Streamlining Research Ethics Review

CIHR and the Strategy for Patient-Oriented Research

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Research Ethics Review and Multi-site Clinical Trials

While Canada has a strong reputation in the area of clinical research, there are a number of inefficiencies which create delays in undertaking multi-site clinical studies.

The process of research ethics review is considered to be one of the causes of such delays.

Presentation Overview

- National and provincial landscape
- CIHR meetings with provinces, international community and national groups
- Clinical Trials Summit co-sponsored with ACAHO, Rx&D and CIHR
- Canadian General Standards Board (CGSB) standard for REBs reviewing biomedical clinical trials
- Strategy for Patient-Oriented Research

National and provincial approaches to streamlining research ethics review

- **OCREB** reviews all oncology studies in Ontario and is considered a model of research ethics review, includes an on-line submission system
- **MICYRN** (Maternal, Infant, Child, Youth Research Network) has developed a strategy to review multi-centred studies related to this population
- **British Columbia** Clinical Research Infrastructure Network utilizes common application and consent forms electronically available
- **Alberta** has a reciprocity agreement signed across 6 REBs, including the 3 Universities
- **Ontario** has established Clinical Trials Ontario with a mandate to streamline research ethics review across Ontario
- **Quebec** is revising an approach to streamlining research ethics review
- **Newfoundland and Labrador**, through legislation, has a single research ethics board for review of clinical trial research

CIHR meetings

CIHR held two meetings on streamlining ethics review of clinical studies

- December 2010 and October 2011

The objectives were to:

- Review existing initiatives in the provinces and internationally;
- Review lessons learned;
- Discuss critical elements for success;
- Determine next steps.

CIHR meetings

What we heard:

- Action is needed urgently;
- Build on success and respect jurisdictions;
- Support national standards and accreditation;
- Integrate current provincial approaches;
- Build trust

Possible Approaches

- Common training and education;
- Common application and consent forms with flexibility for site specific options;
- One review per province per research study.

Clinical Trials Summit

September 2011

Co-hosted by

- Rx&D – Canada's Research-based pharmaceutical companies
- ACAHO – Association of Canadian Academic Healthcare Organizations
- CIHR – Canadian Institutes of Health Research

More than 130 participants from

- patient care sites, industry, government, academic healthcare organizations, universities and other related organizations attended the event.

Clinical Trials Summit

The overarching assumptions guiding the structure of the Clinical Trials Summit and Action Plan were

If We Address...

- Ethics
- Recruitment
- Cost structure
- Admin Issues
- Infrastructure
- Innovation

→

We Improve...

- Cost
- Quality
- Speed
- Relationships

Recommendation 4: Improve efficiencies of ethics reviews & advance strategic issues (like accreditation)

- undertake a feasibility assessment and proposal for
  - a common application form,
  - consent form template,
  - information sharing mechanisms for ethics reviews
- support the work of Health Canada in evaluating standards and accreditation options.

CGSB Standard

CGSB – Canadian General Standards Board

- Standard for research ethics oversight of biomedical clinical trials
- Technical committee consisting of representatives from government, academic and healthcare organizations, REBs, etc.
- Final review and ballot March 29, 2012
- Result: over 82% in favour of the Standard

Streamlining of Research Ethics Review

Common messages:

- Action is needed;
- Build on success and respect jurisdictions;
- Support national standards and accreditation;
- Integrate current provincial approaches;
- Build trust

Streamlining of Research Ethics Review

There is overwhelming support to streamline research ethics review of multi-site clinical studies

- common applications
- consent form template
- accreditation system
- information sharing mechanisms for ethics reviews

Strategy for Patient-Oriented Research: SPOR

SPOR is a National Strategy: involving federal and provincial governments, public and private sectors and patients in a common enterprise.

SPOR is about improving health outcomes and enhancing patient care through health research.

Strategy for Patient-Oriented Research: SPOR

SPOR's objectives include:

- improving the research environment and infrastructure for patient-oriented research;
- providing better research training and mentoring for health professionals and non-clinicians;
- **strengthening organizational, regulatory, and financial support for multi-site studies**; and
- supporting best practices in healthcare.

Ethics in SPOR

The streamlining of ethics review is a priority for SPOR

External Advisory Committee – Streamlining Health Research Ethics Review (SHRER) Committee

Representation from

- Across Canada
- REB oversight and management
- Research Ethics Review Guidelines
- Research community
- Healthcare organizations

SHRER External Advisory Committee

Chair: Sharon Freitag (Past-President CAREB, Director Research Ethics St. Michael's Hospital)

Members:

- Laurel Evans (BC)
- Larry Felt (NL)
- Janet Manzo (OCREB)
- Diane Martz (SK)
- Brian Rowe (AB)
- Tina Saryeddine (ACAHO)
- Susan Zimmerman (Secretariat on Responsible Conduct of Research, SRCR)

Observer: Nathalie Desrosiers (QC)

CIHR Staff: Genevieve Dubois-Flynn and Penny Moody-Corbett

SHRER
External Advisory Committee

Objective:

To assist the SPOR National Steering Committee with streamlining research ethics review and improving the efficiency of patient-oriented research in Canada by:

- Consolidating knowledge on the barriers with respect to streamlining research ethics review,
- Recommending steps to improve the process,
- Identifying tools and strategies to improve the process,
- Exploring opportunities for information sharing and communication among REBs.

The Committee

- Has posted a Communiqué and letter of introduction on the Canadian Association of Research Ethics Boards (CAREB) website.
- Should be a point of contact for those involved in streamlining research ethics review of multicentre studies.
- Will asses the success and challenges of initiatives currently in place to streamline research ethics review.

Visit our Website / Contact us

Website: http://www.cihr-irsc.gc.ca/e/2891.html

***For any other questions, please contact* CIHR Ethics Office:**

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CIHR IRSC

Questions

Canada