

The BC Ethics Harmonization Initiative



Michael Smith Foundation for
Health Research

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Why Harmonization?



Phase 1 Objectives

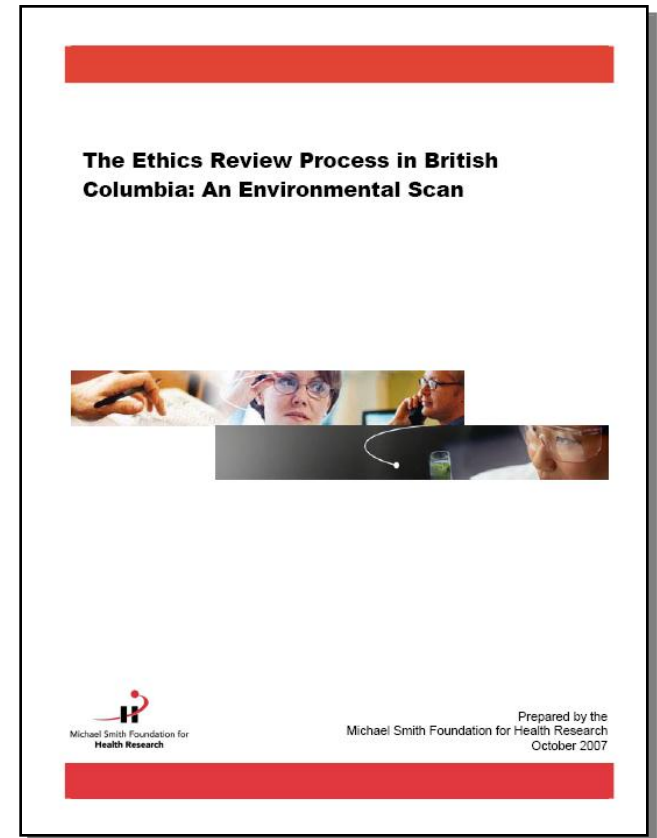
- identify preferred features of a harmonized approach to ethics review in BC
- assess willingness of stakeholders to collaborate
- assist stakeholders to identify possible solution(s) to and make recommendations for next steps

The BC Ethics Harmonization Initiative (Phase I)

1. Environmental Scans
 - REBs in BC
 - Harmonization in other jurisdictions
 - Survey of BC investigators
2. Workshop – November 2007

1. The Ethics Review Process in British Columbia: An Environmental Scan

- To explore processes used in BC for ethics review
- To capture input from all the organizations and institutions with REBs
 - written data request in questionnaire form
 - Individual follow-up interview (1.5 to 2 hrs)
 - Additional short follow-up questionnaire



Results

- 23 REBs identified
- 23 were interviewed
- 22 active, 1 formed this year
- Age of REBs: 0 to 24 years
- Size: 5 to 27 members (mean = 13)
- Total membership across BC = 285

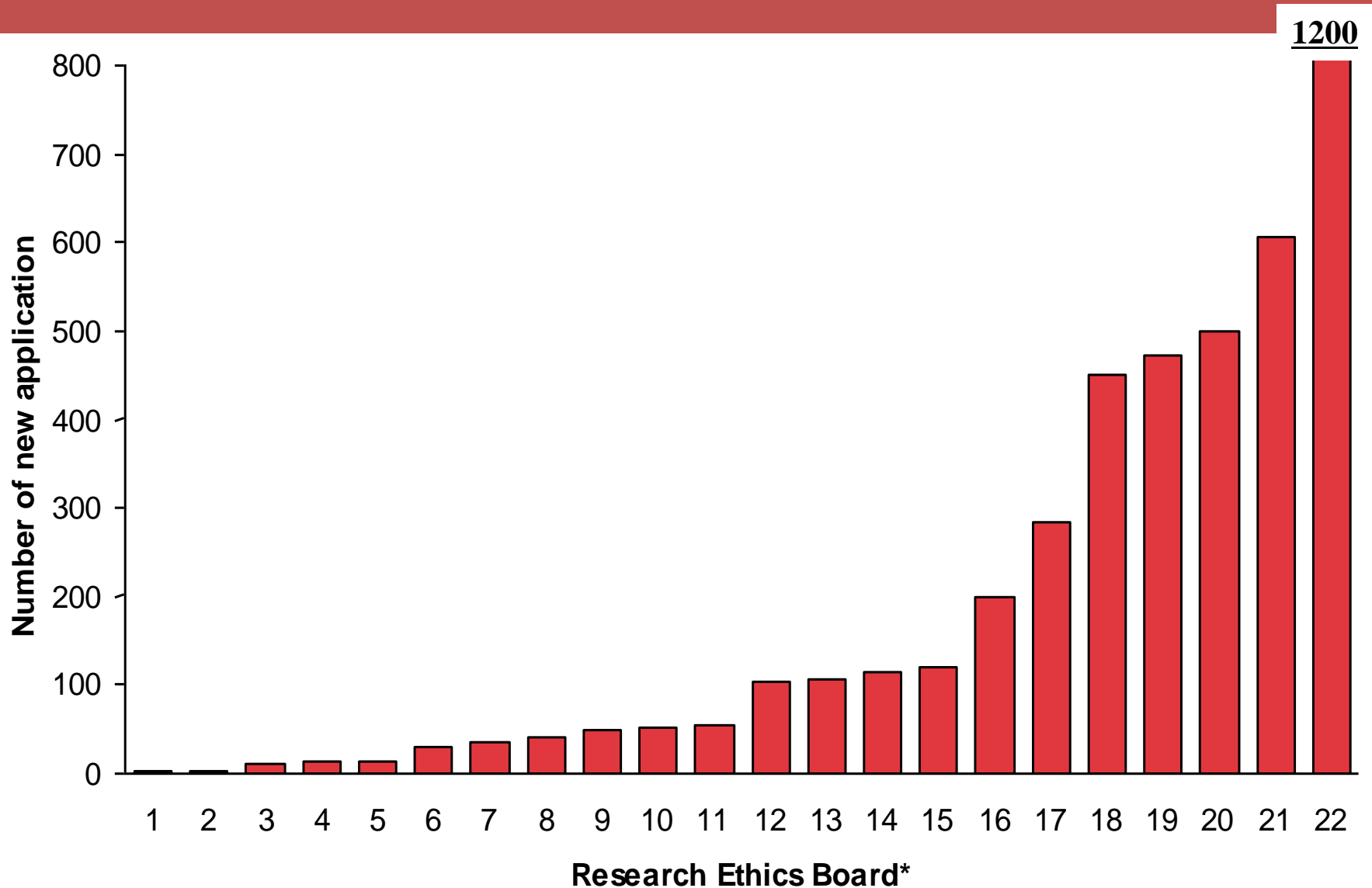
A Snapshot of BC REB Activity - 2

Applications*

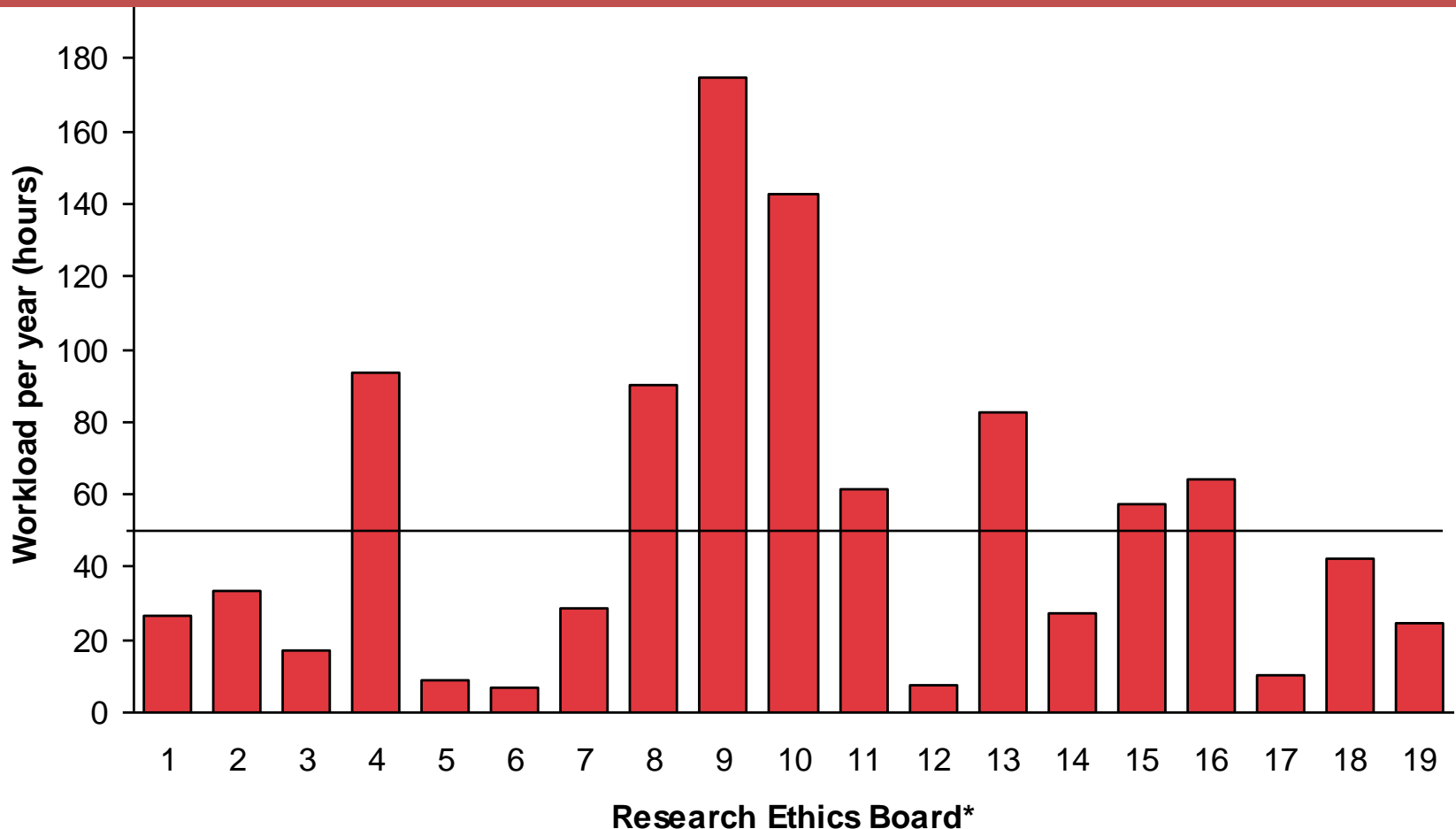
Total protocols reviewed in 2006:	13,593
Average reviewed per REB in 2006:	618
New applications received in 2006:	4,465
Average new applications per REB (2006):	203
Range in new applications per REB (2006):	3 to 1,200

* Note: duplicate multi-site applications uncounted

Volume of New Applications (2006)



Member Workload (2006)

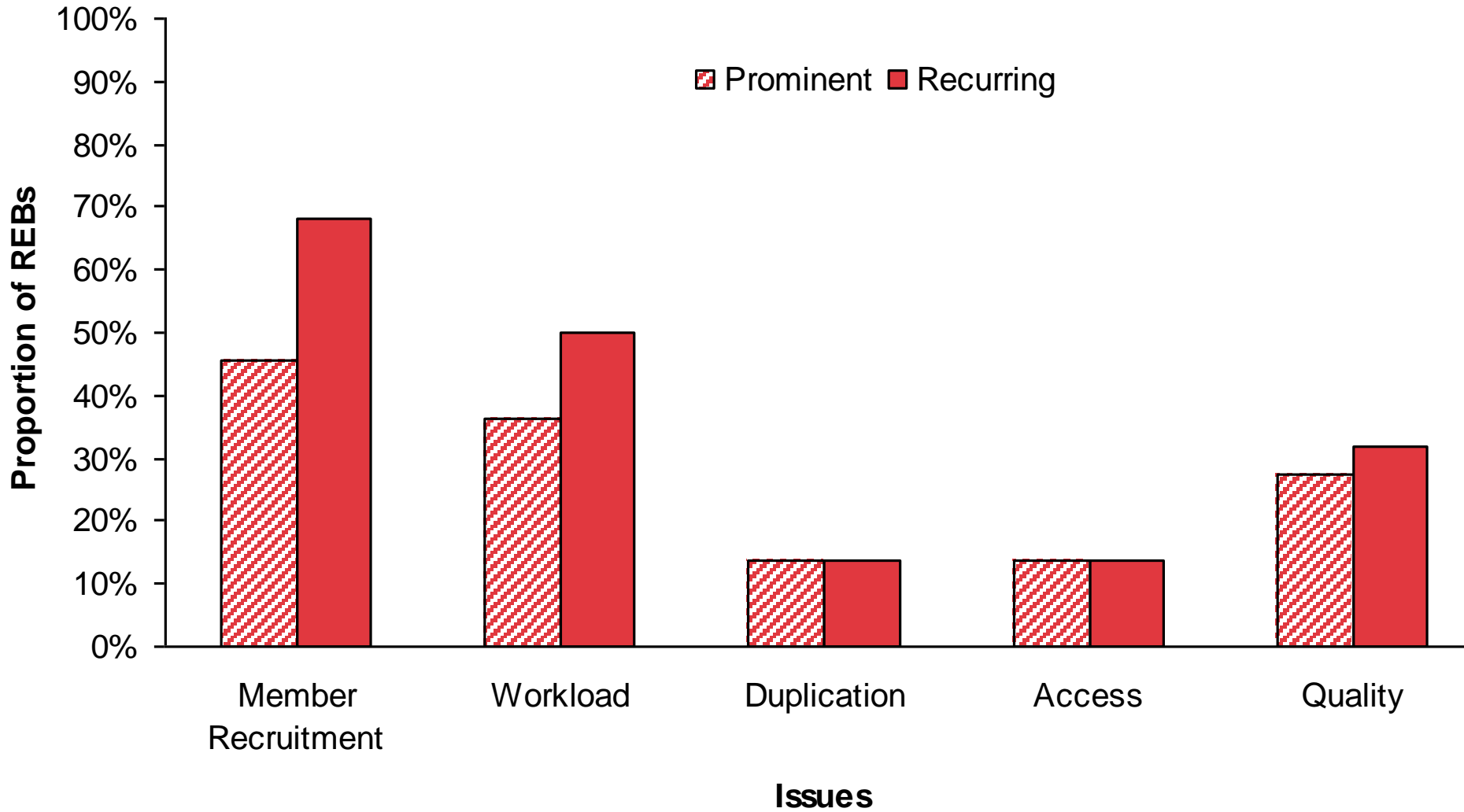


Average per member: 50 hours (range: 7 to 175)

Provincial total: 17,048 hours

Note: additional responsibilities of Chair/Vice-Chair

Reported Issues

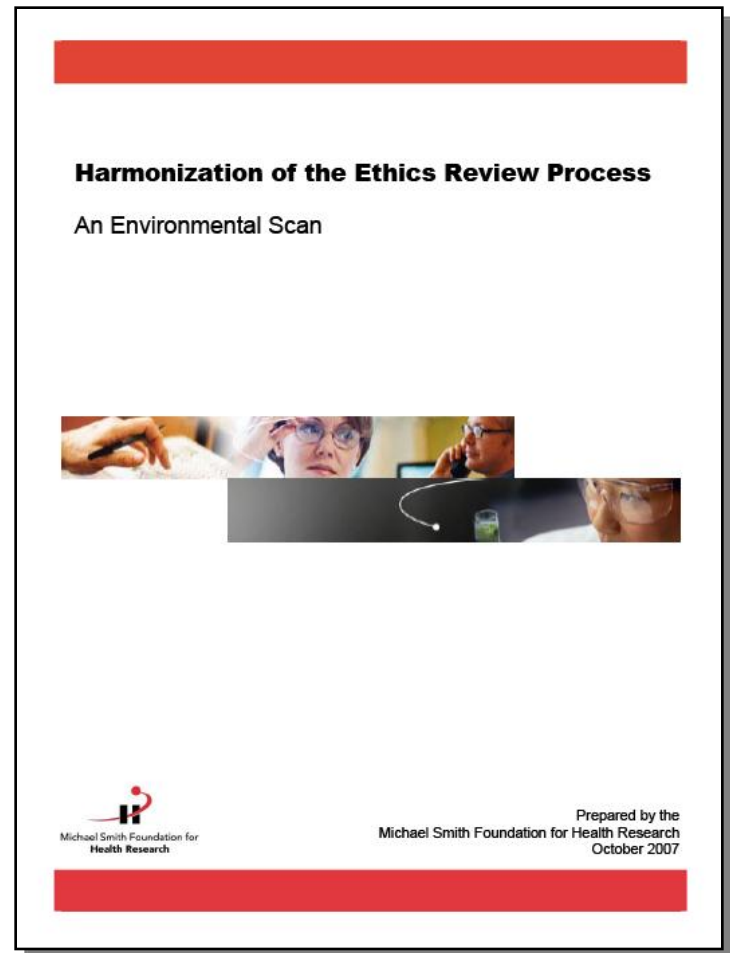


In Summary

- 22 active REBs - human subject research
- variety of sizes, shapes and practices
- high volume of demand
- significant level of duplication
- majority of REBs report recruitment and workload as recurring issues

2. Harmonization Scan

Processes and structures adopted to increase cross-institutional harmonization, across Canada, plus selected examples in the US, EU and in Australia



Types of Approaches

- Decentralized Models
- Central Review Boards
- Disease-Specific Ethics Review
- Regional Ethics Review
- Professional Body Ethics Review
- Cooperative/Collaborative

Canada

- Alberta
- Ontario (Cancer)
- Quebec
- Newfoundland
- Saskatchewan

United States

- The Western Institutional Review Board
- Partners Health Care System
- MACRO
- Biomedical Research Alliance of New York (BRANY)
- National Cancer Institute Central IRB
- IRBNet

World

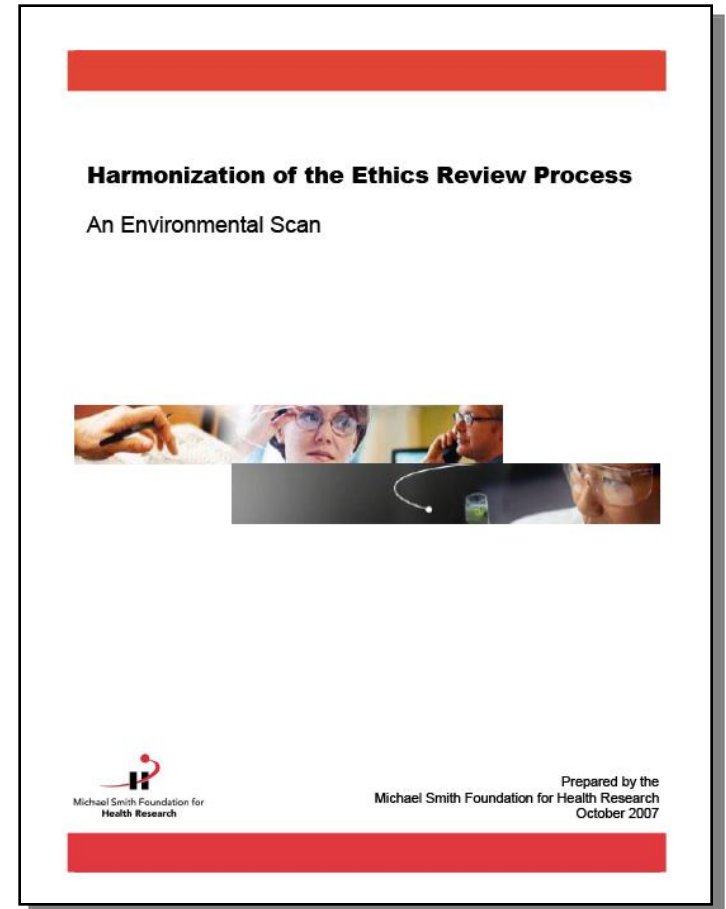
- Cancer Institute of New South Wales
- New South Wales Health
- European Union
- Sweden
- Denmark
- Hungary
- Portugal
- United Kingdom
- The Netherlands
- Australia

In Summary:

- many attempts in many settings
 - varying degrees of success
- no single system has emerged as dominant
- must take into account local realities
- opportunities through information technology
- need to monitor and assure performance quality

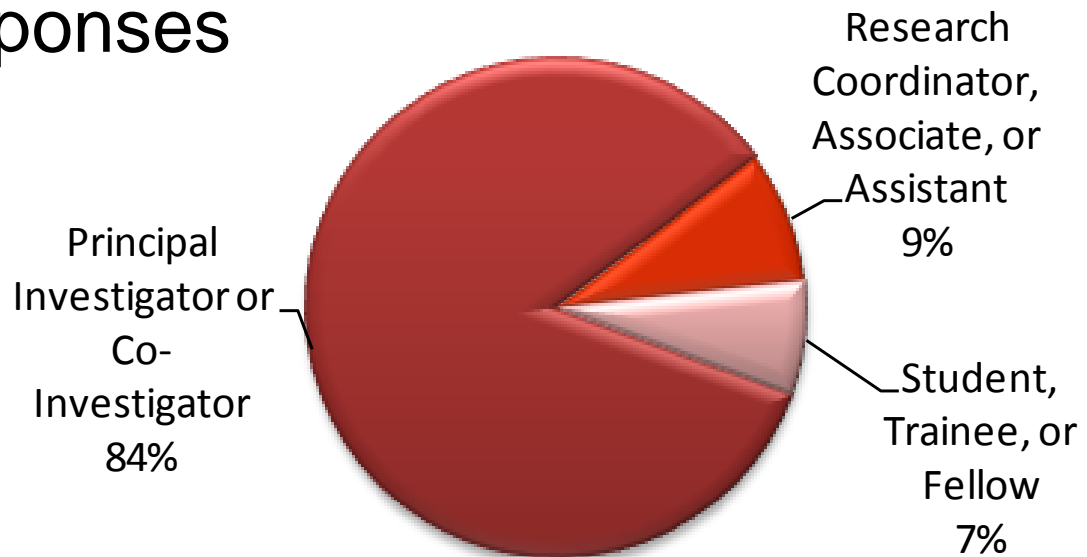
3. Investigator Survey

- Among BC investigators who conduct research studying human subjects, to determine:
 - important characteristics of an effective REB
 - perceived performance of local REBs



Response demographics

- 3,460 invitations via 14 BC institutions
 - duplicate invitations unknown
 - 670 respondents
 - 615 valid responses



Summary

- Largest gaps between importance and performance
 - multiple reviews of multi-centre research
 - time taken to receive approvals
 - lack of consistency

BC Ethics Harmonization Initiative Introductory Workshop



Participants (115)

- VPs of Research
- REB Chairs and Managers
- Representative researchers

Keynote Speaker: Dr. Greg Koski

PhD, MD, CPI – Harvard University, Boston

- ***Effective*** collaborative models for ethics review of research involving human subject require four essential components:
 - Trust
 - Leadership
 - Accreditation
 - Information Technology



Panel Discussion: Canadian Perspectives

- Linda Barrett-Smith, AHFMR, Alberta

*How to determine the appropriate type, level and process for ethics review of **knowledge-generating** activities which involve people or their health information?*

- Claude Dussault, Ministry of Health & Social Services, Quebec

Hybrid mechanism for review of multi-site clinical trials, approved for implementation in April 2008

- Peter Monette, Health Canada

Sponsors' Table for Human Research Participant Protection in Canada - recommends a Canadian Council for the Protection of Human Research Participants to support policy, education, accreditation

Working Groups Deliberation

- Status Quo approach
- Centralized Resource approach
- Common Tools & Processes
- Reciprocal Agreements

The Preferred Approach

- The status quo is not an option
- Creating one provincial REB not ideal
- Reciprocity may work best
- Common IT and processes
- Trust is essential
- Leadership and concerted action

Next Steps

Phase II

- Confirmed Institutional leadership
- Continue facilitation role for MSFHR
- BC Ethics Platform in development
 - Common IT, forms and processes
 - Reciprocity agreements
 - Shared education resources



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 - lack of consistency

For more information

All of our documents and initiative updates are available at:

www.msfhr.org

Or contact us:

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