 66 percent require adverse incidents reports. In short, when the monitoring processes used by REBs in Canada are examined, the nature of the continuing review and monitoring varies. This appears to relate, in part, to a lack of resources for carrying out a monitoring function by the REBs and, in part, to a lack of specifics in the *MRC Guidelines*.[129]

Of particular interest is a statement made in the NCBHR report that there was very infrequent consultation between members of the REBs and the researchers once the protocols had been approved, and that "untoward incidents" were rarely brought to the attention of the REBs. This meant that the "REBs did not always have the most current information about the risks and benefits to human subjects."[130] Such information might conceivably be brought to their attention by feedback from the subjects themselves. In

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[126] NCBHR (1995), *supra* note 29 at 22.
[127] *Ibid.* at 12.
[128] *MRC Guidelines*, *supra* note 7 at 49-50.
[129] NCBHR (1995), *supra* note 29 at 23.
[130] *Ibid.* at 15.

this respect, it is interesting that, while more than 90 percent of the REBs stated that an aggrieved research subject would have access to their members, only about 18 percent indicated that this had ever happened.[131]

To ensure adequate monitoring, the NCBHR report recommended that both institutions and the REBs "further develop and implement mechanisms for the thorough review and monitoring of human research." Among the measures recommended were reports (at least annual) dealing with such matters as significant changes to research protocol and unexpected incidents, as well as termination reports. All these reports should be reviewed by the REB and, for "sensitive protocols," the boards should require a more "frequent and rigorous" process of review, potentially including external monitors. The study went on to recommend that:

> NCBHR and MRC should identify both the mechanisms by which REBs may monitor ongoing research protocols and minimal criteria for adequate monitoring. When sponsoring agencies monitor research within an institution, the monitors for the sponsoring agency should report identified problems to the REB as well as to the sponsoring institution.[132]

The NCBHR's proposed solution to the monitoring problems involves close collaboration between the Council and the REBs. However, the important issue at stake is whether the public interest in protecting the rights of human research subjects can be left to the REBs and the NCBHR, or whether there should be an independent body that carries out this vital function. Coburn, for one, argues that routine monitoring of research protocols must be undertaken by an independent body, if the public is to be guaranteed that there are effective protections against the potential abuse of human subjects. He also suggests that a system of voluntary guidelines directed by the NCBHR is unacceptable because its composition is "heavily weighted to provider and researcher groups, and its 'guidelines' are purely voluntary."[133] If such an independent body is considered necessary for monitoring biomedical research projects on an ongoing basis, then a province-wide body would appear to be an appropriate candidate to shoulder this vital responsibility.

The Tri-Council Working Group also addressed the need for REBs to engage in a process of continuing monitoring and emphasized that ethical issues should be addressed "throughout the life of a research project — from its inception to its conclusion" Indeed, the Working Group noted that it is "*wrong to hold that ethical considerations are no longer relevant once a research proposal receives approval from an REB.*"[134] For example, informed consent should be seen as the objective of an ongoing process that "begins with initial contact with research subjects and carries through to the end of the study."[135] There should be "continuing and meaningful" opportunities for subjects to withdraw from a study and any new information that may

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[131] *Ibid.* at 13.

[132] *Ibid.* at 23. The need for the development of a methodology for effective monitoring had also been recognized at a national workshop on Ethics Review co-sponsored by the NCBHR and the MRC in April 1989. See J.N. Miller, "Ethics Review in Canada: Highlights from a National Workshop, Part 1" (1989) 22 Annals RCPSC 515 at 517.

[133] D. Coburn, "Health Sciences Research Ethics: A Critique" (1993) 13 Health L. Can. 192 at 195-96.

[134] Tri-Council Working Group, *supra* note 8 at 2-4.

[135] *Ibid.* at 2-10.

be material to the process of ongoing consent must be conveyed to the subjects in a timely manner.[136]

A central issue in considering the efficacy of the REB system of regulating biomedical experimentation is compliance. In the Province of Québec, submission of research protocols involving human subjects is required by provincial legislation. However, in the common law jurisdictions of Canada, REBs have no statutory authority. The NCBHR report recommended that both the MRC and NCBHR articulate clear statements as to the consequences of non-compliance with national ethical guidelines or recommendations of an ethics committee. These consequences should include the possible loss or suspension of the privilege of conducting biomedical experiments. It was also recommended that the Universities put processes in place to complement national standards with a view to curbing, detecting and sanctioning non-compliance and misconduct in research.[137]

Another method of ensuring compliance with the decisions made by the REBs would be to restrict the publication of research results to those projects which the REB has certified that the protocol has been followed. Such restrictions would affect the conduct of biomedical experimentation, because unpublishable results are worthless both to the medical community and to the researcher.[138] This result could be achieved by establishing a final reporting requirement, to the REB that approved the protocol, as a precondition to publication. Only those protocols receiving prior REB approval would be permitted to proceed and only those results receiving final REB approval would be published.

The increasing use of *multicentre clinical trials* raises the difficulty that REBs at different sites may make decisions at variance with each other.[139] The NCBHR study indicated that many REBs "requested that there be some central way of considering multicentre trials prior to the protocol being fixed."[140] It is unacceptable that any particular REB should be placed in the position where it is required to review a protocol that, in effect, cannot be changed because it involves a multicentre trial. The Council did not recommend a specific solution to this problem. However, as outlined in the discussion of the RECs in England and Wales, it was suggested that there is increasing support for a national ethics advisory committee to deal with the special problems multicentre trials raise. Such a national committee could give conditional approval to a multicentre proposal. However, each local REC would have the opportunity to approve or to reject it (but not to modify it).[141] This potential solution could well work

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[136] *Ibid.*

[137] NCBHR (1995), *supra* note 29 at 24.

[138] See Law Reform Commission of Canada, *Toward a Canadian Advisory Board on Biomedical Ethics* by Hon. J.-L. Baudouin, M. Ouellette & P.A. Molinari (Ottawa: Law Reform Commission of Canada, 1990) (Commissioner: M. Rivet J.) at 15-16: "In a performance assessment of the committees...the importance of self-discipline by researchers should not be minimized. For the most part, biomedical research culminates in the publication of papers that are widely disseminated in the scientific community. There clearly exists a direct link between compliance with ethical standards, and approval and recognition of the research results by that community. It is not surprising, then, that researchers do comply with the standards, since it is in their own interest to do so."

[139] Meslin, *supra* note 107 at 185.

[140] NCBHR (1995), *supra* note 29 at 15.

[141] *Ibid.* at 29.

in the Canadian context, although it would be more appropriate to consider allocating this function to a province-wide board, when the research centres are located within one province. If the research project concerned involves centres in more than one province or territory, it would be necessary to negotiate the protocols between the respective research groups or, alternatively, to refer the project to a national advisory committee.

On the subject of education for REB members, the NCBHR report indicated that, although most REBs had some form of informal program for the self-education of their members, there was a need for a more formal program to be instituted. The Council recommended that it should "enhance its educational offerings to REBs through its principal publication, Communiqué, and through regional and national workshops, to ensure that members of REBs can effectively perform their review of the ethical and scientific aspects of protocols."[142]

Finally, the NCBHR report found that REBs require more support both at the institutional and the national levels, due to systemic weakenesses ranging from deficiencies in financial and administrative resources, to the need for policy assistance on ethical issues, to the general lack of education and training.[143] Assistance on general policy matters and education and training are functions that could be assumed by a province-wide board.

## IV. Reforming the Regulatory System in Canada

It is clear that a regulatory system, based on the central role played by REBs, is extremely well entrenched, not only in Canada, but also in other countries that share a common legal heritage. There is very little pressure to abandon this system altogether. However, the preceding analysis of current practice in Canada and elsewhere demonstrates that many aspects of the present regulatory system require energetic reform.

### A. *Establishing a Statutory Basis for the Regulatory System*

As has been emphasized above, in the Canadian common law system, REBs effectively function as part of a system of self-regulation since there is no statutory framework that underpins their operation or that establishes their authority over biomedical experimentation. In the Province of Québec, on the other hand, the *Civil Code* clearly articulates some general legal principles concerning the types of biomedical experimentation that are permitted. It requires the approval of an ethics committee, established by the Minister of Health, before children or incompetent adults are allowed to participate as research subjects.

In order to establish the authority of REBs to approve in advance all protocols for biomedical experimentation with human subjects, it is essential that each province and territory of Canada enact appropriate legislation. A breach of a statutory requirement to obtain such prior approval should result in the imposition of a penalty. In addition, such legislation should impose a duty on researchers to provide the appropriate REBs with information about the ongoing progress of the research that has been approved in advance. Such information should be sufficient to permit the REBs to effectively

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[142] *Ibid.* at 21.

[143] *Ibid.* at 25.

monitor the implementation of research protocols to which it has given its stamp of approval. The legislation should also articulate the basic legal requirements for the conduct of biomedical experimentation. As in Québec, it should define the general circumstances in which it is permissible to enroll children and incompetent adults as research subjects.

There may be considerable opposition to enacting such legislation on the part of the medical profession, the universities and researchers, who may assert that statutory intervention has no useful role to play in the complex arena of biomedical experimentation and that it may establish formidable obstacles to medical progress. However, the Law Reform Commission of Canada has responded to such contentions by pointing out that:

> [L]egislative intervention does not mean that society mistrusts its researchers or that it wishes to stop scientific development. To legislate means something else entirely. Where the integrity of the person can legally be endangered, it seems important that limits and rules be clearly defined. It is up to the law to protect basic values, and it cannot and must not leave this role to ethics. Moreover, and contrary to what one might think, there are many researchers nowadays who would like to have a clear idea of what may legally be done and what should be prohibited.[144]

Nevertheless, the legislation in question should stipulate only *general* and *minimal* requirements for the conduct of experimentation. It is critical, for example, that the quasi-criminal sanctions contained in such legislation only be applicable to the most flagrant abuses committed by biomedical researchers. This is not a field in which researchers should feel subjected to significant statutory penalties, even though they have acted in good faith and in accordance with currently accepted standards of investigation approved by REBs. Therefore, it is necessary that legislative intervention be limited to the articulation of minimal standards for the conduct of biomedical experimentation. Equally, it is important that legal requirements be formulated in general terms since REBs must be able to respond swiftly to changes medicine and medical technology and be able to act flexibly in the face of varying local conditions across such a geographically vast country as Canada. If legal requirements are excessively detailed in nature, REBs will lose one of their clear advantages over other decision-making mechanisms that might be harnessed to the task of regulating biomedical experimentation; namely, their ability to adapt swiftly to rapidly evolving circumstances and conditions. In general, one would expect the REBs to require research protocols to meet higher standards than those reflected in the minimal requirements articulated in legislation. These higher standards would be derived from the ethical guidelines that are interpreted and applied by the REBs. However, these guidelines would permit the REBs to respond in a flexible and sensitive manner to the demands of an ever-changing research environment.

As the Medical Research Council of Canada noted a decade ago, there is always a danger that detailed legislative activity in the forum of biomedical research will prove to be excessively rigid in practice:

> Legislation and regulation under law prescribe standard responses to anticipated scenarios. Its potential to apply justly consists in its treatment of broadly-defined

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[144] *LRC Working Paper No. 61*, *supra* note 27 at 58.

> categories of like cases in like ways, and in the finding of operative facts by the authoritative due process of the courts. The ethical assessment of a research proposal may raise a wide range of interests and values, some novel, and may require risk-to-benefit determinations which cannot easily be prescribed or standardized. The facts of ethical priority cannot always be authoritatively established; particular factors may weigh differently at different times and in different circumstances. A proposal may be rejected as premature at one time and be acceptable only a short time later, for instance, because of evolution in the field of inquiry in question.[145]

Furthermore, the MRC underscored that there is a considerable difference between the basic requirements of the law and the standards for the conduct of research that may be imposed through the interpretation and application of ethical guidelines by REBs:

> ...Guidelines can exert an influence beyond their strict limits, while legislation tends to mark the limits of its influence....Guidelines, administered responsibly in an atmosphere of public openness and within a society that respects the judgments of its different parts, can be an effective instrument of ethical control. Indeed, the truly ethical quality of the assessments to be made may atrophy when judgments are directed by law....While breach of the law is generally unethical, a mere conformity with it may not be sufficient for discharge of responsibility....The practice of obedience to law does not necessarily develop [an] awareness of ethical values.[146]

Finally, it should be emphasized that establishing a legislative basis for the operation of the REBs in Canada may well prove to be a considerable benefit to those involved in the conduct of biomedical experimentation, insofar as it may be argued that a researcher who implements, in good faith, a research protocol, that has obtained the advance approval of a local REB, should be considered to have met the required standard of care that must be followed in relation to human research subjects. If this is the case, then the approval of the REB could be raised as a defence to any negligence action brought against such a researcher.[147] This would provide an element of legal certainty that is currently lacking when a researcher embarks on a course of biomedical experimentation.

B. *Enhancing the Membership Requirements of the REBs*

The survey of the functioning of REBs in Canada, the United Kingdom and the United States demonstrates that the issue of membership of the boards is central to policy discussions about their future role in the regulation of biomedical experimentation. The experience in these jurisdictions suggests that active steps need to be taken to ensure that REB decision-making is not dominated by researchers and scientists. One topic that has generated considerable controversy relates to the involvement of laypersons in the decision-making process of the REBs. In this respect, it is important to recognize that there is an increasing number of commentators who argue that REBs should include representatives both of the general public and potential research subjects.

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[145] *MRC Guidelines*, *supra* note 7 at 10.

[146] *Ibid.* at 11.

[147] However, in the case of *Weiss* v. *Solomon*, *supra* note 17, the Court did not appear to attach any weight to the fact that the research had obtained the prior approval of the REB.

Coburn, for one, concurs with the general criticism that Canadian REBs are largely drawn from the ranks of the researcher's professional peers or fellow scientists. Although membership in REBs may include non-researchers and "occasionally token membership from the general public," he asserts that "the subjects of the research themselves and representatives of the general public are seldom involved in a significant and substantial manner."[148] Coburn proposes that representation from the subject populations and members of the general public should be balanced, because "potential subjects are sometimes willing to undergo procedures that violate their rights which other members of the public would not be quite so willing to surrender."[149] However, Coburn argues that representation of the general public should not be limited to those individuals who are selected at random from the general population. Rather, there should also be members with experience in the area of patients' rights and representatives from organizations such as women's health groups.[150]

The question as to what is the most appropriate composition for the membership of research ethics committees has also been addressed by Professor McNeill, who has conducted a comprehensive study of research ethics committees, particularly those from common law countries in the British Commonwealth.[151] Writing in 1993, McNeill parted company somewhat from the views of Coburn and contended that the membership of these committees should reflect a balance between the representatives of science and the representatives of research subjects. In this approach, there would be no room for representatives of the public at large. In McNeill's view, the history of lay participation in research ethics committees indicates that such participation has had very little impact on decision-making practices.

While one should devote attention and energy to the development of substantive ethical rules and principles for the protection of human subjects, it is vital, according to McNeill, to recognize that the application of these rules and principles to specific research protocols inevitably requires a considerable degree of discretion by decision-makers.[152] Research ethics committees are ideal candidates to exercise this discretion because, properly constituted, they represent an impartial balance between the interests of science and the interests of human subjects.[153] This balance can be found by providing equal representation for researchers and subjects on committees of review.[154]

McNeill notes that the interests of science do not necessarily coincide with those of society. In fact,

> [i]t is not society as a whole but some individuals who may benefit from research into particular diseases. The issue then is the conflict between the search for potential benefits for individual sufferers of a disease as against the potential harms, or the risk of harm, to individual subjects of research. In experimentation on human subjects, society cannot be assumed to be aligned with the interests of either science or the subject. It presumably has an interest in both.[155]

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[148] Coburn, *supra* note 133 at 195.
[149] *Ibid.*
[150] *Ibid.*
[151] McNeill, *supra* note 15.
[152] *Ibid.* at 139.
[153] *Ibid.* at 158.
[154] *Ibid.* at 161.
[155] *Ibid.* at 167.

Few would dispute that an interest of research subjects is to be protected from harm, particularly where non-therapeutic experimentation is concerned, because there is no prospect of any benefit to the subject who assumes the risks.[156] Yet, as McNeill points out, a body of research has established that many subjects do not adequately understand the difference between non-therapeutic experimentation and treatment. This is particularly the case when the research occurs in a health care setting where patients have the rationale expectation that medical procedures will be carried out exclusively to benefit their health.[157] In these circumstances, constituent representation is required to adequately protect the interests of the pool of potential research subjects, when decisions are made about the ethical soundness of research protocols. However, this goal has not yet been fully realized within the contemporary practices of ethics review committees in countries such as the United States, Australia, Canada, and the United Kingdom.

Ethics committees in most countries include lay members. It is assumed that these members are there to represent the community. Even if we accept that lay members represent the community, they are typically in the minority, participate less in the committee discussion, are seen (and see themselves) as relatively unimportant and, consequently, have less influence in the decisions reached by the committees.[158]

A study by McNeill, Berglund and Webster in Australia demonstrated that lay members were considered to be "significantly less active and significantly less important" in the deliberations of ethics review committees.[159] This led McNeill to conclude that "the addition of lay and non-scientific members to review committees may not make an appreciable difference."[160] Lawyers were regarded as playing a more influential role, perhaps because they were considered to be "fellow professionals." However, other lay members, including nurses and ministers of religion, were perceived as having relatively little influence on the decisions made by the committees.[161]

As is the case with other commentators in both the United States and the United Kingdom, McNeill believes that, in most countries, the systems of regulation spearheaded by research ethics committees are really "systems for allowing research on human subjects with a minimum of interference."[162] In particular, they do not appear to give priority to the interests of the subjects of research themselves, as would appear to be required by such codes as the Declaration of Helsinki. Instead, they are constituted "as if the priority is the creation of optimal conditions for research on human subjects with a minimum of interference."[163]

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[156] *Ibid.* at 181. In the case of *therapeutic* research, human subjects may have other types of interest at stake. For example, persons afflicted by the HIV/AIDS virus may seek speedy access to experimental therapies in a bid to save their lives, even though the risks associated with such therapies may be relatively unknown. Groups representing the interests of such individuals are increasingly demanding a decision-making role in the process that leads to approval for the use of experimental therapies, particularly those involving new drugs.

[157] P.S. Appelbaum, C.W. Lidz & A.J. Meisel, *Informed Consent: Legal Theory and Clinical Practice* (New York: Oxford University Press, 1987) at 246-47.

[158] McNeill, *supra* note 15 at 195.

[159] *Ibid.* at 91.

[160] *Ibid.*

[161] *Ibid.* at 92.

[162] *Ibid.* at 198.

[163] *Ibid.*

McNeill's solution is to ensure that subjects are represented through some kind of 'participatory democracy':

> Representation is needed when an interest is in competition with other interests, when the views of that group need to be put forward to arrive at a consensus and when those people could not conveniently be present themselves. All three conditions apply to the interests of research subjects in decisions made by research committees and in policy decisions made by national bodies.[164]

McNeill concludes that the membership of research ethics committees should reflect a balance between representatives of researchers and representatives of subjects. The nomination of subject representatives should be a matter for each local committee to address. For example, if a committee located in a hospital routinely reviews protocols that entail the use of patients as subjects, then it would be appropriate to ask a group representing these patients to nominate a representative to the committee. Where subjects are drawn from a variety of sources, other community groups would be requested to nominate suitable representatives.[165] McNeill also suggested that it would be valuable to include both a specialist in ethics and a lawyer on each committee.[166]

McNeill's ideal research ethics committee would resemble the six-member committees originally established in Denmark, consisting of: three 'medico-scientific' members and three lay members. The model committee would consist of two or three representatives of researchers (nominated by the relevant research institutions), two or three experimental subject representatives (nominated by subject representative groups), an administrator, and a lawyer/ethicist (who is independent of the institution).[167] Adoption of this model would involve dramatic changes if implemented in the Canadian context. At present, at least half of the existing REBs consist of ten to 15 members, none of them having a balance that even comes close to the specific balance recommended by McNeill.

However, writing in 1996, McNeill subsequently acknowledged that there was widespread opposition to his suggestion that some members of RECs should serve as representatives of particular interest groups.[168] He cited, for example, the view of Evans and Evans, that it is critical that the process of regulating research be free from the "representation of sectional interests"[169] and the opinion of a report submitted to the Australian Minister of Health, that members of RECs "must be impartial and must not see themselves as representative advocates for a particular group."[170] McNeill considers such criticism to be based on the quicksands of a stereotypical view of the apprehended danger of single-interest groups manipulating the agenda of the RECs and a failure to recognize that the research-oriented members of the committees do, in fact, serve as

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[164] *Ibid.* at 199-200.

[165] *Ibid.* at 209-10.

[166] *Ibid.* at 217-18.

[167] *Ibid.* at 219.

[168] McNeill, *supra* note 10.

[169] D. Evans & M. Evans, *A Decent Proposal: Ethical Review of Clinical Research* (Chichester: John Wiley & Sons, 1996) at 110.

[170] D. Chalmers *et al.*, *Report of the Review of the Role and Functioning of Institutional Ethics Committees: A Report to the Minister of Health and Family Services* (Canberra: Department of Health and Family Services, 1996) at 44.

representatives of the research community and, therefore, need to be counterbalanced by those whose sole interest is in the welfare and protection of research subjects. Nevertheless, he concedes that the appointment of appropriate representatives of those who participate in biomedical experimentation is by no means a simple issue and suggests that it may be a more practical approach to "nominate appropriate 'reasonable people' who can represent the interests of potential research participants without being directly accountable to a particular community group." McNeill admits that this approach amounts to the acceptance of a

> modified notion of representation which consists of appointing community members from nominations of suitable people who would inform themselves of concerns of potential subjects of research. Ideally, they would be nominated by some body from outside of the research institute, or at the very least, be appointed from responses to open advertisement by the other community members of that committee.[171]

It is significant that McNeill takes the view that the research enterprise should be conducted as a *partnership* between all those who participate in it. The very use of the word 'subject' tends to marginalize those upon whom research is conducted since it encourages the notion that they should be passive in the face of the professional expertise of researchers. He points out that people with HIV and AIDS have rejected such passivity and have:

> demanded participation in the process at all levels: including the planning of the research process, the manner in which the research was conducted, and the interpretation of the results. It is my prediction that increasingly research in all fields will require negotiation between those who conduct the research and those who participate as volunteers.[172]

This approach is mirrored in the draft *Code of Conduct for Research Involving Human Beings* prepared by the Tri-Council Working Group, which cautions against treating the subject of research as "an experimental object" and, thereby, "ignoring or compromising his or her full humanity."[173] At a more specific level, the draft *Code* explicitly requires that research with *collectivities* "ought to be conceptualized and actualized as a partnership between the researcher and the collectivity."[174] According to the Working Group, collectivities include "population groups with social structures, common customs, and an acknowledged leadership" and would include not only "nations, cultural groups, small indigenous communities and some neighbourhood groups" but also "families."[175] The draft *Code* requires that researchers ensure that a collectivity has the opportunity both to participate in the design of any research protocol that affects it and to react and respond to the findings prior to completion of the final report and its appearance in "all relevant publications that arise from the research."[176]

Significantly, the Tri-Council Working Group's approach to reconstructing the

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[171] McNeill, *supra* note 10.

[172] *Ibid.*

[173] Tri-Council Working Group, *supra* note 8 at 1-5.

[174] *Ibid* at 13-7.

[175] *Ibid.* at 13-1.

[176] *Ibid.* at 13-5 to 13-6.

membership of REBs in Canada bears a considerable affinity to that recommended by Professor McNeill. Indeed, the Working Group emphasized that membership should be "broad enough socially, as well as scientifically, that it can legitimately represent the society within which it makes decisions"[177] and stipulates that institutional eligibility for funding from any of the three councils (MRC, NSERC and SSHRC) should be made conditional on meeting the following "minimal membership requirements":

> - not less than five (5) members including both men and women;
> - at least two (2) members who have broad expertise in the methodologies or the area(s) of science that is (are) covered by the REB;
> - at least one (1) member who is knowledgeable in the discipline of ethics;
> - at least one (1) member who is knowledgeable in the discipline of law; and
> - at least one (1) member without affiliation to the institution, but recruited from the community served by the institution and/or potential research subjects.[178]

The Working Group's recommendation focusses on the need to ensure that REBs have demonstrated expertise not only in research but also in law and ethics. However, it also included provision for a member from the community or from the pool of potential research subjects. The suggestion that the membership of REBs encompass representatives who may participate in biomedical experimentation as research subjects is in accordance with the view of an increasing number of commentators, such as McNeill, that such representatives are more likely to make a significant contribution to the decision making of REBs than laypersons drawn from the community at large. Furthermore, the membership structure, advocated by the Working Group, would allocate a majority of the decision-making votes to those members who are not scientists.

The author is hopeful that the recommendation of the Tri-Council Working Group on the issue of REB membership will ultimately be implemented. However, it is clear that considerable energy should be devoted to solving the practical problems associated with finding, and appointing, members who represent the community at large or the pool of potential research subjects. As previously mentioned in the discussion of the operation of RECs in the United Kingdom, it is important that there be an independent body to assist in identifying appropriate nominees for membership of the various boards. In the Canadian context, this function could be assumed by a provincial (or territorial) ethics review board which would be responsible for identifying suitable nominees from community groups and organizations that maintain an interest in biomedical experimentation, as well as from those that represent individuals who may become research subjects.

### C. *Supervising and Coordinating the Activities of the Local REBs*

In the common law jurisdictions of Canada, the existing system of REBs operates in a context self-regulation by the local institutions involved in the conduct of

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[177] *Ibid.* at 3-3.

[178] *Ibid.* at 3-3 to 3-4.

biomedical experimentation. Until recently, the only body that assigned itself a mandate to oversee the activities of local REBs was the Medical Research Council of Canada. The Council recognized, in its *Guidelines* of 1987, that researchers themselves have both an "initial and continuing duty" to ensure that their research is ethical. However, it also stipulated that the *major* responsibility for maintaining the appropriate ethical standards still rests with the various institutions that conduct research (through the medium of the REBs).[179] The MRC nevertheless perceived itself as playing a key role in this process by articulating ethical guidelines for biomedical research with human beings[180] and by refusing funding to those institutions that did not follow these guidelines (in accordance with the decisions made by the appropriate REBs). In addition, the Council expressed the view that it had a special duty to foster awareness of ethical issues concerning this type of research. The MRC also suggested that it should assume the responsibility for *monitoring* the activities of local REBs.[181]

The MRC itself was not able to perform a coordinating or monitoring function owing to a lack of resources, however, in 1988, the MRC and Health and Welfare Canada joined together with the Royal College of Physicians and Surgeons to establish the National Council on Bioethics and Human Research (NCBHR). The NCBHR, a private body, was created for a period of nine years, after which its mandate will be reviewed.[182] Its membership consists of five representatives of the Royal College of Physicians and Surgeons, a representative of each of five health care associations, a philosopher-theologian, a lawyer, two community members and the President of the MRC who is *ex-officio*.[183]

The NCBHR furnishes advice to, and engages in consultation with, the various local REBs around the country. Furthermore, the National Council attempts to enhance the mutual understanding of ethical issues on the part of the members of the various REBs by organizing special educational seminars and workshops, by publishing a newsletter, called *NCBHR Communiqué*, as well as, distributing diverse monographs on relevant topics in the field of bioethics.[184] Most significantly, the NCBHR has the authority to establish teams of experts to conduct site visits at the invitation of REBs. Between 1990 and 1993, the NCBHR designated universities with medical faculties as the primary clients for such site visits. The data gleaned from such visits constituted an important component of the Council's recent report on the function of REBs in Canadian medical faculties.[185]

The NCBHR has emphasized that its principal role is to provide *advice* on ethical issues and that the ultimate responsibility for maintaining high ethical standards in the conduct of biomedical experimentation rests firmly on the shoulders of individual

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[179] *MRC Guidelines*, *supra* note 7 at 43.

[180] See Tri-Council Working Group, *supra* note 8. If the recommendations of the Tri-Council Working Group are implemented, then ethical guidelines will, in the future, be issued not only by the MRC but also (on a joint basis) by the NSERC and SSHRC.

[181] *Ibid.*

[182] *Supra* note 133 at 14-15.

[183] *Ibid.* at 14.

[184] See e.g. National Council on Bioethics in Human Research, Consent Panel Task Force, *Reflections on Research Involving Children* (Ottawa: NCBHR, 1993).

[185] NCBHR (1995), *supra* note 29 at 7.

researchers and the REBs.[186] In essence, its mandate is advisory, rather than controlling. Members of REBs have the option to decide whether or not to act on any advice that is given by the National Council. It is significant that, in 1990, the Law Reform Commission of Canada questioned the comparatively narrow basis of this mandate:

> [I]t is not certain whether the Council's mandate (in essence, it can only monitor researchers who themselves asked to be monitored and those who are funded by the founding organizations) extends to private research centres or the research carried out by entirely private entities (Pharmaceutical companies, for example). The Council's activities are therefore not general or comprehensive.[187]

Furthermore, there is a real question as to whether the NCBHR is sufficiently independent from the medical profession and the research community. Its membership consists primarily of representatives who are appointed by professional groups, such as the Royal College of Physicians and Surgeons, the Canadian Medical Association and the Canadian Nurses' Association.[188] Similarly, insofar as the NCBHR is accountable at all for its activities, it would be answerable solely to professional bodies. More specifically, its formal accountability consists of little more than the duty to submit annual reports to the various professional agencies involved in its creation (the MRC, Health and Welfare Canada and the Royal College of Physicians and Surgeons), as well as, to the boards of other organizations that are involved in its operation.

There is little doubt that the NCBHR fulfills an important role in the education of the members of the various REBs in Canada and in the promotion of discussion about ethical issues. However, since it is not visibly "at arm's length" from the medical professions, it may not be the most appropriate body to undertake the critical tasks of monitoring the activities of medical researchers and of ensuring that the members of the REBs perform their duties in accordance with generally accepted standards of ethical decision making within the field of biomedical experimentation. If REBs are to operate on a statutory basis, as recommended above, it is important that an independent agency assume responsibility for coordinating and monitoring their operations. Members of the public are more likely to develop confidence in biomedical experimentation if the REBs are held accountable to a body that is distinct and separate from the medical professions whose members are engaged in such experimentation.

What agency should be assigned the responsibility for coordinating and monitoring the decision making of REBs and for maintaining public confidence in the system by means of which biomedical experimentation is regulated? In Ontario, the *Final Report* of the Enquiry on Research Ethics (1995) recommended that the Government establish a Provincial Ethics Review Board (PERB) to accredit and monitor local REBs in the province.[189] This model is one that is well suited to the Canadian context and, if adopted across the country, would ensure that there would be an independent agency to oversee the operations of REBs in each province and territory.

One of the primary tasks of the PERB would be to ensure that the membership of

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[186] National Council on Bioethics in Human Research, *National Council on Bioethics and Human Research* (Ottawa: NCBHR, 1989) at 3.

[187] *Ibid.* at 15.

[188] *Ibid.* at 12-31.

[189] *Enquiry on Research Ethics: Final Report* (Chairman: David N. Weisstub, Submitted to the Hon. Jim Wilson, Minister of Health of Ontario, Aug. 28, 1995) [hereinafter *Final Report*].

each local REB reflects an appropriate balance of persons engaged in biomedical research, persons with expertise in law and/or ethics, person who represent the interests of research subjects, and members of the local community. The recommendations of the Tri-Council Working Group, discussed in the previous section, provide a suitable starting point insofar as they ensure that researchers will be in the minority in each REB (which would consist of two scientific experts, one expert in ethics, one expert in law, and one member of the local community or a representative of potential research subjects). The PERB would not only be responsible for the accreditation of REBs, which met these membership requirements, but would also assist local boards to identify potential members with expertise in ethics or the law and would help to develop lists of members of the community at large with an interest in biomedical experimentation and of members who represent those persons who may become involved as research subjects. The size of the membership of the PERB would necessarily vary with the population of the particular province or territory concerned, however, the composition of the PERB should reflect the balance of membership that is required for the local REBs.

The PERB would also be responsible for providing information to members of local REBs about ongoing developments in the law and ethics that are applicable to biomedical experimentation. Whenever necessary, it could issue interpretations of existing ethical guidelines should there be a lack of clarity or a degree of uncertainty in the latter. The PERB would organize seminars and workshops to enhance the knowledge base of members of REBs and to encourage interaction with other REBs. In this vein, another important function, that may be performed by the PERB, is the dissemination of information about legal and ethical issues relating to biomedical experimentation, to not only members of the research community and REBs but also to the members of the public at large. In particular, the collection and dissemination of information about decisions made by the PERB and by local REBs is a task that is particularly well suited to this body. Hopefully, the various PERBs across Canada would coordinate their educational activities with the NCBHR, which could bring a more national perspective on its own operations in this area.

As noted earlier, it is recommended that there be a statutory requirement that all biomedical experimentation with human subjects receive prior approval by an REB. The *Final Report* of the Ontario Enquiry on Research advocated the position that, in certain circumstances, such authorization must also be obtained from the PERB. More specifically, the report recommended that, where there is some uncertainty as to the *capacity* of the prospective research subjects to give a valid consent (e.g., if they are mentally challenged, developmentally challenged, children, elderly, or prisoners), then the prior approval of a panel of the PERB should be required for any research protocol which indicates that the subjects will be exposed to a *substantial* risk of harm. In essence, the Enquiry's recommendation implies that, where a vulnerable group of subjects is involved, then the prior approval of a local REB will only be sufficient where the research protocol concerned indicates that there is a "negligible" or "less than substantial" risk of harm.[190] Where the risk is deemed to be substantial, then the prior approval of a panel of the PERB will also be required. Furthermore, whenever its approval is required, the PERB panel should include a representative of the particular group of potential subjects identified in the research protocol. The Report also

[190] *Ibid.*

recommended that a register be established to maintain a record of all protocols involving groups of subjects whose capacity to give a valid consent is in question and that those experiments, that have been approved by local REBs, posing a "less-than-substantial" risk should be periodically reviewed by the PERB, with a view to ensuring that the REBs have been applying appropriate techniques of assessing the degree of risk involved in such experiments.[191]

The PERB would serve a valuable function where research protocols involve multicentre clinical trials. As noted earlier, the increasing use of multicentre clinical trials raises the difficulty that REBs at different sites may make decisions at variance with each other.[192] The NCBHR study of REBs in Canada demonstrated that there was a demand on the part of members of many REBs that there should be "some central way of considering multicentre trials prior to the protocol being fixed."[193] It was felt that no individual REB should be placed in the position where it is required to review a protocol that, in effect, cannot be changed because it involves a multicentre trial. In England and Wales, there is increasing support for a national ethics advisory committee to deal with the special problems multicentre trials raise. Such a national committee could give conditional approval to a multicentre proposal; however, each local research ethics committee would have the opportunity to approve or reject it (but not to modify it).[194] This potential solution could be adapted to the Canadian context (although it would be more appropriate to consider allocating this function to a PERB when the research centres are located within one province). If the research project involves centres in more than one province or territory, it would be necessary to negotiate the protocols between the respective research groups or, alternatively, to refer the project to a national advisory committee, which would be established by the Government of Canada.[195]

The PERB, as a body that is independent from the medical professions and the research community, could assume the vital task of monitoring the actual implementation of research protocols, in order to safeguard the public interest in protecting the rights of human research subjects. If the integrity of the system for regulating biomedical experimentation in Canada is to be upheld, then it is necessary that an independent body conduct the monitoring of ongoing research projects. Local REBs have generally been unable to monitor research projects once they have been approved. This situation constitutes a significant flaw in the regulatory system as a whole. The PERB, if assigned adequate resources to do so, would be an appropriate agency to undertake the routine monitoring of ongoing experiments after they have been approved by local REBs.

## V. SUMMARY

Since the conclusion of World War II, there has been a series of determined attempts, at both the national and international levels, to articulate general ethical principles for the conduct of biomedical experimentation involving human beings. While the refinement of these principles constitutes an ongoing process, there is

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[191] *Ibid.*

[192] Meslin, *supra* note 107 at 185.

[193] NCBHR (1995), *supra* note 29 at 15.

[194] *Ibid.* at 29.

[195] See generally *supra* note 138.

nevertheless considerable debate as to the nature of the most efficacious method of regulating biomedical experimentation at a local level. In most countries that conduct biomedical research, the heart of the regulatory system consists of a process of review by institutional ethics review boards or committees. However, the legal status and authority of these boards and committees is unclear in a number of jurisdictions. In Canada, with the exception of the Province of Québec, REBs have operated at a local level without any formal legislative underpinning and have generally applied a set of ethical guidelines articulated by the Medical Research Council of Canada; in this sense, a system of self-regulation exists in most of the country. While there does not seem to be a widespread sentiment in favour of abolishing the process of ethical review by REBs, there is an increasing number of voices that are calling for significant reforms to the existing system.

The author would recommend that the various provinces and territories of Canada enact legislation that unequivocally establishes the authority of REBs to review all research protocols involving biomedical experimentation with human beings. Such legislation should make it an offence to conduct such experimentation without the prior approval of a local REB, and should articulate general rules governing the conduct of researchers in this field. Furthermore, each province and territory should establish a provincial (or territorial) ethics review board that should be entrusted with the task of coordinating and supervising the activities of local REBs. While the proposed legislation should entrench the *minimal* legal requirements for the conduct of biomedical experimentation, local REBs would be responsible for applying the highest ethical standards which, if the recent recommendations of the Tri-Council Working Group are ultimately accepted, will be endorsed by the three major granting councils in Canada (MRC, NSERC and SSHRC). Also, the membership of local REBs should reflect an appropriate balance between researchers, representatives of the pool of potential research subjects, members of the public with a special interest in biomedical experimentation, and experts in law and ethics.

The provincial (and territorial) ethics review boards should be placed "at arm's length" from the medical professions and the institutions that conduct biomedical experimentation in Canada. Through the process of accreditation, the PERBs would ensure that the membership of local REBs reflects an appropriate balance of interests and would develop lists of potential members, in order to assist local REBs in recruitment. In addition, the PERBs would be responsible for interpreting existing ethical guidelines where there is uncertainty or a lack of clarity; organizing the ongoing education of REB members in relevant fields; and disseminating information both to the members of REBs and to the public at large. The PERBs would also be responsible for performing the vital task of monitoring ongoing biomedical experiments to ensure compliance with ethical requirements and they should be allocated sufficient funds to enable them to discharge this responsibility in an effective manner. Finally, the PERBs would be assigned special responsibilities in relation to those research protocols that involve human subjects whose capacity to give a valid consent to participation may be in doubt or to those that require that research be conducted in a number of different sites.

These proposed reforms would provide more effective protection of the rights of individual research subjects while maintaining the degree of decision-making flexibility that is necessary for the development of medical knowledge in age of ever-changing technology and constantly evolving challenges.