

PANEL ON RESEARCH ETHICS

Navigating the ethics of human research

HIGHLIGHTS of CHANGES

Revised draft 2nd edition of the TCPS
December 2008 – December 2009

New Introduction

- Sets out background to the TCPS and scope of its application

Chapter 1 - Ethics Framework

- Core principles re-organized, re-defined, modified:
 - Respect for persons (includes respect for autonomy as well as respect for those who lack full autonomy)
 - Concern for welfare (refers to the importance of privacy and control of personal information, as well as the treatment of human biological and reproductive materials)
 - Justice (concerns both fairness and equity)
- Explicit reference to academic freedom added

Chapter 2 - Scope and Approach

- Greater guidance with respect to research exempt from ethics review
- Clarified distinction between research and quality assurance activities
- Clarified concept of risk
- New Article 2.4 - REB review not required for secondary use of anonymous information
- Elements in former Appendix are now integrated throughout the Policy

Chapter 3 - Consent

- Distinction made between withdrawal from participation and withdrawal of data
- New Article 3.11 - addition of article on research directives
- Term “consent” used to signify “free, informed and ongoing consent”
- Explicit reference included to researchers’ ongoing responsibility to be aware of legal and regulatory obligations

Chapter 4 - Fairness and Equity in Research Participation

- Title changed from “Inclusion in Research” to focus on issues of fairness and equity in terms of both inclusion and exclusion
- New Articles 4.3 – 4.4 - explicit recognition of children and the elderly, who have historically been inappropriately excluded from research
- New section on inappropriate inclusion in research

Chapter 5 - Privacy and Confidentiality

- More nuanced guidance about balancing confidentiality against legal or professional requirements or ethical consideration that may call for disclosure of information
- Section on consent and secondary use of identifiable information substantially revised into a single article, setting out clear criteria for waiver of consent, including definition of “impracticable”

Chapter 6 - Governance of Research Ethics Review

- Clarification provided on a number of issues, including distinction between independence of REB with respect to decision making versus accountability of REB to institution for integrity of its processes
- Appeal body permitted to overturn negative REB decisions on substantive as well as procedural grounds

Chapter 7 - Conflict of Interests

- Includes a definition of conflicts of interests
- Provides greater direction on how and when to identify, prevent, disclose, manage or avoid conflicts of interests

Chapter 8 - Multi-Jurisdictional Research

- Includes references to existing review models in Canada and relevant international guidelines
- Benefit sharing, protection of participants in authoritarian countries and risks to researchers addressed in former Section C are now addressed respectively in Chapters 4,3 and 2

Chapter 9 - Research Involving Aboriginal Peoples in Canada

- Significant revision of chapter, in large part to harmonize more closely with CIHR's *Guidelines for Aboriginal Health Research*
- Key definitions added with respect to "community" and "community engagement"
- New articles on research agreements, intellectual property, collaborative research, strengthening community capacity, interpretation and dissemination of research results, prospective or secondary use of human biological materials identifiable as originating from Aboriginal peoples

Chapter 10 - Qualitative Research

- Changes primarily in Section B "Research ethics Review of Qualitative Research"
- More specific guidance offered with respect to observational research and exemption from REB review for particular types of observational research
- Some elements of guidance moved to more general chapters in Policy (e.g. exemption for secondary use of anonymous data now in Chapter 2)

Chapter 11 - Clinical Trials

- Definition of clinical trial broadened beyond trials involving drugs
- Greater clarity provided on reporting of adverse and serious adverse events
- Definition of clinical equipoise included in Section G "Placebo-Controlled Studies"
- Greater direction provided on ethically acceptable use of a placebo comparator; scenarios added as illustrations
- Registration requirement modified - all clinical trials within scope of this Policy must be registered before recruitment of first participant

Chapter 12 - Human Biological Materials and Material Related to Human Reproduction

- Title changed from "Human Tissue"
- Definition of "human biological materials" added - consistent with Health Canada and international definitions
- Definitions of materials related to human reproduction consistent with definitions in *Assisted Human Reproduction Act*

Chapter 13 - Human Genetic Research

- No major changes

