What is the TCPS?

• The Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* (TCPS) is a principle-based policy developed for the three federal research agencies (CIHR, NSERC, SSHRC)

• Primary goal: guidance for the ethical conduct of all such research from design to dissemination
Scope of the TCPS

All research involving humans conducted under the auspices of institutions eligible for funding by one or more of the Agencies.

What is NOT covered?

- Any research not associated with an eligible institution
- This includes, for example:
  - independent community-based research
  - research funded by the private sector that is conducted in physicians’ offices
Who is responsible for the TCPS?

Panel on Research Ethics (PRE): 12 volunteers appointed by the presidents of the Research Agencies

PRE’s mandate: “to promote high ethical standards of conduct in research involving humans through the development, evolution, interpretation, and implementation of the [TCPS].”

Supported by the Secretariat on Research Ethics

Evolution: TCPS to TCPS 2

✓ Draft 2nd edition: December 2008
✓ Revised draft 2nd edition: December 2009
✓ Final draft submitted to Agencies: August 2010
✓ Presidents approve TCPS 2: December 7, 2010
What are the aims of TCPS 2?

- Provide continuity
- Clarify, amplify and update the guidance
- Fill gaps
- Identify roles and responsibilities
- Make the Policy more useful and user-friendly

TCPS Foundation: Respect for Human Dignity

- Present in 1st and 2nd editions of TCPS
- Requires research to be conducted in a manner that is sensitive to the inherent worth of all human beings
- Expressed through three core principles:
  - Respect for Persons
  - Concern for Welfare
  - Justice
Clarification of roles

Responsibilities of researchers include:

- Design and conduct of ethical research in accordance with the core principles of TCPS 2
- Awareness of institutional policies including REB requirements
- Awareness of other relevant guidelines and legislation
- Mindfulness of the perspective of the participant
- Ensuring all stages of research are ethically acceptable

Responsibilities of the REB include:

- Initial and continuing review of the ethical acceptability of all research within the scope of TCPS 2
- Functioning impartially and providing a fair hearing to researchers
- Providing reasoned and appropriately documented opinions and decisions
- Understanding institutional policies, other relevant guidelines and legislation
- Educating members and researchers
Chapter 2: Scope and approach

- Research requires REB review when it involves living human participants or human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, from living and deceased individuals (Art. 2.1)

- Research does NOT require REB review when:
  - it relies exclusively on publicly available information (Art. 2.2)
  - it involves the observation of people in public places (Art. 2.3)
  - it relies exclusively on secondary use of anonymous information or anonymous human biological materials (Art. 2.4)

Chap. 2 (cont’d)

Proportionate approach defined (Arts. 2.9 and 6.12)

- A two-stage process
  1. Level of risk determines review
     • Delegated
     • Full board
  2. Reviewers assess risks, benefits and ethical implications
Chapter 2 (cont’d)

- Non-research activities that employ methods similar to research also do not require REB review; examples include:
  - quality assurance and improvement, program evaluation, performance reviews (Art. 2.5)
- Attempt to clarify relationship between research ethics review and scholarly review (Art. 2.7)
- Clarification of proportionate approach to REB review (Section B and Art. 2.9)

Chapter 3: Consent

Elements of informed consent – Art. 3.2
- Requires inclusion of information on:
  - withdrawal of data (d)
  - possibility of commercialization of findings (e)
  - access to information collected; anticipated uses (i)
  - stopping rules; removal of participants from trial (I)
Chapter 3 (cont’d)

• Incidental findings (Art. 3.4)
• Critical inquiry (Art. 3.6)
• Recognition of different types of lack of capacity, including fluctuating capacity (Section C)
  – Introduction of research directives (Art. 3.11)
• Documentation of consent not limited to consent forms (Art. 3.12)

Chapter 5: Privacy and Confidentiality

• Definition of information along a range of identifiability
• Generally, more explicit obligations re confidentiality and disclosure requirements
• Duty on researchers to safeguard confidential information AND duty on institutions to support researchers in maintaining promises of confidentiality (Art. 5.1)
• New: institutions where research data are held must establish appropriate security safeguards (Art. 5.4)
Chapter 5 (cont’d)

• More detailed guidance re:
  – exceptional conditions for secondary use of identifiable information without consent (Art. 5.5)
  – circumstances under which researchers may contact those whose identifiable information is being used without consent (Art. 5.6)

• REB approval required, in general, for data linkage (Art. 5.7)

Chapter 7: Conflict of Interest

Broader array of conflicts included
• Institutional COI (Art. 7.1) as well as researcher and REB member COI
• Discussion of dual role of researchers as a source of COI
• Financial COI included in general COI chapter as well as in chapter on clinical trials
Chapter 8: Multi-jurisdictional research

• Explicit green light for review models other than single-site review
• Examples of multi-jurisdictional models (Art. 8.1)
• Model adopted should be appropriate to the particular research project (Art. 8.2)
• Guidance re ethics review of research conducted outside the researcher’s institution (Art. 8.3)

Chapter 11: Clinical trials

• Definition of key concepts, including clinical equipoise, duty of care, therapeutic misconception (Section A)
• Broader range of clinical trials defined (Art. 11.1)
• Placebo-controlled trials (Art. 11.2)
• Clinical trial registration (Art. 11.3)
Clinical trials (cont’d)

• Systematic literature review part of assessment of proposed research (Art. 11.4)

• Revised guidance on research-attributable risk (Art. 11.5)

• Section on monitoring safety and reporting new information (Arts. 11.7-11.9) replaces former sections on DSMBs and reporting adverse events

Clinical trials (cont’d)

Aim is to make monitoring and reporting duties effective

• by clarifying roles of researchers:
  – to share information in a form that permits REBs to interpret and respond appropriately (Art. 11.7)
  – to promptly report new information that may affect the welfare or consent of participants (Art. 11.8)

• by clarifying role of REBs:
  – To develop procedures to review safety reports and to take appropriate steps in response (Art. 11.9)
Chapter 11 (cont’d)

• Financial conflicts of interest supplements COI chapter (Arts. 11.10 – 11.11)
• Expanded section on analysis and dissemination of trial outcomes (Art. 11.12)

Chapter 12: Human Biological Materials

• Consent and secondary use of human biological materials (Arts. 12.3-12.4)
• Storage and banking of human biological materials (Art. 12.5)
• Research involving embryos (Art. 12.7)
• Incorporates CIHR stem cell guidelines as amended from time to time (Art. 12.10)
• Plans underway to fully incorporate stem cell guidelines into TCPS 2
Chapter 13: Human Genetic Research

• Introduction of plan for managing information revealed through genetic research (Art.13.2)
• Opportunity for participants to make choices about receiving information about themselves, and to express preferences re sharing of that information (Art.13.3)
• Genetic counselling should be available (Art.13.4)

From evolution to implementation

• Current focus: implementation
• Variety of activities planned to facilitate transition to TCPS 2:
  – Regional workshops
  – New on-line tutorial (June launch)
  – Webinars (starting in fall 2011)
  – Enhanced interpretation service
We welcome your comments

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