

Streamlining Ethics Review in Canada

A Matter of Balance
by

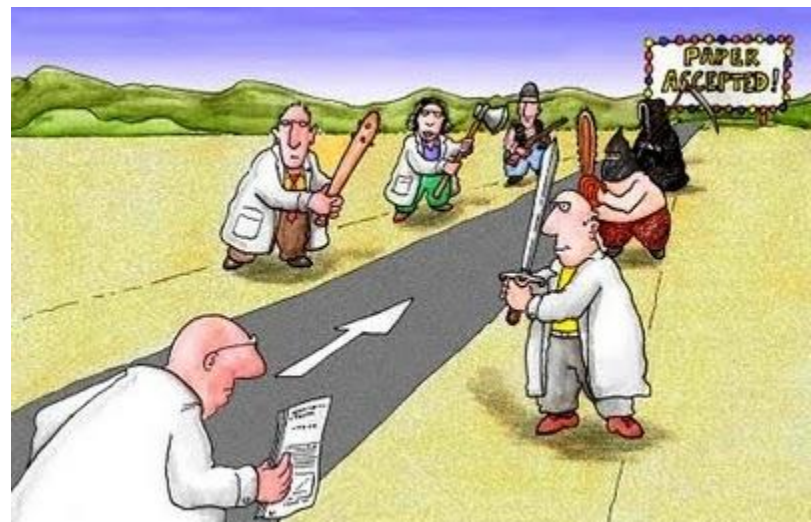
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Session Objectives

- Provide context to inform discussion
 - Background, Issues and hurdles
 - Considerations going forward
- Your Dialogue: What can be done to streamline ethics review to help position Canada
- Identify top 3-4 ideas that can be worked on to advance a more integrated approach nationally

Streamlining Ethics Review: Why bother?

- Ensure protection of the research participants/subjects
- Make Canadian rigor of ethics review a competitive asset, not a barrier to research



What are the issues?



Process efficiency



National, regional & local systems



REB resources



Alignment of ethics initiatives on streamlining



Process Efficiency Issues



- Confusion re types of approvals needed and how to navigate & sequence through “the maze” (REB review, scientific review, administrative approvals)
- Clarity of REB communications about processes (e.g., protocol deviations, SAE reporting)
- Multiple local reviews for multi-centre studies

National and Regional Perspective Issues



- Responsibility at individual site level vs. a REB system perspective within a province or nationally
- Lack of system metrics
- Jurisdictional differences across the country:
 - Legislation and regulations
 - Clinical research is tied to health services which are provincially controlled
- Inter-Organizational Barriers to Collaboration
 - Cultural differences
 - Competition (e.g., for funding, faculty, trainees)
 - Turf protection and historical enmity
- Variability in interpretation of the TCPS leading to mistrust
- Principle of independent review vs. depending on another REB's review

REB Resource Hurdles



- Voluntary nature of the member role
- Incentive structures that don't reward REB service
- REB training needs

But things are moving in the right direction...



- Impetus: Global changes in the research & innovation landscape
- Proactive REBs, Institutions, Industry and Governments
- A number of streamlining initiatives in Canada (AB, BC, NL, NS, ON, SK)

Some Review Model Options



- **Participatory reviews** (informal agreed mutual sharing of forms, information)
 - ? how to maintain voluntary mutual sharing ?
- **Dual reviews** (formal agreement for 1st full review & 2nd review for local considerations only)
 - ? more efficient than multiple participatory reviews ?
- **Delegated reviews** (one REB review accepted without further review by other REBs)
 - ? how to assure expertise ?
- **Central REB reviews**
 - ? how to represent diverse cultural or religious values and practices ?

Things to consider moving forward:



- Recognize complex change takes much time, effort, and careful planning
- Expect obstacles – turf politics, conflicting visions, differing styles & approaches
- Use allies and champions
- Communication & evaluation expertise from the beginning
- Clarity on vision and goals, accountabilities

Striking A Balance



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Balancing Principles



- Speed with quality in the review process
- Focus on key efficiencies, not minor variation
- Different jurisdictions require different change incentives – top down, bottom up, or both
- Applicable guidelines and norms, with flexibility for additional, institution-specific standards
- Aim for metrics that support system level management while respecting institutional needs

Questions

