Options for the Development of an Accreditation System for Human Research Protection Programs

Request for Comments

April 2005

Reply by May 31, 2005

Table of Contents

Page

EXECUTIVE SUMMARY

This document has been prepared by the Task Force for the Development of an Accreditation System for Human Research Protection Programs (HRPPs), established by the National Council on Ethics in Human Research (NCEHR). NCEHR is an independent, non-governmental organization composed of a volunteer council and a small staff with a mandate extending to all research involving humans. Its mission consists in advancing the protection and well being of human participants in research and fostering high ethical standards for the conduct of research involving humans.

In Canada, organizations hosting research involving humans are expected to establish HRPPs comprising all elements that will ensure adequate protection of research participants. Among these elements is a properly constituted Research Ethics Board (REB). REBs are typically established in research organizations, but may also exist as independent entities or be community-based. There is evidence that existing HRPPs vary in their capacity to discharge the responsibilities assigned to them by existing policies or regulations. Accreditation of HRPPs is proposed in response to this challenge. The accreditation process would be based upon standards developed from the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*, existing federal, provincial or territorial laws, regulations or policies, the Good Clinical Practices Guidelines, etc. A sub-committee of the Task Force has worked at developing draft standards (see Appendix A). These standards will also be subject to a wide consultation process.

Accreditation, with its strong emphasis on education both in terms of the self-study and self-examination preceding the accreditation visit and during the visit, encourages a wider awareness of, and commitment to, protection of research participants and subjects by an organization. It promotes a culture of ethical research involving humans within the entire organization. It addresses not only the REB, but other aspects of HRPPs such as the education for researchers, the level of authority and the independence of the organization's program of protection for research participants.

The development of any accreditation system requires consultation with the all stakeholders. The current consultation is one particularly important part of this process.

This report describes a number of options relative to:

- The Organization of the Accrediting Entity
- The Development and Maintenance of Standards
- The Funding of the Accreditation System

We are seeking your comments on this report by **May 31, 2005**. These comments will be compiled and will feed into further consultations and a final report.

ACKNOWLEGEMENTS

Members of the Task Force for the Development of an Accreditation System for Human Research Protection Programs

Dr. Kenneth Davey – Co-chair
York University

Dr. Michael Owen – Co-chair
Brock University

Dr. Barbara McGillivray
University of British Columbia

Prof. Édith Deleury
Université Laval

Dr. Henry B. Dinsdale
Kingston General Hospital

Dr. Deborah Poff
University of Northern British Columbia

Ms. Marianne Vanderwel
Pfizer Canada Inc.

NCEHR Office
Dr. Richard Carpentier
Executive Director

Ms. Felicetta Celenza
Coordinator of Educational Visits

Members of the Sub-Committee on Standards Development

Dr. Michael Owen - Chair
Brock University

Mr. Jack Corman
IRB Services

Dr. Kenneth Davey
York University

Prof. Édith Deleury
Université Laval

Ms. Patricia Lindley
Canadian Association of Research Ethics Boards (CAREB)

Dr. Barbara McGillivray
University of British Columbia

Ms. Susan Sykes
Interagency Advisory Panel on Research Ethics

NCEHR Office
Dr. Richard Carpentier
Executive Director

Ms. Felicetta Celenza
Coordinator of Educational Visits

Production of this document and sample standards for accreditation has been made possible through a financial contribution from Health Canada and the Canadian Institutes of Health Research.

The views expressed herein do not necessarily represent the views of Health Canada and the Canadian Institutes of Health Research.

I. INTRODUCTION

This document has been prepared by the Task Force for the Development of an Accreditation System for Human Research Protection Programs, established by the National Council on Ethics in Human Research (NCEHR). NCEHR is an independent, non-governmental organization composed of a volunteer council and a small staff with a mandate extending to all research involving humans. Its mission consists in advancing the protection and well being of human participants in research and fostering high ethical standards for the conduct of research involving humans. The terms of reference for the Task Force, found in the 2004 Information Bulletin[1] (www.ncehr-cnerh.org), require it to consult stakeholders, including research participants and members of the public on potential models of accreditation. This Options Paper represents one of the steps in that consultation. Reports of meetings of the Task Force[2] can be seen at www.ncehr-cnerh.org.

This paper outlines options for the organization that would undertake the accreditation of Human Research Protection Programs (HRPPs) in Canada, for the way in which the accreditation standards would be developed and maintained, and for methods of financing the initiative. HRPPs refer to a "*system composed of independent elements that come together to implement policies and practices that ensure appropriate protection of research participants*".[3] These elements include, among others, research participants, researchers, research ethics boards, and the authorities ultimately responsible for the organizational HRPP. The Task Force argues strongly that in the interests of enhancing the protection of human research participants, it is the overall Human Research Protection Program of an organization that becomes accredited. Such organizations include universities, hospitals, communities, governmental departments or private sector entities, including private Research Ethics Boards. Research Ethics Boards (REBs) and their operation, additional components such as education for researchers, and organizational commitment to the protection of human participants will all be important elements of HRPPs to include in the accreditation process.

This paper is being widely distributed to individuals and organizations that might have an interest in the subject. The Task Force is seeking responses to the paper from any organization or individual. Responses can address any issue or concern, but we hope that responses would at a minimum address the following questions, providing comments on them.

1) **Do you or your organization support the development of a system of accreditation as outlined in this document?**

2) **Of the options described in the various sections, are there particular options that you or your organization favours?**

3) **Among these options are there particular issues that you or your organization feel need further or special attention?**

[1] http://www.ncehr-cnerh.org/pdf/publications/task_force/TaskForceBulletin_1-1.pdf
[2] http://www.ncehr-cnerh.org/english/task_force.php
[3] Federman, D., Hana, K., Rodriguez, L., Responsible Research: A Systems Approach to Protecting Research Participants, Washington, The Institute of Medicine, 2003, p. 1.

4) **Among these options, are there any that you or your organization find unacceptable?**
5) **Are there additional options that you or your organization would like the Task Force to consider?**

Replies can be sent electronically to **options@ncehr-cnerh.org** or by hard copy to NCEHR at:

Consultation on Options Paper
National Council on Ethics in Human Research
240 Catherine St., Suite 208
Ottawa, Ontario
Canada K2P 2G8
Telephone: (613) 233-5445
Fax: (613) 233-0658

If you have any question about this consultation, please contact Dr. Richard Carpentier, Executive Director of NCEHR at the above number or write to: **rcarpentier@ncehr-cnerh.org**

IT IS ESSENTIAL THAT REPLIES BE RECEIVED BEFORE MAY 31, 2005

Once replies have been received and analyzed, the Task Force will invite a group of knowledgeable persons representing various stakeholders (research participants, the general public, funders, regulators, researchers, REBs and organizations conducting research) to a workshop that will examine selected options and the issues that surround their implementation. That should enable the Task Force to produce a final report to NCEHR as rapidly as possible.

II. WHAT IS ACCREDITATION?

It is important to understand what is implied by the term "accreditation". For the purposes of this document, the Task Force is agreed on the following definition.

Accreditation is a self-assessment and peer-assessment process used by organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the system.

Accreditation is thus different from licensure, which is normally issued by a government authority to recognize that an individual has met a set of minimum standards or competence. "Unlike licensure, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards, rather than adherence to minimal standards"[4]. While certification shares some of the characteristics of accreditation, it is most frequently focused on the competence of individuals and involves standards set by government or professional organizations. The Public Assurance System proposed by the SSHRC Standing Committee on Ethics and Integrity[5] shares many of the characteristics of an accreditation system, but is more narrowly focused on REBs and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* rather than the broader HRPP.

The establishment of an accreditation process is an essential requirement for many self-regulating professions. Along with government regulations, codes of conduct, etc. it provides the essential protections for human subjects of research.

An earlier Task Force[6] report identified some characteristics of a system of accreditation for systems of protection of human research participants. The present Task Force has accepted these. Thus, this paper is based on the following assumptions.

- The system of accreditation should, at least initially, be **voluntary**, if only because currently there is no mandatory requirement for accreditation. Of course, accreditation may eventually be required by regulatory bodies and/or by funders of research.

- The system of accreditation must be **flexible** from several perspectives. It must recognize the differences among organizations, including: universities, not all of which will engage in the full range of research on humans; hospitals, both those connected to universities, and community hospitals; government departments and agencies, many of which conduct research on humans; organizations in the private sector; and REBs not connected to an institution, such as community

[4] International Society for Quality in Health Care, *Toolkit for Accreditation Programs*, 2004. Available at: http://www.isqua.org.au/isquaPages/Accreditation/ISQuaAccreditationToolkit.pdf
[5] Social Sciences and Humanities Research Council, *Public Assurance System for Research Involving Humans in Council-Funded Institutions*, Report of the SSHRC Standing Committee on Ethics and Integrity, August, 2001. Available at: http://www.sshrc.ca/web/about/policies/PAS_e.pdf
[6] *Report of the NCEHR Task Force to Study Models of Accreditation for Human Research Protection Programs in Canada*, 29 March, 2002. This Report is available at: http://www.ncehr-cnerh.org/english/NCEHR_Task_Force_Rpt.PDF

REBs and independent for profit REBs. It must recognize the differences in methodological approaches to research in the various disciplines. The flexibility of accreditation with its ability to respond promptly to changing circumstances is one of its major advantages over the regulatory process.

- The system must be **transparent**, so that the public has free access to the standards and the process. The results of the process, at least in terms of the institutions that have achieved accreditation, should also be available to the public.

- This transparency will help to render the system **accountable** to stakeholders, especially research participants and subjects, and to the public.

- The accreditation system should be based on **review by external peers and the public**, including the participants or subjects of research. The review would involve a site visit following a period of guided self-study.

- The system would be **based on standards** derived from existing policies, regulations, guidelines (both domestic and international) and best practices. They would be established in consultation with stakeholders. The basic policy most widely used in Canada is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS),* but additional policies and regulations will apply, for particular jurisdictions, and types of research. Standards for accreditation generally set higher goals than regulations. Standards would evolve and change over time through regular review and updating.

- The system should be **educational**, with the objective of continuous quality improvement in the process of ethical review, rather than simply meeting a minimum standard. With the evolution of the standards, the quality of the review process will increase. The strong educational component is an element usually not appreciated by those unfamiliar with the process.

- While recognizing the legitimate interests and responsibilities of the provinces in oversight of REBs, the system of accreditation should be **national in scope** and involve national standards, with the flexibility noted above. That is, the system would be national in scope in the sense that its services would be available across the country and take into consideration unique provincial and territorial requirements.

Given the global nature of the research enterprise, and the emergence of international standards, the accreditation process should recognize these influences. The arms-length-from-government nature of the accreditation process facilitates interaction across national borders and continents.

The Task Force also recognizes that the accreditation process must consider the entire system for protection of research participants within an organization. It therefore makes sense to accredit a program rather than individual REBs. For example, such considerations as education for researchers, and the level of authority and independence of its program of protection for research participants would also be considered. There might, however, be some flexibility around this matter, as some organizations might apply for accreditation limited to components of their program, leaving others to a later assessment. As mentioned earlier, flexibility will also be required in the accreditation system to ensure it can address different REB structures, such as regionally based REBs, independent REBs, in-house REBs, or multi-site REBs.

Accreditation is customarily awarded for a specified term (3-5 years). During the term, regular interim follow-up is often required to ensure that the standards continue to be met until the next review cycle.

III. WHY DOES CANADA NEED A SYSTEM OF ACCREDITATION?

The Report of the earlier Task Force[7] documented some of the issues that have led NCEHR to conclude that a system of accreditation is desirable. The prime objective is to enhance the protection of the volunteer participants on whom the research depends. These include:

- A recent increase in research and innovation activities, particularly in the general field of health. This growth is not limited to research in the natural and medical sciences, but includes social research impinging on health policy. Not all of this research involves humans. There is no reliable estimate of the number of humans involved as participants or subjects. NCEHR, as a result of information gathered on site visits to two of the "research intensive" universities, has conservatively estimated that about 3,000,000 individual Canadians are research participants in projects conducted at Canadian universities.

- The number of clinical trials of drugs in Canada has increased greatly in recent years. This has been accompanied by a major shift of trials away from academic centres so that the majority is conducted in community hospitals and physicians' offices.

- The report lists a number of highly visible Canadian cases in which ethical breaches have occurred. These transgressions have not led to sanctions similar to those in the United States, where federal research funding was discontinued to entire research institutions until corrective action was taken.

Apart from the lapses that have occurred in the system, there is increasing concern about the lack of consistency in the application of ethical processes in human research as well as the lack of a generally applicable oversight mechanism for the systems of protection for human participants. The federal granting agencies have instituted increasing oversight of the institutions that receive their funding, and Health Canada regulates Phase I-III clinical trials. No comparable system exists for this largely invisible, but significant, research enterprise involving humans that operates outside the universities. Similarly, while the Interagency Advisory Panel on Research Ethics (PRE) has launched web-based training in the requirements of the *TCPS*, we are still lacking a more general system of education for REB members, researchers and administrators that include other policies and other research jurisdictions, nor are there national standards for such education.

There is increasing concern about the potential for conflict of interest of researchers and their institutions. For example, questions have been raised about the propriety of the financial involvement of investigators with the sponsors of research and about a close relationship of the ethics approval process with the promotion of research. Experience from the quality improvement site visit program of NCEHR has demonstrated that these potential conflicts may not be recognized by the researchers or their institutions. An accreditation process with appropriate standards will draw attention to the potential perceived conflicts for institutions, their REBs and their researchers and methods by which such actual or potential conflicts of interest can be managed.

[7] *Report of the NCEHR Task Force to Study Models of Accreditation for Human Research Protection Programs in Canada*, 29 March, 2002. This Report is available at:
http://www.ncehr-cnerh.org/english/NCEHR_Task_Force_Rpt.PDF

The research enterprise involving humans in Canada depends on a supply of willing volunteers. Interviews with research participants during education and quality improvement site visits by NCEHR revealed that while some of the volunteer activity occurs in the expectation of benefit for the participant, an equally powerful motivator is genuine altruism. If the confidence of the public in the systems that protect the volunteer research participant is in any way eroded, all of those involved in the enterprise, researchers, their organizations and the funders of research are affected. It is in the best interests of all that the public retain confidence in the system by increasing the credibility of the REB review and approval process.

Research is becoming increasingly collaborative and international in scope so that research on humans often involves more than a single organization or funding body, sometimes in more than one country. Currently, it is customary for the REB of each organization to conduct a full review of such protocols, resulting in duplication of effort and often frustrating delays for the researchers. A system of accreditation, based on agreed and readily accessible standards might reduce the number of REBs that would feel compelled to conduct full reviews of the same protocol by allowing a system of mutual recognition. The key to any system of mutual recognition is that each party must have confidence that the other parties will adhere to similar standards. Accreditation provides a basis for improved communication and shared responsibilities between REBs, nationally and internationally with a possible movement to networks of REBs that share workload. A system of accreditation would offer enhanced opportunities for synergy among the stakeholders.

Accreditation, with its strong emphasis on education both in terms of the self-study and self-examination preceding the accreditation visit and during the visit, encourages a wider awareness of, and commitment to, protection of research participants and subjects by an organization. It promotes a culture of ethical research involving humans within the entire organization.

There are clearly a number of different issues to be addressed with regard to the governance of research involving humans in Canada. A number of recent reports, such as those from the Canadian Biotechnology Advisory Committee[8] and the House of Commons Standing Committee on Health[9], have recommended an important role for accreditation in addressing these issues. However, it is also important to note that accreditation, in itself, will not address all governance issues raised in this document and elsewhere.

[8] Canadian Biotechnology Advisory Committee, *Biotechnology and the Health of Canadians*, December 2004. Available at: http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI-Final_Dec-13-04-E.pdf/$FILE/BHI-Final_Dec-13-04-E.pdf

[9] House of Commons, Standing Committee on Health, *Opening The Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*, Ottawa, April 2004. Available at: http://www.parl.gc.ca/infocomdoc/Documents/37/3/parlbus/commbus/house/reports/healrp01/healrp01-e.pdf

Nevertheless, a system of accreditation will benefit all of those concerned with research involving humans. The **research participants**, and the **public** in general, will have a greater confidence in a system that is performing to a set of readily accessible standards, and the admirable willingness of the public to volunteer as participants should be enhanced. **Researchers** will benefit from the increased confidence of the public and the participants, and from the respect and increased confidence that the system will engender in other organizations and jurisdictions. **Organizations** will have a set of standards to embrace and administrators within those organizations will have increased confidence that their systems are operating effectively and independently. An independent assessment of institutional systems for the protection of human participants will increase the confidence of **funders and regulators** that organizations are adhering to high ethical standards in their research involving humans. The **economic activity** that increased research involving human participants has brought to Canada will be supported and protected.

IV. WHAT SHOULD BE THE ACCREDITING ENTITY?

In addressing the organization of the entity that would undertake the accreditation process, the Task Force has identified five processes as essential to accreditation:

- The setting, maintenance and ongoing revision of standards
- The process of assessment, assumed to involve self-assessment plus a site visit
- The formal granting of accreditation
- Feedback to the policy forming entities, responsible for the policies and regulations that govern ethical research on humans
- Follow-up between evaluation cycles to ensure that standards continue to be met

The Task Force also recognized that there are assumptions held by the community at large that need to be addressed.

First, there is the assumption that the entity will in some way represent the interests of the "stakeholders", a term that includes a group of organizations that has yet to be defined. The stakeholders will also include, crucially, members of the public and research participants or subjects. The number of possible organizations that may self-identify as stakeholders is likely to be large.

One of the key challenges for the accreditation entity, no matter its ultimate design, is that it must be operationally effective while being open to diverse stakeholder groups. If the accreditation entity is weighed too heavily on the side of official representation by key stakeholder groups, it may not be able to function effectively due to potential conflicts among stakeholders, or the inability to obtain quick decisions. If, on the other hand, key stakeholders are not intricately connected to the entity, then the accreditation regime may not receive adequate support to be effective. Whatever model is ultimately selected, there will need to be a consideration of what steps can be taken to resolve this challenge.

Second, there is the widely held perception in the community that NCEHR will "do" accreditation. That perception that may be naïve or misplaced, but it needs to be addressed. It is important to recognize that NCEHR, as currently constituted, is an organization in which the membership of Council is drawn from a broad spectrum of scientific and scholarly disciplines, including philosophy and law, together with research participants, aboriginal people, and the public. Over the 16 years of its existence, its function and mode of operation have evolved. Today NCEHR conducts a number of educational programs, one of which, the Quality Improvement Site Visits has a superficial resemblance to the procedures used in accreditation. NCEHR also plays an important role in identifying and analyzing emerging issues in the field of human research ethics, and in establishing a number of international liaisons.

Third, the entity will want to be able to undertake contracts, and to protect itself from liability, suggesting that it should be a formally incorporated entity.

Against this background, the Task Force identified four general options. The Task Force has not attempted at this stage to provide detailed characteristics of each option: that can be done after the initial consultation is complete.

Organizational Option 1
NCEHR transforms itself into the Accrediting Entity

In this model, NCEHR would convert itself into an organization specifically to undertake accreditation. It would evolve from an organization based on individuals into one based on stakeholder organizations, research participants and members of the public. NCEHR as it currently exists would thus disappear, the argument being that the educational activities for which NCEHR is best known could be subsumed by the reconfigured NCEHR. The reconfigured NCEHR would continue to undertake its current responsibilities, but add accreditation as a major (and likely pre-occupying) activity. It would retain the name, but alter its membership. This entity would also be responsible for all of the functions identified above.

The major consideration in this model is whether a Council composed of stakeholders rather than individuals is capable of undertaking the current responsibilities, including the analysis of emerging issues, the operation of workshops and the national annual conference, all of which depend on expert knowledge residing in individuals rather than in organizations. Would the development of a program of accreditation remove the necessity for such activities? The Task Force has not consulted NCEHR about its reaction to such an arrangement, but puts forward the option for consideration.

Organizational Option 2
The Accrediting Entity retains a connection to NCEHR

In this model, the new entity would be established as a subsidiary of NCEHR, for example, a "Council on Accreditation of Human Research Protection Programs" (CAHRPP). The accrediting entity would be attached to NCEHR as a separate but closely related enterprise. It would preserve the current organization and functions of NCEHR. The closeness of the relationship could vary in a number of ways, but the essence of the model would be that CAHRPP would undertake the accreditation process, and would forward the report and recommendation to NCEHR. NCEHR would itself then issue the accreditation certificate. In addition, NCEHR might also oversee the establishment and continuing review of standards, thus arranging for that process to be at some distance from the assessment process. Such a separation is a feature of some of the accreditation programs that the Task Force has examined. This arrangement would confer credibility on the process by ensuring NCEHR's continuing involvement, at least in the early years of the process. This model might also allow the continuance of the Quality Assurance Site Visits to those organizations not yet ready to embark on accreditation.

There is a spectrum of possibilities for the interaction between the two bodies. At one end of the spectrum, there might be a separately incorporated entity, related to NCEHR by mutual representatives on the respective Boards, perhaps with joint membership on specific committees. On the other end, NCEHR might establish an Office of Accreditation, governed by an advisory committee made up of key stakeholders.

Organizational Option 3
A New Accreditation Entity

Under this option, a new entity, for example, a "Council on Accreditation of Human Research Protection Programs" (CAHRPP) would exist as an independent incorporation. The Canadian Council on Animal Care represents a general organizational model, but the functions of the CAHRPP would be broader and different. It might have a self-identifying membership of stakeholder organizations, with a smaller Board elected from the membership, and including members of the public and research participants. This option was the approach taken in the U.S. by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). It was founded by seven organizations.

Another potential model for a new entity is The Canadian Patient Safety Institute (CPSI) since it is based on a multi-stakeholder framework. Under this scenario, the accreditation entity would commence with an Interim Advisory Committee composed of senior representatives from key stakeholder groups including universities, research organizations, professional groups, research funders, and governments. This committee would then nominate members for the Board of Directors from the wider community of stakeholders including research participants. Members of the Board of Directors would be sought for their experience and insights rather than their organizational affiliations.

Other specific models are no doubt possible, but whatever the details that emerge, the major issue would revolve around credibility. Would a new and entirely independent organization composed of stakeholders be able to establish the trust that would lead to wide acceptance? This body would be responsible for all five of the functions outlined above, although it might choose to establish an arm's length committee to oversee the development and maintenance of standards (see section on Standards).

Organizational Option 4
Use an Existing Organization

Under this option, an existing accrediting organization from Canada or the United States might be approached to establish a program of accreditation in Canada. There are Canadian organizations already involved in the accreditation of health related programs. In addition, there are at least two organizations in the US currently involved in accreditation of human research protection programs. One of these organizations might be able to adapt its standards to recognize *TCPS*, the Health Canada regulations and the emerging provincial requirements. There could be variations on such an arrangement ranging from the US organization simply offering its service within Canada either on a short term or more permanent basis, to establishing a Canadian organization. Under this arrangement, the entity would perform all five functions associated with accreditation.

V. HOW SHOULD THE ACCREDITING STANDARDS BE SET AND MAINTAINED?

There are several issues to be addressed. There is first the matter of the initial development of standards. The Task Force was informed by a variety of sources that, typically, the standards for many accreditation systems were initially developed by a few persons expert in the policies, practices and regulations affecting the organizations to be accredited, sometimes advised by consultants familiar with the language of accreditation standards.

Standards evolve as new policies and regulations are developed or existing policies are refined, and the matter of how the standards will keep pace with these changes also needs to be addressed.

The question of the form of the standards is often raised. However, the Task Force has observed that the differences among various forms is more apparent than real, and that the apparent differences consist largely of differences in terminology. The Task Force attaches less importance to this issue, and has included as an appendix a set of standards drawn up by a small expert working group. These are focused at present on a small part of the *TCPS* and are included simply as an illustration of what standards might look like. The working group will continue its work with a view to making available a draft set of standards for consideration by whatever organization is established. It will consult with appropriate persons and organizations during the process.

A major issue for Canada is the complexity of the regulations, policies and guidelines that might apply for an institution, depending on its geographical location, the disciplinary breadth of the research undertaken involving human subjects, and the source of the funding for the research. Thus, the basic policy is the *TCPS* (itself defined as an evolving document). To this must be added the regulations and policies developed by the Provinces and Territories, as well as the developing privacy policies, both Federal and Provincial/Territorial. For research involving clinical trials, there are regulations developed by Health Canada, and for research funded by sources in other countries, there may be additional guidelines and regulation. The standards to be developed will have to recognize these additional requirements, although not all such standards will apply to every institution or to all REBs within an institution.

The organizational task imposed by this complexity is daunting, but the task is rendered less formidable by a recent report commissioned by Health Canada[10]. Indeed, this report might form a model for the organization of the standards.

Against that background, the Task Force has identified only two options for general models for the development and maintenance of the standards.

[10] Marie Hirtle, Martin Letendre, Sébastien Lormeau, *A Comparative Analysis of Process Requirements for Canadian Research Participation Protection Programs: Final Report from Biotika*, May, 2004. Correspondence to: hirtlem@sympatico.ca

Standards Option 1 - Engage a Professional Standards Organization

In this model, a professional standards setting organization, such as the Canadian Standards Association or the Canadian General Standards Board, would be contracted to establish the standards. As part of their service, such organizations organize and manage the process to develop the standards, but the content of the standards is developed by a committee of technical experts drawn from stakeholders. The standards are developed through a consensus approach. Thus, the process would have direct access to experts, and the product would be recognized as part of the national standards system. Such professional standards setting bodies, while traditionally identified with standards for manufactured goods, have gained recent experience with establishing standards for processes, including safety standards for cells, tissues and organs for transplantation. Cost and time are considerations with this model: it is not uncommon for standards development to require several years. A further consideration is whether such a process would be accepted by the academic community. There is a tradition in the health community of organizations developing their own standards.

Standards Option 2 - Engage an Expert Committee

In this model, the standards would be established, reviewed and maintained by a Standards Committee, composed of experienced and knowledgeable persons in research ethics. The Committee would engage an expert in standard setting to provide advice and guidance and ensure that appropriate standards practice and language were employed. The standards that emerged would still be presented to the stakeholders for consideration and comments, but there might be greater confidence in their utility if they had been developed under the guidance of experienced and knowledgeable individuals. The membership of the committee would be crucial. Membership should be based on experienced individuals rather than on constituencies.

The Relationship of the Standards Setting Body to the Accrediting Entity

The matter of the connection of the standards setting organization to the entity undertaking the operation of the accrediting process needs to be considered. Obviously, the entity setting standards needs to receive feedbacks from the accreditation process, as well as from stakeholders, but the nature of that connection can vary. In some accreditation processes that we have examined, the maintenance and adjustment of the standards is seen to be a function for the staff of the accrediting body. In others, however, an entity connected to, but separate from the accreditation operation undertakes the task, receiving input not only from the accreditors, but from the accredited and other stakeholders. This is said to avoid the development of attachment to the status quo that might otherwise occur in the accrediting organization. Advice on the question would be an early responsibility of the accrediting entity.

VI. HOW SHOULD THE SYSTEM BE FINANCED?

This section of the paper is not intended to identify the dollar value of the costs of an accreditation system. That will be done if and when the accrediting entity emerges from the consultative process and prepares a business plan. These costs are likely to be considerable, but the financial costs should be balanced against the potential costs and risks of continuing to operate in Canada without the oversight that a properly designed and operating system of accreditation will bring.

This section identifies some options for financing the accrediting entity. There will be costs other than the basic operating costs of the accrediting entity, principally the costs borne by an organization in preparing for an accreditation site visit: these costs are not considered here.

There will be two phases in the funding required for the establishment and operation of an accreditation program. There will be a period of organization, or start up, consisting of at least the following:

- The identification and appointment of a Board of Directors or Advisory Board representing principal stakeholder organizations, the research participants and the public
- The recruitment of appropriate staff
- The identification of appropriate office space
- Devising a business plan for both phases of the operation
- The completion of the instruments of accreditation, in consultation with the stakeholder:
    - The standards
    - The questionnaire that directs the self-study
    - The terms of accreditation and follow-up
- Training for site visitors
- Development of a website
- Testing the process at selected organizations (there may be some experimental variations)
- Marketing the process to organizations

The second phase is, of course, the operation of the accreditation program. This will involve:

- The development of an appropriate process to ensure that standards are kept up to date
- Continued training of site visitors to ensure and meet demand
- Delivery of a program of preparation and education to participating sites
- Recruitment of staff necessary to meet demand
- Reporting regularly to stakeholders about policies
- Development of annual reports from accredited sites between cycles of accreditation

The potential sources of funding may include:

- The Canadian regulators of research (the federal government, principally Health Canada, the provincial and territorial governments, some organizations)
- The funders of research (granting agencies, charitable foundations, the private sector, government departments, both federal and provincial-territorial)
- Other relevant government departments that do not fund research directly, such as Industry Canada (this department will have an interest because of the economic significance of research involving humans)
- The organizations to be accredited

Of course, the sources of funding might be different for the two phases, start up and operation.

Against this background, the Task Force has identified the following broad options:

Funding Option 1 - Fee for Service

In this option, all of the costs are covered by a charge levied against those entities seeking accreditation. These fees are likely to be significant, and as a consequence, this may not be a realistic option. It is, however, the way in which costs are being covered for the U.S. organization, the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Although the AAHRPP start-up costs were also incorporated into the fee for service, these costs might be met by a different mechanism.

Funding Option 2 - Funding from Government

In this model, all of the costs would be met by government. This model is based on the concept that the accreditation process is a general public good that justifies the costs being covered in this way.

Funding Option 3 - A Consortium of Stakeholders

In this model, the costs would be covered by a consortium of stakeholders, each agreeing to pay some proportion of the agreed costs. Its chief merit would be the signal of commitment to the protection of research participants or subjects by members of the consortium.

Funding Option 4 - A Blend of the Options

It is possible, of course that some combination of these options might operate. Thus, a single entity might agree to finance the start up phase, and a consortium might agree to cover the operating costs with some contribution from a fee for service.

Whatever arrangement is selected, it will be important that the accrediting body have appropriate controls in place to ensure financial accountability and transparency while operating at a sufficient distance from the funders to minimize any perceptions of conflict of interest.