



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

ACCREDITATION

PROGRESS REPORT



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Previous Events

- **Fall 1999: NCEHR includes development of accreditation in its vision statement**
 - Endorsed by MRC, RCPSC, Tri Council Advisory Group, Funders of NCEHR, and later by Committee on Ethics, CIHR
- **November 1999: NCEHR creates Task Force to Study Models of Accreditation**
- **January 2000: Canada Gazette calls attention to need for accreditation**
- **Fall 2000, The NCEHR coordinating committee recognises need for accreditation, suggests HC and NCEHR work together**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Previous Events

- **March 2002 Task Force to Study Models of Accreditation issues final report**
- **November 2003 NCEHR establishes a new task force for the development of an accreditation system for human research protection programs**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Terms of reference

- **Undertake the consultations necessary to establish a list of stakeholders that represent the broad range of research methodologies and organizational modalities involved in research on humans, as well as a broad range of research participants and communities**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Terms of reference

Convene one or more meetings of stakeholders to obtain advice that will allow it to:

- **Establish a mechanism for the development of standards of accreditation informed by TCPS and other policies and regulations**
- **Propose detailed operational models for the accreditation process**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Terms of reference

- **Propose an appropriate model for the operation of the accrediting entity**
- **Identify the essential prerequisites for the success of an accreditation system**
- **Report on the feasibility of operating pilot studies on one or more operational models**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Membership

- **Two co-chairs:**
 - Michael Owen, Brock University
 - Ken Davey, York University
- **Edith Deleury, Laval University**
- **Henry Dinsdale, Kingston General Hospital**
- **Deborah Poff, UNBC**
- **Marianne Vanderwel, Pfizer Canada**
- **Barbara McGillivray (*ex officio*)**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Tentative work plan-3 phases

- **Planning Phase**
 - **Develop list of stakeholder organisations (to be contracted to a consultant)**
 - **Develop annotated list of policies and regulations from which standards can be developed (to be contracted to a consultant)**
 - **Draft an options paper to be used in consultation phase**



Tentative work plan-3 phases

- **Consultation Phase: we hope to communicate widely and regularly**
 - One or more rounds of consultations with stakeholders using successive drafts of the Options Paper
 - One at least of the consultations will be in the form of a meeting
- **Reporting Phase**
 - Prepare and distribute draft report



First Meeting, 16-17 April

- **Presentations about accreditation**
 - RCPSC
 - PEQAB
 - Quebec's system
 - Task Force on Models of Accreditation



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

First Meeting, 16-17 April

- **Achieved agreement on broad characteristics:**
 - Based on review by peers and public
 - **Voluntary**
 - Based on standards derived from existing policies and best practices in consultation with stakeholders
 - Educational, with objective of continuous improvement in quality



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

First Meeting, 16-17 April

- **Characteristics:**
 - Input from Provinces and Territories, but national in scope
 - **Transparent**
 - **Accountable to stakeholders, especially the participants, and the public**
 - **Flexible in accommodating various modes of research**
 - **Recognise global and international influences**



First Meeting, 16-17 April

- **The accreditation process would involve not only the REBs, but also the entire system for protection of participants in an institution**
- **It is important to keep the community informed on a continuing basis**



Second Meeting 4 June

- **Presentation from AAHRP**
- **Preliminary discussions on:**
 - **The organisation of the accrediting entity**
 - **Standards development**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

The Accrediting Entity

- **Non-governmental**
- **Community expectations re NCEHR involvement**
- **Identified five possible major models:**
 - **A new free-standing entity**
 - **A transformed NCEHR**
 - **A subsidiary of NCEHR**
 - **Contracting to an existing organisation**
 - **An agency of the Federal Government**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

New entity

- **Model is CCAC**
- **Separately incorporated body with a board made up of representatives from key stakeholder organisations**
- **Might include other stakeholder organisations in a wider membership**
- **Principal issue involves establishing credibility**



Transformed NCEHR

- **NCEHR transformed from current membership of individuals to one of representatives from key stakeholder organisations**
- **Retain existing functions**
- **Accreditation becomes major and pre-occupying activity**
- **Is there a continuing need for NCEHR as currently configured?**



Entity attached to NCEHR

- **Principle is that NCEHR retains its current configuration, but issues certificate of accreditation on advice from the accrediting entity which retains a connection to NCEHR**
- **Wide spectrum of organisational relationships possible**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Entity attached to NCEHR

- **Two ends of spectrum:**
 - Separately incorporated entity, related to NCEHR by mutual reps on Boards, perhaps with joint membership on specific committees
 - NCEHR establishes an Office of Accreditation, advised by a advisory committee made up of key stakeholders



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Contracting to existing organisation

- **Might invite AAHRPP to develop standards, conduct accreditation**
- **Could involve a number of models**
 - AAHRPP operates from US, using standards modified for Canada, some site visitors from Canada
 - AAHRPP develops a Canadian operation
 - AAHRPP operates in transition to an independent model



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

A Federal Agency

- Might resemble free standing organisation as in Option I
- Would carry authority of federal legislation
- Does not fit normal model of accrediting bodies



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Who Sets the Standards

- **General agreement that stakeholder consultation is essential**
- **However, the task involves expert knowledge**
 - Expertise in the language of standards
 - Expertise in practical ethics of human research



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Who sets the standards

- **Two broad models:**
 - **Engage a professional standards setting organisation to undertake the entire process**
 - **Establish an initial working committee, assisted by a consultant familiar with standards**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Long Hiatus

Occasioned primarily by lack of funding , but some work possible in background:

- Report commissioned by HC from BIOTIKA on the various policies, regulations and guidelines, Canadian, Provincial-Territorial, US and international
- Preliminary drafts of some parts of the Options Paper
- Formation of small expert subcommittee, chaired by Michael Owen, to produce examples of standards from a small part of TCPS
- NCEHR office is working on stakeholder list



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Initial Funding for Task Force

- **From HC/CIHR, beginning in December 2004**
- **Produce completed draft of Options paper**
- **Produce a version of standards based on some section of TCPS**
- **Use these standards in a trial on a site visit**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

But (There Is Always A But)

**MUST BE COMPLETED BY 31
MARCH 2005 !!!**

**This by volunteers
all of whom have day jobs**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Current Status

- **Expert sub committee is meeting immediately after this meeting**
- **Drafts of part of the options paper are with the Task Force, who will meet later this month**
- **List of potential stakeholders in process**
- **The report from Biotika will be very useful**



National
Council on
Ethics in
Human
Research

Conseil
national
d'éthique
en recherche
chez l'humain

Draft Outline Of Options Paper

- I. What Is Accreditation?**
- II. Why Does Canada Need A System Of Accreditation?**
- III. What Should Be The Accrediting Entity?**
- IV. How Should The Accrediting Standards Be Set And Maintained?**
- V. How Should The System Be Financed?**