

Interagency Advisory Panel and Secretariat on Research Ethics

The Evolving Interface Between Research Ethics & Human Rights



**A Brave New World: Where Biotechnology & Human Rights Intersect:
Ottawa, 14 April 2005**

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Government of
Canada

Gouvernement du
Canada

Canada

Overview

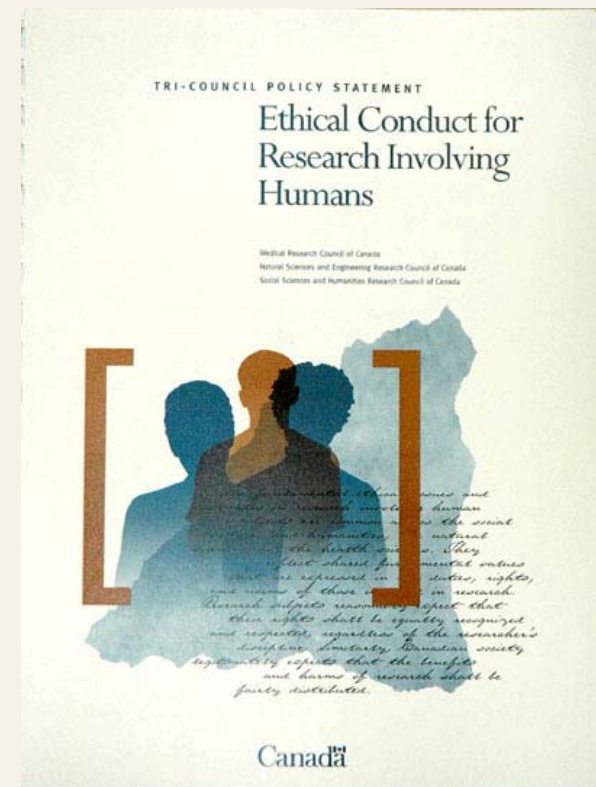


- Ethics & Human Rights: Shared Interface
- TCPS: Drawing on an Evolving Heritage
- Classic & Modern Research Ethics Themes
- A Tri-Agency Response
 - PRE's Mandate, Structure, & Process Values
 - Sample TCPS Projects
 - A Culture of Research Ethics

TCPS : Drawing on an International Model of Research Ethics



- **Standards:** what substantive principles?
- **Structure:** independent, pluralistic & accountable
- **Process:** democratic, fair, transparent



What Substantive Standards? TCPS, 1998



- Unified National Interdisciplinary Norms
- Guiding Ethical Principles
- 5 General Sections
E.g.: Consent, Privacy, Ethics Review
- 5 Specific Sections
E.g.: Inclusion, Clinical Trials, Genetics, Tissue

Human Rights & Ethics: Shared Values, Principles & Standards



- Human Dignity
- Autonomy/Informed Consent
- Equality
- Privacy/Confidentiality
- Freedom of Inquiry
- Justice
 - Fair Benefits, Burdens & Access
- Respect of Person/Community
- Public Participation



TCPS Guiding Ethical Principles



Respect for

Human Dignity, Informed Consent, Vulnerable Persons, Privacy, Justice (Inclusiveness, Balancing Harms & Benefits)

E.g.,: Respect for Vulnerable Persons “Respect for human dignity entails high ethical obligations towards vulnerable persons -- to those whose diminished competence and/or decision-making capacity make them vulnerable. *Children*, institutionalized persons... Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.”

TCPS Ethical Framework



Ethics and Law

“The law affects and regulates the standards and conduct of research involving human subjects in a variety of ways, such as privacy, confidentiality, ...competence, [h]uman rights This legal context for research involving human subjects is constantly evolving*Further, though ethical principles cannot preempt the application of the law, they may well affect its future development or deal with situations beyond the scope of the law.*” (emphasis added)

The Context of Ethics and Human Rights



- Nuremberg Era: PRE & Post
- Inclusion in Research: Children
- Cloning and Novel Biotechnology
- Respecting Communities: Indigenous Peoples

Nuremberg Era & Lessons: Protection



What are the standards
& limits for human
“experimentation”...
“scientific” inquiry..
“research”?



Protecting Dignity: Consent +



- UK: Slater v. Baker UK, 1767
- Germany: *Reich Minister of the Interior Circular on Human Experimentation, 1931*
 - Experimentation shall be prohibited in all cases where consent has not been given...
 - Experimentation involving children or young persons under 18 years of age shall be prohibited if it in any way endangers the child or young person;

Protecting Dignity: Consent +



Germany: U.S. v. Karl Brandt et al. (1947)

- WWII Military Experiments: malaria, aviation, euthanasia, sterilization, using concentration camp prisoners
- Nuremberg Code: “voluntary consent of the human subject is *absolutely essential*.... Duty... for ascertaining consent lies on the individual ” undertaking the experiment
- Rights-Duties: Ethico-Legal Relations
- Codified: *International Covenant on Civil & Political Rights*, 1966:

Protecting Dignity: Consent +



Moore v. University of California, 1990

- Consent: Tissue, Cell Lines & Patents
- Bodily Property & Personhood?
- Duties of Consent & Loyalty
- Rights to Bodily Integrity, Autonomy, Honesty

Paediatric Research: From Over Protection to Inclusion



- Should children have the right to access the full benefits of research?
 - Consent
 - Equality
 - Justice



Justice: Inclusion & Access



- Tri-Council Policy Statement, 1998:
 - Researchers shall not exclude on the basis of such attributes as culture, race, sexual orientation, age, “unless there is a valid reason for doing so.”
 - “Those who are not competent to consent for themselves shall not be automatically excluded from research which is potentially beneficial to them as individuals, or to the group that they represent.”

Justice

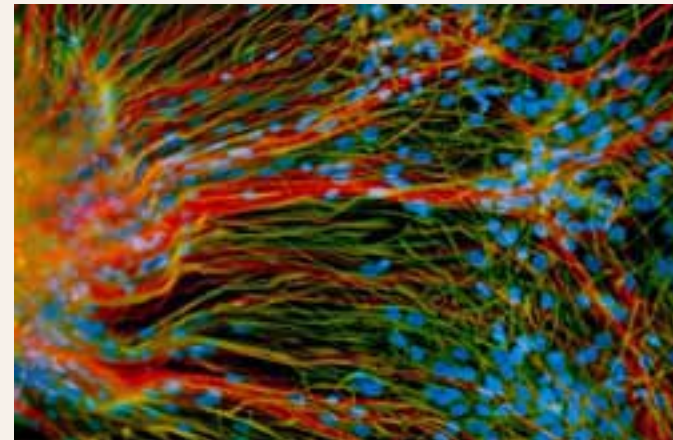


- United States:
 - *Pediatric Research Equity Act (2003)*
 - *Best Pharmaceuticals for Children Act (2001)*
 - “There is a moral imperative to formally study drugs in children so that they can enjoy equal access to existing as well as new therapeutic agents.”
American Academy of Pediatrics, 1995
- Canada:
 - Health Canada Office of Paediatric Initiatives

Cloning and Novel Biotechnology



Would the cloning of humans accord with the principle of respecting human dignity?



Resolving Value Conflicts: Weighing Rights, Duties, Freedoms & Interests



- German National Ethics Committee Opinion: Reproductive purposes & cloning for the purposes of biomedical research (2004)
 - Autonomy: reproductive freedom
 - Freedom of research & thought
 - Personal rights: safeguarding of future self-determination
 - Human dignity

Protecting & Promoting Human Dignity: Cloning



- *Assisted Human Reproduction Act (Canada, 2004)*
- *UNESCO Universal Declaration on the Human Genome and Human Rights (1997)*
- *Europe: Convention on Human Rights & BioMedicine (1997) & Additional Protocol on the Prohibition on Human Cloning (1998)*

Indigenous Peoples: Sovereignty, Cultural & Intellectual Property



What is the relationship between human rights, community rights & research ethics?



Freedom & Self-Determination



- “All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.”

Article 1 of International Covenant on Economic, Social and Cultural Rights

- Countering Bio-Piracy via Innovative Laws, Guidelines & Partnerships

Sovereignty & Respect of Culture



Philippines, 1997:

Indigenous Peoples' Rights Act

- Right to collective intellectual property and royalties from any derivatives of research conducted in their territories
- Right to preserve and develop their cultures, traditions and institutions
- Right of participation in the direction of education, health etc...

Respect, Justice, Consent



- ***Peru, 2002: Law introducing a protection regime for the collective knowledge of indigenous peoples derived from biological resources***
 - Respect, protection, preservation, development of collective knowledge
 - Fair and equitable distribution of the benefits derived from the use of that collective knowledge
 - Ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples

Sample TCPS Research Ethics Challenges



- Update: Bio-Banking & Genetic Norms?
- Consent: Continuing, Proxy, Group, Assent
- Inducements: Gifts, Monies & Free Consent
- Protection of Privacy/Confidentiality Anonymity
- Nonconsensual Secondary Use of Data
- Discourse/Definitions: “Vulnerable” Populations

Structural Response – PRE's Mandate (2001-09)



Includes Duties to:

- Promote high ethical standards
- Help Interpret & Implement the TCPS
- Address Issues, Practices & Context
- Advise Agencies on *Evolution* of the TCPS
 - New Research Developments?
 - Gaps & Updates?
 - New Ethics Issues, Models, Standards?

Structure & Process: PRE's Interdisciplinary Voice



- *Howard Brunt*, Nursing (BC)
- *Marlene Brant Castellano*, Aboriginal Studies (ON)
- *Bruce P. Clayman*, Research Administration (BC), Acting Chair
- *Pierre Deschamps*, Law and Ethics (QC)
- *Anne Dooley*, Education and Public (SK)
- *Norman Frohlich*, Political Science (MB)
- *Paul Johnston*, Engineering (ON)
- *Derek J. Jones*, Law and Ethics (*ex officio*)
- *Samuel Ludwin*, Medicine (ON)
- *Ian Mitchell*, Medicine and Ethics (AB)
- *Florence Piron*, Anthropology (QC)
- *Susan Sykes*, Psychology (ON)
- *Will van den Hoonaard*, Sociology (NB)

Evolving the TCPS: Process Values



- **PRE's 1st Principles**
 - Deliberative evolution of the TCPS
 - Multidisciplinary and inclusive
 - Diversity of approaches
 - Consultation, open, transparent
 - Collaborative partnerships
 - Regional, national and international
- **Formal Public Process Mechanisms of Community Engagement**

Sample PRE Activities



- Research Involving Aboriginal Peoples
- TCPS Procedural & Definitional Reforms
- Consent: Sharing Clinical Trials Data
- CIHR Stem Cell Guidelines & the TCPS
- Social Sciences & Humanities Research
- Interpreting the TCPS: PRE Guidance
- TCPS Online Tutorial

Interagency Advisory Panel on Research Ethics (PRE)
...Cultivating a Culture of Research Ethics...

TCPS: Defining our Research Ethics Future



**Evolving Ethical Standards:
Towards a Sustainable
Culture of Research Ethics**



"Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)"

www.pre.ethics.gc.ca