



The National Council on Ethics in Human Research

February 22, 2005

What is NCEHR?

- Established by Health Canada, the Medical Research Council and The Royal College of Physicians and Surgeons of Canada in 1989
 - Became NCEHR with broader mandate in 1997
 - Incorporated in 2003
 - An independent, non-governmental organization composed of volunteers and a small staff with mandate extending to all research involving humans
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What is NCEHR?

- Governance
 - 1989 – Coordinating Committee (HC, MRC, RCPSC)
 - 1995 – enlarged to include new funders (HC, MRC, SSHRC, NSERC, RCPSC)
 - 2001 – last meeting of the Coordinating Committee; no replacement group

What is NCEHR?

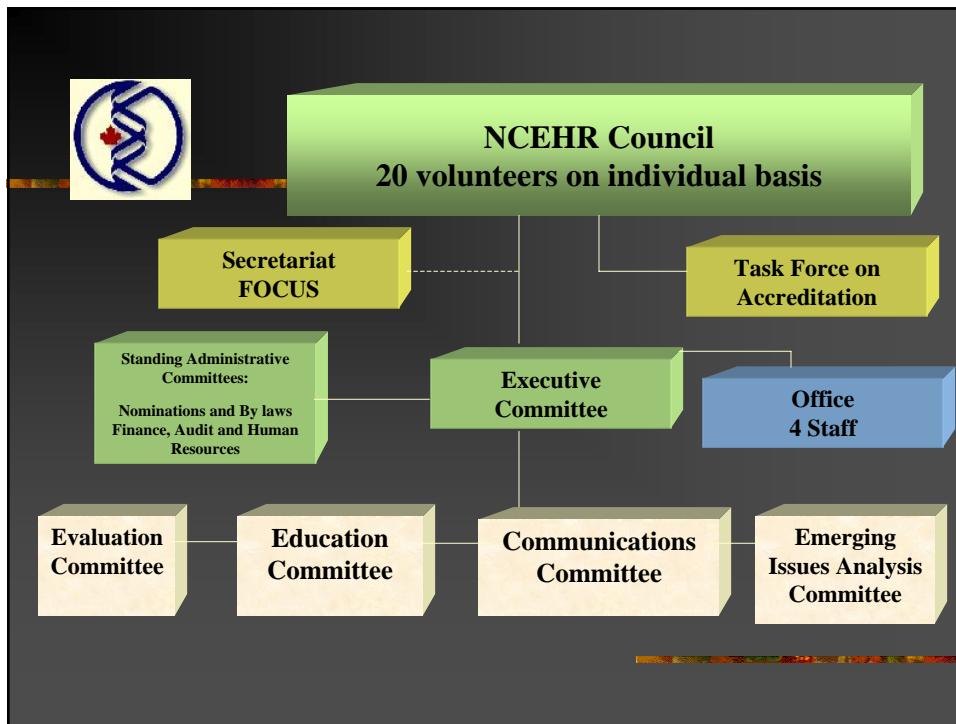
- Sources of revenue:
 - CIHR, Health Canada, and The Royal College of Physicians and Surgeons of Canada
 - Contracts from CIHR, SSHRC, NSERC through IAPRE
 - Contracts from UNESCO, OHRP, WHO
 - Self-generated through educational activities
- Great financial pressure with funding uncertain and increased costs due to move
- Need to secure sustainable funding, with multi-year commitment

What is NCEHR?

- Council membership from a broad spectrum of academic disciplines, philosophy, law, research participants, aboriginal people, public
- Current President Dr. Barbara McGillivray (Dept. Medical Genetics, UBC)
- President-elect, Dr. Glenn Griener (Dept of Philosophy, U of Alberta)
- 12 organizations as observers at meetings (funders, CCAC, academic organizations)
- Official liaison with the US Government Office for Human Research Protections (DHHS)

Mission Statement

- **To advance the protection and well being of human participants in research and**
- **To foster high ethical standards for the conduct of research involving humans**



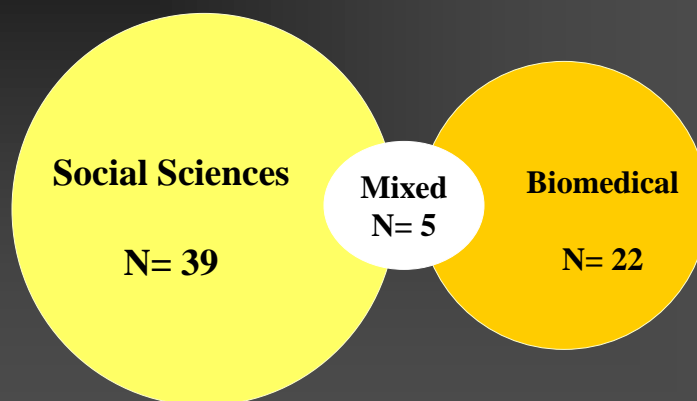
Areas of Activities

- Quality Improvement Site Visits
- Emerging Issues Analysis
- Educational Programs
- Communications
- National and International Liaisons
- Strategic Planning 2005

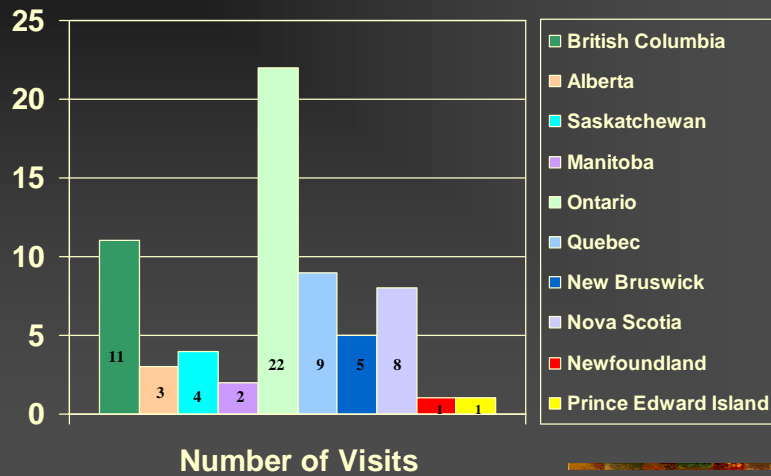
Quality Improvement Site Visits

- By-invitation site visits with confidential reporting - help institutions establish research participants protection programs respectful of regulations and policies (82 over time)
- Analysis and dissemination of findings
- Identification of Best Practices
- Inventory of Canadian Research Ethics Boards (Sponsored by CIHR-Health Canada-OHRP)
- REBs visited: Social sciences, biomedical, Aboriginal, private, governmental, community-based
- Joint visits planned with OHRP in major academic institutions

Site Visits Post TCPS N= 66



Provincial Distribution N= 66



Emerging Issues Analysis

- Response and comments on national and international documents and issues
- Studying of outstanding research ethics issues
- Identification of new issues

Educational Programs

- Annual National Conference – registration 250
- Regional and individualized institutional training
- REB 101: Basic training for knowledge and skills development for social sciences and biomedical ethics review (biomed = 10; social science = 5)
- Ethics training for Aboriginal communities' REBs; documenting and publicizing the process
- International Annual Conference : FOCUS
 - Quality Improvement and Performance Evaluation in Systems of Human Research Protection (Montreal 2003)
 - Conflicts of Interest (Washington 2004)
 - Ethical Issues in Social Science Research (Montreal, 2005)

Communications

- Listserv for sharing of solutions and best practices and to disseminate information to the Canadian research ethics community (500 registered)
- Web site (www.ncehr-cnerh.org)
- Communiqué (Newsletter) on yearly basis; last theme issue on social science research
- Publications of proceedings (e.g. Genetic Research in Aboriginal Populations)

National and International Liaisons

- Liaison with relevant national and international organizations, including OHRP
- Secretariat for the Forum for Institutional Review Boards (IRBs)/Research Ethics Boards (REBs) in Canada & the United States (FOCUS) –OHRP and WHO as partners
- Member of the Canadian Commission for UNESCO
- Member Global Summit of National Bioethics Advisory Bodies (WHO)
- Observer, European Conference of National Ethics Committees (COMETH)

Shared Goal, Shared Tasks

“We urge the various leading stakeholders of health research involving human subjects to work together to develop a governance system for health research involving human subjects that can meet the following objectives: the promotion of socially beneficial research; the protection of research participants; and the maintenance of trust between the research community and society as a whole.”

Standing Senate Committee on Social Affairs, Science and Technology,
The Health of Canadians – The Federal Role Volume Five: (2002)



Task Force to Study Models of Accreditation for Human Research Protection Programs in Canada

Chaired by Dr. Henry Dinsdale
Kingston General Hospital,
Queen's University
1999-2002

Report from Task Force

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.



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

Co-Chairs: by Ken Davey, York University
Michael Owen, Brock University
2003-

Composition

- Co-Chairs: Ken Davey, York University
and Michael Owen, Brock University
 - Edith Deleury, Laval University
 - Henry Dinsdale, Kingston General Hospital,
Queen's University
 - Deborah Poff, UNBC
 - Marianne Vanderwel, Pfizer Canada
 - Barbara McGillivray (*ex officio*)
- Observers: Health Canada, Health Dept
Quebec, IAPRE

Task Force for the Development of an Accreditation System

- Builds on the work of previous Task Force
- Sense of urgency (US lead) to move forward to preserve public trust. Increasing support:
 - Standing Senate Committee on Social Affairs, Science and Technology
 - Royal College of Physicians and Surgeons of Canada
 - House of Commons Standing Committee on Health
 - Canadian Association of Research Ethics Boards (CAREB)
 - Canadian Biotechnology Advisory Committee
 - CIHR Standing Committee on Ethics

TF Current Activities

- Current funding: Health Canada and CIHR
- Development of an Options Paper describing possible alternatives for the organization and the operation of the system of accreditation.
- Development and testing of a subset of standards based on TCPS and GCPs
 - CAREB, IAPRE, Quebec, Private REB, Health Canada and Industry are represented on ctte
- Compilation of a list of stakeholders for consultation purposes

What Are the Benefits of Accreditation?

- Ensures the Canadian Public and research participants that adequate safeguards are in place to protect their well being
- Increases the quality, performance, and efficiency of human research participants protection programs and ensures a high degree of compliance with policies and regulations
- Ensures government and all research sponsors that the research they fund meets the highest ethical standards and that all appropriate policies, guidelines and regulations are in place to maintain public trust.
- Improves competitiveness in an increasingly demanding international environment

NCEHR Moving Forward

Building on our strengths:

- Continue to develop and offer educational opportunities for the whole spectrum of research disciplines
 - **Develop basic level and focused thematic education**
 - E.g. Indigenous populations
 - **Web-based format education**
 - **Initial education for REB lay members**
 - **Website section for research participants**
- Increase the number of quality improvement visits
 - **Improve identification and dissemination of best practices**
 - **Improve reporting back mechanisms**

NCEHR Moving Forward

- Emerging Issues
 - How to identify, analyze and identify best way to deal with it
 - Some examples:
 - Serious adverse events
 - Research with Indigenous populations
 - Biobanks
 - Participatory research
 - Product: conference, report, shared action

NCEHR Moving Forward

- Task Force on Accreditation
 - Initiate consultations with stakeholders on options for accreditation and the development of standards
 - Develop a business plan
 - Collaborate on general discussions about governance (e.g. CIHR initiatives)
- Strategic Planning
 - Respond to community request for longer term planning
- Increase interaction with stakeholders
- Seek increased and stable resources for improvement of service delivery