

## Task Force on Accreditation

Ken Davey  
Michael Owen

## Working Group on Standards

- 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*.

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- 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
  - Allow site visitors (educational or accreditation visits) to assess an institution's and/or REBs' performance.
- Made-in-Canada standards are to be based TCPS, federal, provincial or territorial laws and regulations or policies, Good Clinical Practices Guidelines, etc.
- Made-in-Canada standards would be comparable to 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.

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- What do standards evaluate
  - Structure
    - What you have
  - Process
    - What you do
  - Outcome
    - What you achieve

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- 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

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- Standard Setting is a peer-driven process
  - Standards reflect input of stake-holders
  - Standard reflect best practices
  - Standards are achievable

## NCEHR – Working Group on Standards

- Proposed Phase I areas draft standards:
  - Human Research Protection Program (HRPP)
  - REB Oversight
  - REB Review Methods (Process)
  - Elements of Ethics Review
  - Conflict of Interest Management (Process)

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- Proposed Phase II Draft Standard:
  - REB Decision Making
  - Appeals Process
  - Procedures During Ongoing Research
  - Close Out of Protocols/Studies

## NCEHR – Working Group on Standards

- Human Research Protection Program (HRPP)
  - Assurances (if required)
  - Responsible Committee or Individual
  - Authority and Autonomy
  - REB Composition
  - Documented Processes for Compliance and Non-Compliance
  - Systematic Budgeting for HRPP
  - Record Keeping of Research Protocol Approvals

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- REB Oversight
  - Responsible Individual
  - REB Meetings
    - Quorum
    - Frequency of Meetings
    - Attendance
    - PI Attendance
    - Timelines

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- REB Review Methods (Process)
  - Full Review
  - Expedited Review
  - Exemption from Review
  - Multi-centre Study Review

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- Elements of Ethics Review
  - Documents Required
  - Scientific or Scholarly Review
  - Ethical Review
  - Financial and/or Conflicts of Interest Review

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- **Conflict of Interest Management (Process)**
  - Conflict of Interest for REB Members – Documented Process
  - Conflict of Interest for Researchers – Documented Process
  - Conflict of Interest for Institutions – Documented Process

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Standard	AAHRPP	NCQA	Hirtle	TCPS
HRPP	Standard I-1, I-2, I-3, I-4, I-5, II-1 D, II.1.E	Standard INR1, INR2, INR6, IRB1,	Item 1 & 2	Articles, 1.1, 3.1, 3.2, 3.3, 3.5, 3.6, 7.1,
Research Oversight	Standards 1-1c, II-1.F,	Standard INR2, IRB 2, IRB5	Items 2 & 3	Articles 1.2, 1.4, 1.14, 4.1, 1.8
REB Review Methods	Standard II-2, II-8,	Standard IRB3, IRB4	Item 4	Articles 1.1, 3.1, 1.7, 1.9
Elements of Ethics Review	Standards II-2, II-4, II-5, II-6, II-7, III-1, III-2	CRB1, CRB2, CRB3, CRB4, CRB5, CRB6	Item 5	Articles 1.5, 1.6, 1.9, 2.1, 3.1,
Conflict of Interest	Standards I.3.G, 1.3.H, II.1.C, III.1.A	Standard INR3	Items 5 & 6	Articles 4.1, 7.3
REB Decision Making		IRB3, IRB5	Item 6	Articles 1.2, 1.7, 1.8, 1.9, 4.1
Appeals Process			Item 7	Articles 1.10, 1.11
Procedures During Ongoing Research	Standard III-2,	Standard INR5, IRB-3B, IRB-3C, IRB-3D	Item 8	Articles 1.13, 2.1
Close Out Protocols				

## Time Frame: Budget Permitting

- March 7, 2005
- March 30, 2005
- April 30, 2005
- May 2005
- June/July 2005
- August-December 2005
- April 2005—Feb 2006
- April 2005-Feb 2006
- March 2006
- WG draft selected standards
- WG/TF Report on Draft Standards
- WG/TF Work Plan
- Presentation to CAREB for Feedback
- Consultations with Stakeholders
- Draft standards – Phase II
- Develop Manual for REBs
- Integrate Draft Standards in Educational Sites Visits
- Final Report to Tri-Council, Health Canada and Stakeholders

## NCEHR – Working Group on Standards

- Questions
- Thank you