

Experts Committee for Human Research Participant Protection in Canada

By Marianne Vanderwel
Member, Expert Committee

Disclaimer

- These slides are presented by Marianne Vanderwel on behalf of the members of the Expert Committee
- Members of the Expert Committee participated as individuals on the Committee and not as representatives of their employers or other stakeholder group.

Background

■ Sponsors Table

- Alberta Ministry of Health and Wellness
- The Association of Canadian Academic Healthcare Organizations
- The Association of Faculties of Medicine of Canada
- The Association of Universities and Colleges of Canada
- Canada's Research-based Pharmaceutical Companies
- The Canadian Federation for the Humanities and Social Sciences
- The Canadian Institutes of Health Research
- Fond de la recherche en santé du Québec
- Health Canada
- Health Charities Coalition of Canada
- Research Canada
- The Michael Smith Foundation for Health Research
- The Natural Sciences and Engineering Research Council
- The Social Sciences and Humanities Research Council
- The Royal College of Physicians and Surgeons of Canada

■ Experts Committee was created in summer 2006

Committee Mandate

- “To provide expert advice on the development of a system for human research participant protection in Canada, considering accreditation and alternative models, and taking into account different levels and types of risk in research.”
- To build on previous work through the last decade

Members of Experts Committee

- Mr. Arthur Kroeger, Past-Chancellor of Carleton University, Chair
- Professor John R.G. Challis, at the time of appointment, Vice President (Research) and Associate Provost, University of Toronto (Physiology)
- Dr. Karen Cohen, Associate Executive Director, Canadian Psychological Association, Clinical Assistant Professor, University of Ottawa (Psychology & Accreditation)
- Mr. Jack Corman, President/Secretary, Institutional Review Board (IRB) Services Inc. (Clinical Trial Regulations & Private REB Administration)
- Me. Pierre Deschamps, Avocat, Faculte de droit, L'Universite McGill (Law & Theology)
- Dr. Jocelyn Downie, Canada Research Chair in Health Law and Policy, Professor of Law and Medicine, Dalhousie University (Law & Philosophy)
- Dr. Serge Gauthier, Professor, Faculty of Medicine and Chair, Faculty of Medicine Ethics Institutional Review Board, McGill University (Neurology & Ethics)
- Ms. Patricia Lindley, Director, Office of Research Ethics Administration, Dalhousie University (REB Administration)
- Dr. Deborah C. Poff, Professor, Department of Philosophy and Political Science, University of Northern British Columbia (Philosophy)
- Dr. Dorothy Pringle, Chair, Committee on Human Subjects Research and Professor Emeritus of Nursing, University of Toronto (Nursing)
- Dr. Vincent Sacco, Professor, Department of Sociology, Queen's University (Sociology & Criminology)
- Dr. Hal Weinberg, Director, Office of Research Ethics, Simon Fraser University (Physiological Psychology)
- Mrs. Marianne Vanderwel, at the time of appointment Director, R&D Oversight - GCP and Pharmacovigilance, Pfizer Inc. (Pharmaceutical Quality Management and Accreditation)
- Dr. Jonathan C. Yau, Clinical Associate Professor, Faculty of Medicine, University of Calgary and Chief of Medicine, Rockyview General Hospital (Internal Medicine & Hematology)
- Dr. Peter Monette of Health Canada provided Secretariat support.

Committee Work Plan

- Monthly Meetings (1.5 days from Sept 2006 to April 2007)
- Invited presentations
 - NCEHR
 - PRE
 - Canadian Council on Animal Care
 - Association for the Accreditation of Human Research Protection Programs – AAHRPP
 - Office of Human Research Protections – OHRP
 - Dr. Sue Dodds, Wollongong University (Australia)
 - SSHRC Public Assurance System
 - Canadian Council for Health Services Accreditation
- Discussion and analysis of presented materials
- Review of relevant literature / documentation
- Drafting of an Interim Final Report, *Moving Ahead*
- Public consultations on the Interim Final Report (from Aug 2007 to Nov 2007)
- Discussion and analysis of submissions (Winter 2008)
- Final Report to be released May 2008

The ‘Non-System’ as it Stands Now

- “Canada would benefit from an enhanced system to protect the participants of research studies.
- The conduct of such research is governed currently by what is effectively a complex patchwork of regulations and guidelines, developed over time by a variety of agencies and organizations, operating under various jurisdictions and mandates and, by and large, independent of one another.
- Over the course of the past decade or so, governance measures have been put in place by a number of players, each acting in the best interests of research participants, but resulting in a ‘non-system’”

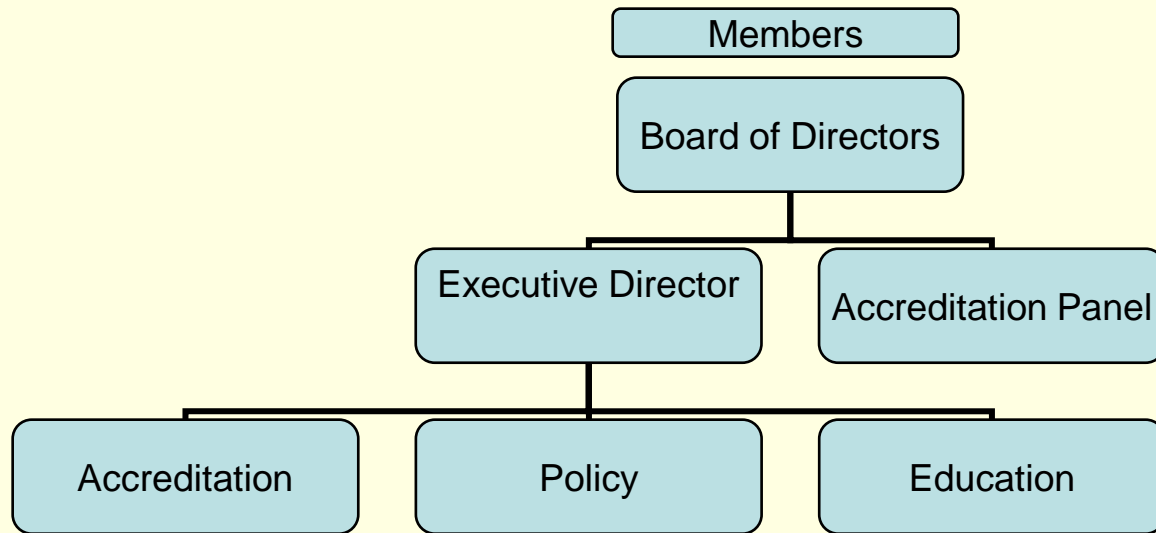
Options for reform

- Staying with the Current Situation
- Public Assurance System
- Accreditation models
 - NCEHR
 - AAHRPP
- Canadian Council on Animal Care model
- Regional and National REBs
- Federal law

The Canadian Council for the Protection of Human Research Participants (CCPHRP)

- Non-governmental Organization
 - Members, Board, Staff, public representation plus community experts (e.g., site visitors)
- One Participant Protection System which includes the following *inter-related* functions:
 - ACCREDITATION: develop standards and establish an accreditation process
 - POLICY : incorporate existing policy and build on work of NCEHR and PRE
 - EDUCATION: facilitate / coordinate educational opportunities

Organizational Chart of CCPHRP



Attributes of the System

- be comprehensive and broadly applicable to all types of human research
- be respectful of the division of powers among federal, provincial, and territorial governments
- be flexible and permit safeguards for participants to be tailored to the character of the proposed research
- be peer-participatory in all functions
- be inclusive of all stakeholders
- be publicly accountable
- be administratively and financially efficient

Some Potential Benefits

- For researchers:
 - Fewer duplicate reviews for multi-site research
 - Enhanced efficiency in ethics review resulting in timely decisions
 - Improved access to tools for education in research ethics
 - Greater transparency in the process for reaching decisions and greater consistency across REBs.
- For sponsors of research:
 - Greater assurance that funded research meets high ethical standards for the protection of research participants
 - Improved consistency of ethics review across sites
 - Reduction in delays attributed to multiple review requirements.

Some Potential Benefits

- For organizations:
 - A stronger culture of responsible conduct of research within the organization at all levels
 - Reduction of risks to research participants
 - Increased effectiveness of processes that are proportionate to the volume / nature of research conducted by the organization
 - A basis for mutual recognition of ethics reviews at other organizations involved in multi-site research.
- For the public:
 - Greater assurance that adequate safeguards are in place to protect the well-being of the public when they choose to participate in research
 - Improved trust with researchers, research organizations, funders, and the research results
 - Increased opportunities to participate in the process of research participant protection.

What we heard from the consultations ...

- Research participants seem reasonably well protected in some sectors, but overall there is no way to really know
- Problems with current system vary across disciplines
- There is a need for greater inclusiveness of public and research participants as well as much broader representation of research perspectives
- Some clear cut opinions on issues (for / against new Council) but an important proportion of comments were nuanced, finding some advantages and some disadvantages with the proposed system
- Can one size fit all?
- Fixing the problems versus widespread reform

Implementation of recommendations

- Requires a phased-in approach
- Bridge financing from federal government
- To establish broad reach, must have full support by Sponsors' Table members and other affected organizations
- Fully functional Council could cost approximately \$10 million/year with possibility of some cost recovery

Recommendations

1. That the Sponsors' Table, together with a broader representation of organizations and members of the public, establish a process for the implementation of the Committee's proposals for the establishment of a comprehensive system of research participant protection in Canada, together with the creation of a Canadian Council for the Protection of Human Research Participants.
2. That the Council be given responsibility for the inter-related functions of accreditation, policy, and education.
3. That the federal government provide the necessary bridge financing for the period in which the Council is being established, and that members of the Sponsors' Table, together with other interested stakeholders, establish permanent funding arrangements for the longer term.
4. That the members of the Sponsors' Table commit to require that all research that falls under their respective jurisdiction be approved by an REB in an accredited PEERH once the accreditation system is operating.
5. That particular efforts are made to ensure that ethical oversight of research projects is in each case kept proportional to the degree of risk in the project.
6. That all organizations that undertake research ensure that their REBs and PEERHs are given adequate support, in the form of human and financial resources, training in ethics, and recognition of and compensation for service on REBs.

What's next?

- Release Final Report and Recommendations, *Moving Ahead* (May 2008)
- Sponsors' Table will determine the most appropriate way forward
- www.hrppc-pphrc.ca