

**FINAL**  
**Report of the Task Force**

Established by the  
National Council on Ethics in Human Research

*To Study Models of Accreditation for  
Human Research Protection Programs in  
Canada*

*March 29, 2002*



National Council  
on Ethics in  
Human Research

Conseil national  
d'éthique en recherche  
chez l'humain

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Le Rapport est également disponible en français sous le titre suivant :

*Rapport final du Groupe de travail établi par le Conseil national d'éthique en recherche chez l'humain pour étudier les modèles d'accréditation des programmes de protection des participants à la recherche au Canada.*

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## Executive Summary

The National Council on Ethics in Human Research (NCEHR) created a Task Force to Study Models of Accreditation for Research Ethics Boards in Canada at its November 7, 1999, meeting. This decision was taken after considering the important increase in clinical trials and in the number of Canadians involved, the work of the Therapeutic Product Directorate to introduce new regulations, the move in the United States to introduce a program of accreditation for Human Research Participant Protection Programs and several indications that the current system of protection for human participants in research needs to be strengthened. NCEHR's interest in this project followed logically from its 12-year experience with site visits and educational programs assisting REBs and research institutions.

Different models of oversight were reviewed by the Task Force including accreditation. The establishment of a program of accreditation for Human Research Participant Protection Programs would benefit all those involved in research involving humans, primarily research participants whose trust is paramount to preserve.

In order to succeed and produce the benefits expected, an accreditation program should: be voluntary (although it could be obligatory to fulfill specific functions); be peer-based; including non-affiliated lay persons; be based on agreed standards; be both educational and rigorously evaluative; be performed at arm's length from the organizations accredited; be flexible so as to accommodate all types of research settings and research communities; enjoy buy-in from stakeholders; be accountable to the public and research participants; and be subject to performance evaluation, including independent auditing.

Accreditation should be undertaken by an independent organization at arm's length from performers, promoters and funders of research. Such an accreditation program, which would require significant resources, would be complementary to policies and regulations aimed at ensuring the protection of human participants and the proper conduct of research.

The Task Force believes that the process to develop an accreditation program is critical to its success. Of paramount importance is a process, which results in the buy-in of all key stakeholders.

The Task Force recommends to Council:

- That it affirms the need for a nation-wide oversight process for the ethics review of research in humans in Canada based on standards;
- That such an oversight takes the form of an accreditation program to be conducted by an arm's-length, non-governmental organization;
- That NCEHR facilitate discussions with organizations that would be stakeholders or observers in a new Program of Accreditation for Human Research Participants Protection Programs.

This final version of the Report has benefited from commentaries received after the release of the draft Report and from discussions held at the meeting of the NCEHR Council in November 2001.

## 1.0 Mandate and Membership of the Task Force

At its November 7, 1999 meeting, the National Council on Ethics in Human Research created a Task Force to Study Models of Accreditation for Research Ethics Boards in Canada.

**A useful definition of accreditation has been developed by The International Society for Quality in Health Care:**

*A self-assessment and external peer assessment process used by health care organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health care system.*

Accreditation is a continuing quality improvement process. It provides an external validation of performance. It is neither an audit nor an inspection. Existing regulations and policies are used as a starting point in developing the purpose and scope of standards.

### **Task Force Membership \***

Henry Dinsdale (Chair)	Professor Emeritus, Neurology, Queen's University Active Medical Staff, Kingston General Hospital, Past-president, NCEHR
Carol Clemenhagen	Past Executive Director, Medical Research Council of Canada, Past President, Canadian Hospital Association
Pierre Deschamps	Professor, Faculty of Law, McGill University Member of the Working Group on Ethics, Quebec Ministry of Research, Science and Technology, Member of the Evaluation Committee, NCEHR
Michael Enzle	Professor of Psychology & Research Policy Coordinator, Office of the Vice President (Research), University of Alberta
John Foerster	Professor of Medicine, University of Manitoba Director of Research & Chair, Research Review Committee, St. Boniface General Hospital, Chair of the Evaluation Committee, NCEHR
Thérèse Leroux	Professor of Law, Centre de Recherche en Droit Public, Faculty of Law, University of Montreal, Member of Council and Member of the Emerging Issues Analysis Committee, NCEHR
Janet Storch	Professor and Director, School of Nursing, University of Victoria, President, NCEHR
NCEHR Staff:	Richard Carpentier, Executive Director Geneviève Dubois-Flynn, Evaluation Coordinator

\* Affiliations are as of the time the Task Force was initiated.

## 2.0 Context for the Task Force

The National Council on Ethics in Human Research (NCEHR) is a non-governmental voluntary organization established in 1989 by Health Canada, the Medical Research Council of Canada and The Royal College of Physicians and Surgeons of Canada. Its mission is “*to advance the protection and promotion of the well-being of human participants in research and to foster high ethical standards for the conduct of research involving humans.*” An important way that NCEHR achieves its mission is through its work as a national educational resource for Research Ethics Boards (REBs).

Prompted by the absence of an oversight mechanism to review the work of REBs in Canada, NCEHR developed a program of voluntary site visits to Canadian research institutions almost a decade ago. Visits were designed to advise and assist institutions in their ethics review process for research involving humans. Data obtained through those visits, summarized in a 1995 report, documented not only the contributions of the dedicated volunteers in the process, but also the shortcomings in compliance with guidelines (*Communiqué, 1995 Volume 6, Number 1*).

NCEHR remained concerned about the issue of oversight and subsequently produced a report detailing options available for improved oversight (Fortin-Leroux Report, 1996). Action by other countries following research misadventures, particularly by the USA, further highlighted the inaction in Canada about these issues. NCEHR, realizing the situation had to be addressed further, established this Task Force to Study Models of Accreditation for Research Ethics Boards.

An Accreditation Program aims at improving the performance of *all* Programs for the Protection of Human Participants in Research. The Task Force considers that it should be accompanied by educational activities and demonstration site visits, as the program develops to reach all research sectors.

The publication of new Regulations for clinical trials by the Therapeutic Products Directorate (TPP) was an additional impetus to develop a plan for accreditation. TPP invited input from NCEHR during the development of the new Regulations.

### 2.1 The Rapid Increase in Research and Innovation Activities

There have been significant increases in investment in research and innovation during the past few years. Increases in the budgets of federal research agencies and the creation of the Canadian Institutes of Health Research (CIHR) are concrete examples of the strong support of Canadians for a robust research and innovation agenda. This means increased research activities and greater numbers of human participants involved in research in the social sciences, humanities, natural sciences, engineering, as well as medical research.

Another significant increase in investment is the percentage of the health care system budget applied to the cost of drugs. It now outstrips the costs of hospitals or physicians. This growth in recent years is predicted to continue. It has been accompanied by a 20%

increase in the number of clinical trials, involving untold numbers of patients. Canada is third in location for clinical trials worldwide, after the European Union and the United States. The research-based pharmaceutical industry is the single-largest funder of medical research in Canada. In 2000, the pharmaceutical industry estimated its investment in research at \$1 billion.

Statistics Canada estimates \$3,3 billion as the gross expenditures on health research and development for the year 2000:

•	Federal Government	\$446 million
•	Provincial Governments	\$183 million
•	Business Enterprise	\$1,083 million
•	Higher Education	\$889 million
•	Private Non-Profit Organizations	\$323 million
•	Foreign	\$383 million

*Statistics Canada, Estimates of Total Spending on Research and Development in the Health Field in Canada, 1988 to 2000*

Canada has several internationally recognized academic leaders in clinical trials research. Currently, these experts initiate a minority of the total number of clinical trials in Canada, and that number continues to decrease. During the last decade, the percentage of clinical trials based in academic centres decreased from 80% to 40%. Industry has shifted trials to non-academic community hospitals and physicians' offices in order to obtain faster turn-around time. That shift means fewer investigator-initiated trials and an increase in the percentage of trials reviewed by private sector for-profit REBs. This industrialization of clinical research creates challenges for those concerned about the quality of the oversight of ethics review. It occurs at a time when reports indicate that the system for protecting Canadians participating in research is sub-optimal.

## **2.2 A Growing Problem of Public Trust in the Integrity of Research Ethics**

Maintaining the trust of Canadians in the integrity of research ethics and especially the protection of research participants is crucial to ensure continuing support for research. A recent report sponsored by the Law Commission of Canada expressed concerns about the accountability of the system of protection for research participants.

“...we were surprised to see how substantial the gaps were between the ideals expressed in policy and the ground arrangements for accountability, effectiveness and the other criteria for good governance.”

*Law Commission of Canada, The Governance of Health Research Involving Human Subjects, page iii*

Issues in human research in Canada receive extensive national media coverage:

- The current court case (2001) addressing the use of inmates to test LSD at the *Federal Prison for Women in Kingston* in the 1960s; where a professional involved has confessed to assault and negligence for giving LSD to a teenaged inmate. This case is reminiscent of an earlier case involving *Dr. Ewen Cameron* in Montreal;
- The *Report of a Coroner Inquiry in Quebec City after the death of Mr. Gabriel Lessard* (2001) in a clinical trial under the supervision of Dr. Fernand Labrie at the Centre hospitalier de l'Université Laval. The Report concluded that the REB was not properly informed of changes to the protocol and that communication and medical follow-up within the research team were lacking. In a subsequent lawsuit, Dr. Labrie claimed that public exposure of the trial through the Coroner's Inquiry had compromised the recruitment of research participants;
- The *Auditor General's Report* (1999) on the use by the Department of National Defense (DND) of an anti-malarial drug in troops in Somalia and the absence of proper consent and monitoring for efficacy or adverse reactions;
- The case involving *Dr. Nancy Olivieri* (1998), at the Hospital for Sick Children in Toronto, where a confidentiality agreement with the sponsor of the research infringed on the obligation, perceived by the researcher, to alert research participants of a possible risk in the trial;
- The lawsuit by *Maziade v. Parent* (1998), at the Centre hospitalier de la Sagamie in Chicoutimi which, among other things, demonstrated the absence of an obligation to submit research to the REB of each institution in which the research was performed;
- The case involving *Dr. Roger Poisson* (1994) in Montreal, where the researcher admitted having falsified data in a Breast-Cancer Trial;
- The *Weiss v. Solomon* (1989) trial in Montreal where the Court found that insufficient information was provided in the consent form about the risks involved in the clinical trial and that the REB had failed to request additional screening and security measures that would have increased the safety of the trial.

Such public exposure of inappropriate scientific conduct or inadequate ethics oversight threatens to undermine public trust in the integrity of research and research ethics. This in turn could jeopardize the very generous support of Canadians for research and their participation in research activities. In the United States, Federal sanctions arising from breaches of research protocols have led to suspension of research in a number of leading US academic centres.

There are increasing examples of public and professional concerns about research issues and vulnerabilities in research with humans in Canada. They include:

- lack of a consistent mechanism for research ethics oversight that would enable verification and accountability of a system intended to protect research participants (research subjects);
- absence of standard training requirements for REB members and researchers in research ethics;
- lack of public oversight of private REBs that act independently or through Contract Research Organizations hired by drug companies, raising concerns about their independence and conflict of interest;

- concern about researchers' real or perceived conflicts of interest. Private business interests may bias the ways in which researchers approach the protection of research participants. There are also growing concerns about institutional conflicts of interest. This was a major consideration in the fatal Gelsinger gene transfer case in Philadelphia;
- concern about the safety and oversight of gene transfer trials;
- requirement for Canadian researchers to meet USA educational standards for US-funded research in humans in absence of similar Canadian standards.

### **3.0 Presentations to the Task Force**

The Task Force invited input from groups experienced in accreditation or involved in research with humans. These presentations allowed for the study of several existing models of accreditation and assessment of their strengths and shortcomings. The Task Force collected information on accreditation programs and heard about or from the following organizations:

- Canadian Council on Health Services Accreditation
- Canadian Council on Animal Care
- The Royal College of Physicians and Surgeons of Canada
- Canadian Psychological Association, Programs Accreditation
- Independent REBs (IRB Institutional Review Board Services, Inc.)
- Canadian Institutes of Health Research
- Chairs of REBs (Ottawa, Queen's)
- US Office for Human Research Protections

Dr. Dinsdale and Dr. Carpentier also attended a meeting of the Committee on Assessing the System for the Protection of Human Subjects of Research held in Washington under the auspices of the Institute of Medicine Board on Health Sciences Policy, December, 18-19, 2000.

## **4.0 International and National Perspectives on the Accreditation of Human Research Participant Protection Programs**

### **4.1 International Perspectives**

#### **4.1.1 United States**

Accreditation of Human Research Participant Protection Programs (HRPPP) is being implemented in the U.S. The decision to proceed with accreditation came after a year of lively discussions and decisive action to adjust the governance of ethics oversight for research in humans. Discussions involved the highest levels of government, including Congress and the Senate, the Secretary for Health and Human Services and the President. A major objective was to avoid situations of real or perceived conflicts of interest between agencies that fund research and organizations charged with the protection of research participants.

The Department of Health and Human Services (DHHS) contracted with the Institute of Medicine (IOM) to review and recommend a set of standards for the accreditation of Human Research Protection Programs, and an evaluation system to assess the performance of the accreditation program. The IOM Report, *Preserving Public Trust*, was released in April 2001.

Accreditation will be undertaken initially by two non-governmental organizations independent from the programs being accredited: the Association for the Accreditation of Human Research Protection Programs (AAHRPP), and the National Committee for Quality Assurance (NCQA). The latter will focus its work on the Veteran Administration Research Institutions.

A consortium of national organizations has joined with AAHRPP to develop "a voluntary, peer driven, educationally focused accreditation program for human research protection, using a site visit model that employs a rigorous set of performance standards and outcome measures."

At a press conference held in June 2001 to launch the new accrediting body, AAHRPP, Dr. David Korn, Senior VP for Biomedical and Health Sciences Research of the Association of American Medical Colleges (AAMC) said:

"We intend that AAHRPP become the gold standard for the research enterprise. Accreditation by AAHRPP will help ensure consistency and uniformity of human research participant protections among all institutions that conduct biomedical, behavioral, and social sciences research. And it will help sustain public confidence and trust that, in these accredited organizations, the safety of human research participants remains the first and foremost concern."

In addition to AAMC, AAHRPP is supported by the Association of American Universities, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, the National Association of State Universities and Land-Grant Colleges, the National Health Council, and Public Responsibility in Medicine and Research. AAHRPP intends to start testing their standards and be fully operational in 2002.

These organizations chose the accreditation model and standards developed by the AAHRPP over the more formal one proposed by NCQA because they thought the AAHRPP proposal was more educational and that its overall approach was more adaptable to the variety of situations in universities. The strong links between AAHRPP and PRIMR, the educational organization that created AAHRPP, was seen as a positive factor.

### **4.1.2 New Zealand**

New Zealand has a program of accreditation that applies to approximately 20 Regional and Institutional Research Ethics Committees (RECs). The Ethics Committee of the Health Research Council (HRC) manages the program. The authority to accredit RECs comes from the Health Research Council Act (1990), Section 25, which empowers the HRC Ethics Committee to provide approval to other Ethics Committees to act on its behalf.

The program is managed through application and reports and does not involve site visits. RECs must abide by the National Standards for Ethics Committees developed by the National Advisory Committee on Health and Disability Service Ethics.

### **4.1.3 France**

There are 48 *Comités consultatifs de protection des personnes dans la recherche biomédicale* (CCPPRB). They review approximately 3,000 new biomedical applications per year. They are established regionally. A region may have more than one committee. They are accredited (agrés) by the Minister of Health. These committees have a legal existence. There is no reference to visits nor to standards other than what is found in the law that establishes them (*Code de la santé publique - Révision 2000*).

## **4.2 The Canadian Context**

### **4.2.1 Federal Government and Agencies**

There is currently no accreditation process in Canada that deals with the protection of human participants in research. A Secretariat of the Tri-Council (CIHR, SSHRC, NSERC) has requested that universities receiving funding from federal granting agencies submit their policy documents for review by the federal research granting councils. Results from that exercise have not been made public but officials indicate that the level of compliance is low. Community hospitals, clinics, some teaching hospitals and private doctor's offices, the sites of most clinical research, would not have been included in that review. A Memorandum of Understanding is currently being signed by institutions receiving funds from the agencies. It includes provisions for withdrawing funding in case of noncompliance with ethics requirements. In September 2001, SSHRC proposed a Public Assurance System. It is seeking comments on the document.

### **4.2.2 Provincial Developments**

The College of Physicians and Surgeons of Alberta created an REB to review research proposals involving community-based physicians, the only jurisdiction in Canada to do so. The aim was to ensure that all research conducted by physicians licensed in the province received an adequate ethics review.

The Province of Alberta has designated six REBs to review research under its newly implemented Health Information Act. The implementation manual for the Act adopts the fundamental requirements for REB constitution and operation from the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

The Province of Newfoundland and Labrador is seriously considering establishing through legislation, a Provincial Health Research Ethics Board with the mandate to approve and the power to stop any health research involving humans in the province.

The Department of Health in Quebec published a major document in June 1998: *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*. It has initiated a program of designated REBs that report annually to the Department of Health. The *Fonds de recherche en santé du Québec* has developed standards on research ethics and scientific integrity. The Auditor General for Quebec released a Report in June 2001 in which he noted several deficiencies in the ethics oversight system and recommended several improvements. The Report notes the absence of an accreditation system and its development in the U.S., but does not specifically recommend that it be initiated. The Department is reviewing the Auditor General's recommendations, which may lead to improvement in the oversight of REBs.

## 5.0 Models of Accreditation

### 5.1 The 1996 Fortin-Leroux Report sponsored by NCEHR

In 1996, NCEHR published a Report entitled *Reflections on Monitoring Ethics Review of Research with Human Subjects in Canada*. The Report has been influential in providing information on the strengths and weaknesses of different models of oversight for ethics review in Canada.

**Table of the Strengths and Weaknesses of the Models Presented**

Models	Strengths	Weaknesses
Informal Visits	<ul style="list-style-type: none"> <li>• education and training</li> <li>• flexibility</li> </ul>	<ul style="list-style-type: none"> <li>• no guarantee of universality</li> </ul>
Visits within formal framework	<ul style="list-style-type: none"> <li>• more consistent monitoring</li> <li>• atmosphere conducive to information exchange</li> </ul>	<ul style="list-style-type: none"> <li>• no guarantee of universality</li> </ul>
Accreditation or certification	<ul style="list-style-type: none"> <li>• status is clear</li> </ul>	<ul style="list-style-type: none"> <li>• repercussions of non-compliance uncertain</li> </ul>
Investigation	<ul style="list-style-type: none"> <li>• compellability</li> <li>• universality</li> </ul>	<ul style="list-style-type: none"> <li>• complex structure</li> <li>• rigorous formalism</li> </ul>

Louis-Nicholas Fortin, Thérèse Leroux *Reflections on Monitoring Ethics Review of Research with Human Subjects in Canada, Ottawa, 1996.*

## 5.2 The 2001 Institute of Medicine Report

The Institute of Medicine (IOM) in the United States studied three models of interaction between accreditation and government regulations:

### a) Accreditation as a supplement to government regulation.

In this model, entities already regulated by government seek accreditation as a mark of excellence. It indicates a standard above and beyond government regulation. It has been achieved by only a fraction of regulated entities.

### b) Accreditation substitutes private regulation for public regulation.

Accreditation of institutions of higher education is an example of this model. Formal government regulation is absent. Accreditation is the only oversight system.

Another variant of non-government voluntary accreditation is seen under Medicare's "deemed-status" program. In that circumstance, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) uses its hospital accreditation programs as an alternative to state certification. JCAHO is accepted in lieu of federal standards as a basis for medical participation in Medicare.

There are significant benefits in the use of accreditation as an alternative to regulation and to the deemed-status model in particular. Accreditation reduces the cost of oversight to government. Costs are met primarily by user fees rather than taxes. Non-governmental accreditation programs are much more flexible and responsive than regulatory programs. They are not bound by the rigidities of administrative rule-making procedures and more responsive to their constituencies.

Accreditation, however, also has its costs. It is not directly accountable to the public. If it is not established with an arm's length approach, there may be concern that the "fox is guarding the henhouse". Furthermore, if accreditation is to be more than a pro-forma exercise, it can be resource intensive.

### c) Accreditation ensures compliance with standards on the basis of interpretation of regulatory standards determined by the government or another entity.

This type of accreditation program offers guidance about regulatory compliance.

The Report finds in favor of this third model. It is a method to improve the implementation of existing regulations.

The Task Force established by NCEHR considers that an accreditation model that aims, at a minimum, to ensure compliance with existing regulations and policies serves the public interest. *To succeed however, it must be truly educational and work hand in hand with existing educational programs.*

The complementarity of accreditation and regulation is described in Section 13.

## 6.0 Key Elements of an Accreditation Program

NCEHR's Task Force identified the following necessary important elements for a successful accreditation program:

- It is *voluntary*, but required to fulfill specific functions;
- The review incorporates *peers*, as well as non-affiliated *lay persons* to ensure broad perspective and transparency of the process;
- It is *based on standards*, developed with stakeholders and kept up to date by an ongoing review/consultation program to adjust to a rapidly evolving environment;
- It is *educational* as well as rigorously *evaluative*: a major objective is the demonstration of continuing improvement of programs under review;
- It is done by an organisation at *arm's length* from the program/organisation it is accrediting;
- It is *transparent*, with a clear description of the process, including goals, objectives, and mechanisms to ensure *natural justice*, i.e. incorporation of an appeal process;
- It is *flexible* to adjust to different research settings and adapt to rapid changes in the research and regulatory environments;
- It is *simple* to avoid the unnecessary increase of bureaucratic burden imposed on institutions and to avoid confusion among those participating in the program;
- It enjoys *buy-in* from major stakeholders, including government, universities and industry;
- It is *accountable* to the public, including research participants, possibly by being subject to review by the Auditor General's office. Other means of ensuring accountability of the program should be explored, including independent auditing;
- The accreditation body *adheres to internationally agreed methods of accreditation* and seeks to be accredited through a program of accreditation for accreditation bodies.

## 7.0 What Should Be Accredited?

The entity to be accredited would include all components essential for the program of protection of human participants in research. The functional arrangement of the program will vary depending upon the type of organization being accredited. Examples include hospitals, universities, private clinics, freestanding REBs and government. Some components of the protection program may be external to the organization. AAHRPP has described the focus of its program as follows:

*“The accreditation program will focus not only on institutional review boards and investigators, but on institution-wide efforts to promote and ensure the protection of human participants in biomedical, behavioral and social sciences research.”*

The Task Force believes that it is a useful description of the focus of an accreditation program.

## 8.0 How Does Accreditation Begin?

The Task Force's review of the history of successful accreditation programs revealed that they begin with a steering committee of volunteers concerned about the subject under study. Initial planning may be complex and costly. A major expense is the development of standards, which may be subsidized by stakeholders. The power of the model is the synergy that is created by evaluating the standards among the stakeholders.

An accreditation process cannot be tagged on to an existing accrediting agency when the program to be accredited involves different stakeholders and encompasses a large, specialized and evolving body of knowledge, issues and locations. The accrediting agency from the outset must embrace broad understanding of the matters under review, sensitivity to the issues and concerns of the stakeholders. It must be fully dedicated to the objectives of its mission. For example, the Canadian Council on Animal Care (CCAC) could not be expected to accredit hospitals nor should the Canadian Council on Health Services Accreditation (CCHSA) evaluate animal care or programs of human research protections that require very specialized skills and a broad knowledge base. The gestalt of those organizations reflects their respective and longstanding missions and responsibilities. This must be true of the organization responsible for accreditation of human research protection programs in Canada. These considerations are fundamental to the recommendations of the Task Force (see below, Sections 14 and 15).

The standards should not discriminate against the smallest members in the group (e.g. small community hospitals). Peer review is the key.

Success also requires validity and reliability of the standards. The usual sequence in developing an accreditation program is:

- Step A:** DEVELOP AND TEST STANDARDS IN COLLABORATION WITH STAKEHOLDERS; RECRUIT AND TRAIN ACCREDITATION TEAMS
- Step B:** FINALIZE BUSINESS PLAN
- Step C:** COMMENCE ACCREDITATION PROCESS AND DESIGN PROMOTIONAL MATERIALS
- Step D:** IMPLEMENT GOVERNANCE
- Step E:** EDUCATION OF STAKEHOLDERS
- Step F:** EVALUATE THE ACCREDITATION PROCESS

## 9.0 What Are The Benefits From An Accreditation Program?

- **Benefits for the Canadian Public**

An accreditation program would benefit the Canadian Public by ensuring that adequate safeguards were in place to protect their well being when they choose to participate in research activities. Ensuring public trust is fundamental to maintaining enrollment in trials and continuing support for research.

- **Benefits for Government**

A properly established accreditation program will play an important role in assisting the Canadian government to discharge its duty of care for the health and safety of Canadians who participate in research. As a research funder and regulator, the Government will benefit from an outside, independent, yet reliable accreditation process that will maintain public trust in the safety of clinical trials of drugs and devices and other forms of research in humans. Through an educational approach, the accreditation program will strengthen Research Ethics Boards and the overall governance of research involving humans. An accreditation program that nurtures trust and provides assurance that protection measures and review processes are in place and effective is consistent with the Law Commission of Canada's sponsored study's support for the conclusion by the U.S. Office of Inspector General that a "Trust but verify approach" is needed. (*Law Commission Report, page ix*)

Benefits derived by government from accreditation programs conducted by non-government, independent organizations include:

- Improved performance within existing regulations;
- Greater acceptance by peers. Regulations are seen as top-down;
- Greater flexibility than regulations;
- A process that goes beyond minimal standards of regulations;
- Accreditation program standards can be used by government and referenced in policies or regulations (e.g. FRCP/S and CCAC);
- Avoidance of jurisdictional federal/provincial problems.

- **Benefits for the Therapeutic Products Directorate**

Accreditation will benefit the Therapeutic Product Directorate in its work under the new regulations on clinical trials. Review by REBs is now mandated for all clinical trials. The accreditation program will help the Directorate ensure that REBs function according to regulations and policies and that adequate protection for research participants is in place for all clinical trials.

- **Benefits for the Granting Agencies**

Accreditation will benefit granting agencies (whether federal, provincial, or voluntary) ensuring that the research they fund meets the highest ethical standards and that all appropriate regulations are in place to maintain public trust. It will remove the perceived conflict of interest when a research sponsor also provides ethical oversight.

- **Benefits for the Pharmaceutical Industry**

An accreditation program will benefit the pharmaceutical industry. Industry has demonstrated leadership in developing the Good Clinical Practice Guidelines. However, the industry needs to be assured that these are applied in ethics review, along with regulations and other important ethical requirements. At a workshop organized by the Medical Research Council in 1999, it was emphasized that Industry would welcome a program of accreditation:

“Certification or Accreditation of research ethics boards would provide industry and the research community with some confidence that they meet regulatory and ethical requirements.”

Medical Research Council, Report from the February 9-10 Workshop,  
*Research Ethics: Maximizing Effectiveness, Ottawa, April 1999, p. 7.*

- **Benefits for Foreign Research Sponsors**

Mutual recognition between countries of accreditation for human research protection programs would ensure high standards of international-based research. Mutual recognition of accreditation programs exists for medical schools and specialty training, as well as for psychology. Such mutual recognition would also ensure continuous access to international funding by Canadian researchers.

## **10.0 Need For An Independent Accrediting Body**

The history of accreditation programs records that successful accreditation is done by independent organizations, arising from concerns of professionals engaged in the practice. An accreditation program must be rigorous in its assessment of programs under review, yet educational, in order to help institutions and individuals reach agreed upon standards. This is accomplished only by a peer-based approach. The Auditor General of Canada recently emphasized the importance of such a non-governmental/peer-based approach in standard setting:

“Health Canada acknowledges that the Food and Drug Act and Regulations have not kept pace with scientific and technological advances, and has begun to implement approaches based on standards, which it hopes will offer greater flexibility. Under this concept, standards can be developed by recognized standards development organizations or professional bodies and can be referenced in Regulations. The government remains accountable for the effectiveness of the regulatory regime.”

*Sheila Fraser, Auditor General of Canada, May 31, 2001*

The need for an independent accrediting body is stated clearly in the Report from the Institute of Medicine in its second recommendation:

“Organizations formulating accreditation standards and carrying out the accreditation process should be independent, non-governmental organizations. These organizations should include within their programmatic leaderships the perspectives of the relevant stakeholders in the applicant HRPPP community (i.e. institutions, investigators, sponsors and participants)” (page 11).

The IOM Report identifies the significance of the independence of the organization that performs accreditation:

"An accreditation process is only as credible as the organizations that carry it out. The foremost criterion is independence. Organizations formulating standards and conducting the accreditation process should:

1. be national in scope;
2. be familiar with the operations of institutions that apply for accreditation; and
3. incorporate the perspectives of research participants within their programmatic leadership.” ( page 11)

## **11.0 An Accountability Framework for Accreditation of Programs for the Protection of Research Participants**

A program of accreditation for Human Research Protection Programs must enjoy the trust of the Canadian Public, stakeholders and Governments. The Government of Canada and the Voluntary Sector have undergone in depth discussions that emphasize the autonomy of both sectors, while recognizing the need to utilize and build on standards of best practice to ensure accountability and transparency and to maintain public trust.

A non-governmental, non-profit organization providing accreditation must have buy-in from all major stakeholders. The Task Force notes that informal discussions with potential stakeholders of an accreditation program, identified serious concerns should government be the major force behind the establishment of an accreditation program.

The *Panel on Accountability and Governance in the Voluntary Sector* (The Panel) defines accountability as:

... the requirement to explain and accept responsibility for carrying out an assigned mandate in light of agreed upon expectations. It is particularly important in situations that involve public trust. However, a commitment to accountability should be thought of not only as answering to external audiences, but also as a constructive tool for organizational development, enhancing management practices, self-evaluation and strategic planning.

*Building on Strength: Improving Governance and Accountability in Canada's Voluntary Sector - Final Report, February 1999.*

The Panel proposed that effective board stewardship involves eight key tasks:

1. steering toward the mission and guiding strategic planning;
2. being transparent, including communicating to members, stakeholders and the public and making information available upon request;
3. developing appropriate structures;
4. ensuring the board understands its role and avoids conflicts of interest;
5. maintaining fiscal responsibility;
6. ensuring that an effective management team is in place and overseeing its activities;
7. implementing assessment and control systems; and
8. planning for the succession and diversity of the board.

Performance of these key tasks is important to ensure appropriate accountability. The Auditor General of Canada has addressed this issue, proposing a governing framework for new arrangements that includes elements of accountability, reporting, transparency and protection of the public interest. The elements of that framework are indicated by the Panel as follows:

**To ensure credible *reporting*:**

- Clear public objectives
- Concrete performance expectations
- Appropriate performance measurement and reporting regime

**To establish effective *accountability mechanisms*:**

- Clear roles and responsibilities
- Performance expectations that are balanced with capabilities
- Well-defined management structure
- Appropriate monitoring regime
- Partner dispute resolution mechanisms
- Specific evaluation provisions
- Procedures to deal with non-performance
- Appropriate audit regime

**To ensure adequate *transparency*:**

- Public access to information
- Communication of information on key policies and decisions

**To protect the *public interest*:**

- Citizen complaint and redress mechanisms
- Public consultation/feedback mechanisms
- Policies to promote pertinent public sector values

The Task Force subscribes to the tasks outlined by the Panel and the governing framework proposed by the Auditor General. The Task Force believes that one important way by which such a program can be accountable to the public and government is by being audited by the Auditor General of Canada. This would provide the necessary assurance that the program maintains high standards of accountability.

Another means of ensuring adequate accountability to government would be to implement regular auditing of the Accreditation Program by an independent body. The Task Force notes some interesting suggestions contained in a Report from a Health Canada Working Group under the heading of Shared Model:

### **Methods to Verify Compliance**

Accreditation and peer-review programs would be developed and co-ordinated by medical and professional associations. The government would ensure compliance to regulations by auditing accreditation systems and by inspecting service providers.

Health Canada, Working Group on Reproductive and Genetic Technologies, *Report on Discussions of Potential Regulatory Frameworks For Reproductive and Genetic Technologies*, Ottawa, May 2001, p.33.

The Task Force believes it constitutes a helpful model to explore in the context of the Accreditation of Human Research Participants Protection Programs.

## **12.0 Education is Intrinsic to Accreditation**

Discussions have evolved around the issue of the compatibility of a role in education for an organization responsible for accreditation. The Task Force considers that education and accreditation must not only be consistent but also mutually reinforcing. Indeed accreditation can be seen as part of the educational process. On the one hand, the accreditation report provides a learning experience, on the other hand, preparation for and participation in the accreditation process is inherently educational. Most importantly, there must be a good fit between the processes and materials used for education and the process of accreditation. Otherwise the organizations subject to accreditation can rightly complain of inconsistency and misdirection.

The *International Standards for Accreditation Bodies*, which serve to assess the performance of accrediting organizations, clearly incorporate requirements to offer education services.

### **“STANDARD 10 EDUCATION SERVICES**

Education services are systematically designed and implemented to meet quality standards and client needs, as follows:

#### **10.1 Program Design**

10.1.1 Education programs and services are systematically designed to take into account:

- client requirements and course feedback
- issues relating to accreditation standards and the accreditation program and its processes
- topical matters of direct relevance to quality and accreditation.

10.1.2 There is a systematic evaluation of clients' needs, changes in accreditation processes and standards, and changes in the external environment that is taken into account when designing and reviewing the education program.

10.1.3 The education program is set and reviewed at planned intervals and outlines learning outcomes.

10.1.4 Courses and modules:

- are designed with clear objectives and target groups
- are clearly marketed indicating the nature and level of the course
- have resource material that is up-to-date, checked and validated.

## **10.2 Program Delivery**

10.2.1 Courses are delivered using staff and tutors with expertise in the subject area.

10.2.2 Resource material and information provided supporting each course, are consistent with the accreditation program and are designed to meet the learning outcomes of the program and the learning needs of the clients.

10.2.3 Resource material meets pre-set production standards.

10.2.4 Each education course or session is evaluated, and the feedback is used to improve the program.”

*Agenda for Leadership in Programs for Health Care Accreditation (ALPHA),  
International Standards for Health Care Accreditation Bodies*

It is essential that an accreditation program be coordinated with educational services. Appropriate educational materials will focus attention on accreditation processes, standards and their interpretation. Accreditation will be linked to appropriate educational measures. Although related, accreditation and education should be treated as two distinct functions each with a distinct time frame and direction.

Education services should focus on basic training, education about policies and regulations, and research ethics issues. The Task Force believes that there is added value in these two functions being closely related, yet independent.

## **13.0 How will Voluntary Program of Accreditation Relate to Government Regulations?**

As a voluntary program of Accreditation develops, the Federal government may find it necessary to introduce legislation, regulations or other oversight mechanisms to ensure the protection of the safety and well-being of Canadians who volunteer as research participants. For example it may want to ensure that accreditation is required to fulfill certain functions, or to ensure efficient sanctions. From what has been said above, accreditation is best conducted as a delegated function, which can be embedded within a shared model of oversight. The Auditor General of Canada has studied the case of delegated arrangements, and especially the issue of accountability in such circumstances. Noting the need for a balance between independence and efficiency with accountability, the Auditor General wrote:

“Delegated arrangements are set up to be independent of the day-to-day involvement of the government and to be exempt from its rules and regulations. They are intended to have flexibility and the freedom to take reasonable risks and adopt innovative ways of delivering federal objectives. (...) In our view, appropriate and adequate accountability to Parliament and the government can be balanced with the autonomy and flexibility these

arrangements require. Reasonable accountability to Parliament is not synonymous with control by the government and should not necessarily be interpreted as bringing these entities under government control or into the federal accounts, or invalidating their independence.”

Auditor General of Canada, *Involving Others in Governing: Accountability at Risk*, Report of the Auditor General of Canada – 1999, Chapter 23, Ottawa, November 1999.

The independence of a voluntary Program of Accreditation for Human Research Protection Programs is essential to ensure a successful implementation and continued operation. Yet, the interaction between voluntary accreditation and legislation or regulation may be seen as a continuum. Both approaches have their strengths and limitations. A combination of the two would improve the overall approach to the protection of human participants in research. This issue was addressed in a Report from the Inspector General at the Department of Health and Human Services:

A collegial mode of oversight is one that focuses on education and improved performance. It emphasizes a trusting approach to oversight, rooted in professional accountability and cooperative relationships. A regulatory mode focuses on investigation and enforcement of minimum requirements. It involves a more challenging approach to oversight, grounded in public accountability. It is helpful to consider external hospital oversight in terms of a continuum, characterized by the collegial approach on one side and the regulatory approach on the other.

Gibbs Brown, June *The External Review of Hospital Quality: A Call for Greater Accountability*, 3.

## **14.0 Board of Accreditation**

The Task Force considered several organizational options for the development of a Program of Accreditation.

The development of a Board of Accreditation would require discussions with stakeholders to determine the process and composition of the Board. It would be premature to offer a definitive composition of the Board of accreditation before appropriate consultations with stakeholders take place. The Task Force considers that stakeholders need to be included in the protection of human subjects. Among the criteria for selecting membership are expertise, independence to avoid real or perceived conflict of interest, and genuine support of the Board’s mission.

Potential members of the Board of Accreditation or invited observers of the Board could include the following:

- Association of Universities and Colleges of Canada (AUCC)
- Association of Canadian Medical Colleges (ACMC)
- Association of Canadian Academic Healthcare Organizations (ACAHO)
- Association of Canadian Faculties of Dentistry (ACFD)
- Canada’s Research-Based Pharmaceutical Companies (Rx&D)
- Canadian Association of Research Ethics Boards (CAREB)

- Canadian Association of University Research Administrators (CAURA)
- Canadian Association of University Schools of Nursing (CAUSN)
- Canadian Bioethics Society (CBS)
- Canadian Council of Departments of Psychology (CCDP)
- Canadian Institutes of Health Research (CIHR)
- Health Canada
- Industry Canada
- National Council on Ethics in Human Research (NCEHR)
- Natural Sciences and Engineering Research Council (NSERC)
- Social Sciences and Humanities Research Council (SSHRC)
- Representatives of research participant's organizations, and
- Lay representatives.

Health research is the area of most immediate importance for the development of an accreditation program. Discussions with other sectors of research involving human subjects are underway and the results of these discussions might well be later integrated in program development.

The Board of Accreditation would provide annually, publicly available reports on the performance of the Program. The objective would be to provide consistency and uniformity across the broad spectrum of research with humans.

The Task Force remains concerned about the true independence of the process of accreditation and recognizes that various alternatives will have to be assessed during consultation with stakeholders in the context of the developing governance structure in Canada.

The Task Force acknowledges that several accreditation programs exist such as the CCHSA for hospitals and health care facilities and the Canadian Psychological Association for psychology programs. However, most existing programs are more narrowly focused on individual disciplines or professions; by contrast, a program of accreditation for research involving humans must cover a very wide spectrum of activities ranging from the humanities and social sciences through biomedical disciplines to clinical research. Given that the various constituencies have a range of experience with submission of protocols to REBs, which varies from the well established to very recent, there would have to be sensitivity to this range of experience. Thus while it is essential that the same standard be applied across the range of research involving humans, the timing of the shift from a purely educational mode to an accreditation mode may have to vary depending on the experience of a particular REB. These unique requirements of the Program emphasize the importance of the connection between education and accreditation.

The Task Force notes that NCEHR, through its existing program of site visits has gained experience of the challenges facing those constituencies for which the requirement of REB scrutiny of protocols is relatively recent. NCEHR is well positioned to undertake an enlarged mandate that would incorporate accreditation of Canadian REBs. However, a successful accreditation program requires commitment of key stakeholders. Therefore

whether NCEHR should be encouraged to expand its mandate to include the development of a separate program of accreditation would depend upon the outcome of consultations with those stakeholders.

The development of a business plan on which to base a program of accreditation will be a key component in a successful launch and continued operation of an Accreditation Program.

## **15.0 Recommendations:**

The Task Force recommends to Council:

- That it affirms the need for a nation-wide oversight process for the ethics review of research in humans in Canada based on standards;
- That such an oversight takes the form of an accreditation program to be conducted by an arms-length, non-governmental organization;
- That NCEHR facilitate discussions with organizations that would be stakeholders or observers in a new Program of Accreditation for Human Research Participants Protection Programs.

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## List of Acronyms

<i>Acronym</i>	<i>Organization</i>
AAHRPP	Association for the Accreditation of Human Research Protection Programs
AAMC	Association of American Medical Colleges
ACAHO	Association of Canadian Academic Healthcare Organizations
ACFD	Association of Canadian Faculties of Dentistry
ACMC	Association of Canadian Medical Colleges
AUCC	Association of Universities and Colleges of Canada
CAREB	Canadian Association of Research Ethics Boards
CAURA	Canadian Association of University Research Administrators
CAUSN	Canadian Association of University Schools of Nursing
CBS	Canadian Bioethics Society
CCAC	Canadian Council on Animal Care
CCDP	Canadian Council of Departments of Psychology
CCHSA	Canadian Council on Health Services Accreditation
CCPPRB	Comités consultatifs de protection des personnes dans la recherche biomédicale
CHA	Canadian Hospital Association
CIHR	Canadian Institutes of Health Research
CPA	Canadian Psychological Association
CSSA	Consortium of Social Science Association
DHHS	Department of Health and Human Services
DND	Department of National Defense
FASEB	Federation of American Societies for Experimental Biology
FMALA	The Federation of Medical Licensing Authorities of Canada
FRCP/S	Fellows of The Royal College of Physicians and Surgeons of Canada
GCP	Good Clinical Practice Guidelines
HC	Health Canada
HRC	Health Research Council
HRPPP	Human Research Participant Protection Program
IOM	Institute of Medicine
IRB	Institutional Review Board
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MRC	Medical Research Council
NACHDSE	National Advisory Committee on Health and Disability Service Ethics
NCBHR	National Council on Bioethics in Human Research
NCEHR	National Council on Ethics in Human Research
NCQA	National Committee for Quality Assurance
NSERC	Natural Sciences and Engineering Research Council
NHC	National Health Council
OHRP	Office of Human Research Protection
PRIM&R	Public Responsibility in Medicine and Research
REBs	Research Ethics Boards
RECs	Research Ethics Committees
Rx&D	Canada's Research-Based Pharmaceutical Companies
SSHRC	Social Sciences and Humanities Research Council
TPD	Therapeutic Product Directorate
TPP	Therapeutic Products Programme