



*National Council on Ethics in Human Research  
Task Force for Development of an Accreditation System for  
Human Research Protection Programs  
Sub-Committee on Standards Development*

## *Appendix A*

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# Proposed Draft Standards for the Accreditation of Human Research Protection Programs

April 2005

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# **Report from the Sub-Committee on Standards Development**

## **Introduction**

The Sub-Committee on Standards Development generated a list of nine standards, which it proposes to develop further. These proposed standards will reflect the content of the TCPS and other Canadian and international guidelines governing human subject research and the experience of the NCQA/VA and AAHRPP, Inc.

The Sub-Committee focused on three standards and developed partially a fourth. These preliminary draft standards are:

1. Human Research Protection Program.
2. Research Ethics Board Composition and Operations.
3. Research Ethics Board Review Methods (Process).
4. Research Ethics Board Review (Content).

## **What is a standard?**

A standard is a statement defining performance expectations, structures or processes that must be observable in an organization requesting accreditation. It often involves the transformation of normative statements in descriptive statements. For example, if a policy requires that *REBs “should” be composed of at least 5 members*, the standard would read something like *the REB “is” composed of at least 5 members*.

- Standards are based on regulations, policies, and ‘best practices’.
- Standards are not equivalent to making new policy.
- Standards development involves translating existing policies, regulatory, legal, and ethical requirements in statements of expected performance that serve as tools for institutions and REBs to assess their level of compliance with existing policies, regulations and other requirements.
- Standards allow site visitors (for educational or accreditation visits) to assess an institution’s and/or REBs’ performance.
- Made-in-Canada standards are to be based on the TCPS, federal, provincial or territorial laws and regulations or policies, Good Clinical Practices Guidelines, etc.
- Made-in-Canada standards would be comparable to the US and other international standard setting.
- Standards will be evolving.
- Best practices may exist as special reports, or be observed at the time of site visits.

There are different kinds of standards. They may evaluate:

- A Structure (What you have)
- A Process (What you do)
- An Outcome (What you achieve)

Standards will reflect the breadth and complexity of research in Canada.

- Clinical research
- Operations research
- Behavioural and social science research
- Law, business, and the humanities

Standard Setting is a peer-driven process

- Standards reflect input of stake-holders
- Standard reflect best practices
- Standards are achievable

## ***Standard 1: Human Research Protection Program***

The organization has a systematic and comprehensive HRPP established by the highest levels of the organization.

**INTENT:** That the organization commits to assuring that the rights and welfare of human research participants are protected.

- *Element 1.1 — Written Policies and Procedures*

The organization has and adheres to written policies and procedures for HRPP appropriate to the volume and nature of the research involving human participants conducted under its auspices.

- *Element 1.2 — Authority and Autonomy*

- a. The organization delegates responsibility for HRPP to an official with sufficient standing, authority and independence to ensure implementation and maintenance of the program.
- b. The organization establishes a Research Ethics Board(s) with the authority for the ethical review of research involving human participants under the auspices of the organization.
- c. The organization establishes and resources a Research Review Unit/research ethics office. That the organization has and follows written policies and procedures to the effect that the whole Research Review Unit, including the REB, is to function independently of other entities regarding the organization in its role in protecting human participants (AAHPRR 1.3.C).
- d. The organization assures the independence of the REB(s) to fulfill their primary obligations... (Reference TCPS 1.2).

- *Element 1.3 — Systematic Budgeting for HRPP*

The organization assures human and financial resources of the REB(s) to fulfill their primary obligations.

## ***Standard 2: Research Ethics Board Composition and Operations***

The REB(s) is (are) constituted and operates in a manner consistent with pertinent policies, guidelines, regulations and laws governing the human research it reviews.

**INTENT:** That the organization commits to assuring that the Research Ethics Board reports to the senior level of the organization and its composition is appropriate to the nature and volume of human research conducted by the organization, and that it has appropriate records keeping processes.

- *Element 2.1 — Responsible Individual*
- *Element 2.2 — REB Composition*
  - The membership of the REB is at least five persons.
  - Two members with broad expertise in the methods or in the area of research that are covered by the REB.
  - One member who is knowledgeable in ethics.
  - At least one member who has no affiliation with the institution but is recruited from the community(ies) served by the REB.
  - For biomedical research, at least one member who is knowledgeable in the relevant law.
  - Include both men and women and consider other elements of diversity.
- *Element 2.3 — REB Meetings - The REB meets regularly to discharge its responsibilities. (TCPS 1.7, 1.9)*
  - **Quorum:** will be a minimum of 50% of the members and must be consistent with composition requirements established by guidelines, regulations for the ethical review of research (e.g., Code civil Article 21 & Plan d'action ministeriel).
  - **Frequency of Meetings:** REB has regular meetings according to a published schedule but may have additional meetings as required.
  - **Attendance:** REB has policies and procedures requiring attendance of members.
  - **Principal Investigator Attendance:** REB has procedures to accommodate requests of Principal Investigators and/or Qualified Investigators who wish to meet with the REB. Principal Investigators cannot be present during decision-making/deliberations on their protocols.
- *Element 2.4 — Documented Processes for Compliance and Non-Compliance*
  - The REB ensures that the research is monitored for compliance by all those involved in the research.
- *Element 2.5 — Record Keeping of Research Protocol Approvals*
  - REBs maintain accurate and complete records for each REB review for a minimum period of three years after the completion of the study.

- This record includes:
  - Minutes of meetings (including attendees);
  - Submitted documents (including protocol, ICF, amendments, etc.);
  - Correspondence related to approval of the ethics submission;
  - Correspondence with researchers;
  - Date of receipt of original ethics submission proposal;
  - Date of original REB approval;
  - Date of most recent REB approval;
  - Date by which REB continuing review must occur.

### ***Standard 3: Research Ethics Board Review Methods (Process)***

**Standard:** The organization/REB has and follows written policies and procedures for the ethical review of research proportionate to the potential risks and harms presented to the human participants and consistent with pertinent Canadian and international regulations, guidelines, and laws.

- *Element 3.1 — REB requires Full Review as the default (TCPS) or all research involving human participants and has and follows written procedures for Full Review of research involving humans.*
- *Element 3.2 — REB has and follows written procedures for expedited review.*
- *Element 3.3 — REB has and follows written procedures for studies exempt from ethical review.*
- *Element 3.4 — REB has and follows written procedures for review of research in emergency situations.*

### ***Standard 4: Research Ethics Board Review (Content)***

The REB establishes and follows documented methods to ensure ethical, scientific/scholarly, and conflicts of interest review of research involving human subjects, proportionate to the risks and harms presented to participants.

- *Element 4.1 — Elements of Ethics Review*
  - Documents Required
- *Element 4.2 — Scientific or Scholarly Review:*
  - The REB has and follows documented methods for scientific and scholarly review.
- *Element 4.3 — Ethical Review*
- *Element 4.4 — Financial and/or Conflicts of Interest Review*

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### Sub-Committee on Standards Development

**Dr. Michael Owen - Chair**

*Brock University*

**Mr. Jack Corman**

*IRB Services*

**Dr. Kenneth Davey**

*York University*

**Prof. Édith Deleury**

*Université Laval*

**Ms. Patricia Lindley**

*Canadian Association of Research Ethics  
Boards*

**Dr. Barbara McGillivray**

*University of British Columbia*

**Dr. Susan Sykes**

*University of Waterloo*

*NCEHR Office*

**Dr. Richard Carpentier**

*Executive Director*

**Ms. Felicetta Celenza**

*Coordinator of Educational Visits*

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