



# Harmonization of Clinical Trial Agreements

An Initiative of the Council of Academic Hospitals of Ontario  
Insight Conference – October 2, 2007



# Agenda

Insight Conference  
Tuesday October 2, 2007

- History of Ontario initiatives to standardize clinical trial agreements
- Introducing the CAHO initiative
- Purpose
- Status
- Elements of the Principles Document
- Purpose and use of the Best Practices Document
- Next steps
- Seeking input



## Seeking the ultimate clinical trial agreement

- UK Model Agreement
- MAGI Model Agreement
- Other models?



## Why does Canada need a different model?

- UK system is different from Canadian context
- MAGI model agreement challenges & status
- Negotiation timelines have become a serious barrier to conduct of research
  - Estimates go as high as 12 months per negotiation



# Challenges to agreeing on content of clinical trial agreements

- Content
  - Issue identification vs. word-smithing
    - Tackle the principle & the words will follow
  - Harmonization with other organizations
  - Bargaining power
  - Negotiation strategies
- Development of a principles document



# OICR Initiative

- OICR formerly Ontario Cancer Research Network (OCRN)
  - Industry, academic hospitals & community hospitals
  - Process & content working groups
  - Content stalled at point where needed to commit to principles



# UofT Policy Harmonization

- **Clinical Study Agreements Working Group (CSAWG)**
  - A group of Toronto based hospitals
  - Had achieved harmonization of policies regarding clinical trial agreements at UofT\*
- **Harmonization of policies at UofT**
  - Ability of companies to negotiate with multiple UofT-affiliated hospitals

\*C.D. Naylor for the Research Committee and Clinical Study Agreements Working Group of the Toronto Academic Health Science Council, “Early Toronto experience with new standards for industry-sponsored clinical research: a progress report” 2002 CMAJ 166(4)



# Council of Academic Hospitals of Ontario Initiative

- OICR content working group
  - Draft document with multiple choice principles
- CSAWG document
  - Principles used within UofT affiliated hospitals
- Council of Academic Hospitals of Ontario
  - 25 academic hospitals Ontario-wide
  - “Provides a focal point for strategic initiatives” – [www.caho-hospitals.com](http://www.caho-hospitals.com)
  - Draft principles document based on CSAWG document
  - Shared with member hospitals and to a limited extent, with industry for comment



# CAHO Steering Committee Members\*

- **Arthur Slutsky**, Vice President, Research, St. Michael's Hospital; Chair
- **Michelle Moldofsky**, Manager, Contracts Office, The Hospital for Sick Children
- **Laurel Evans**, Business Services Coordinator, St. Michael's Hospital
- **Karen Arts**, Director Business Development, Ontario Cancer Research Network
- **Sarah Lampson**, Clinical Trial Agreements and Contracts Specialist, Hamilton Health Sciences
- Tamara Birkenheier, Research Contracts Specialist, Mount Sinai Hospital
- Paul Macpherson, Grants and Contracts Services, University Health Network
- Valerie Sales, Director, Clinical Studies Resource Centre, University Health Network
- Ron Heselgrave, Head, Research Ethics Board
- Deidre Henne, Director, Internal Audit and Research, Hamilton Health Sciences
- Marie Lynch, Chief Governance and Corporate Services and Chief Privacy Officer, St. Joseph's Healthcare Hamilton
- Sandi Machado, Manager, Grants and Contracts Office and Clinical Research Administration, Lawson Health Research Institute
- Marisa Akow, Director, Research Administration, Ottawa Health Research Institute
- Connie Day, Associate Vice President, Medical Administration, Credit Valley Hospital
- Samuel Ludwin, Vice President, Research Development, Kingston General Hospital
- Sharyn Szick, Administrative Director, University of Ottawa Institute of Mental Health Research
- Joe Gilbert, Vice President, Research, London Health Sciences Centre

\*As of January 2007

\*\***Bolding** indicates Working Group members.



# Principles Document

- “Statement of Principles to be Considered When Negotiating a Clinical Studies Agreement”
- Purpose
  - Clear and up front about principles expected
  - Strategies of negotiation and issue identification matter
  - Seek consensus on the basics of a clinical trial agreement
  - Limit number of issues to negotiate



# Elements of Principles Document

- Superior principles
- Publication
- Intellectual Property
- Confidentiality
- Privacy
- Indemnification
- Limitation of Liability of Institution/Investigator/  
No Warranties
- Disclosure of existence of contract & Use of name
- Parties' obligations
- Dispute resolution & governing law/jurisdiction
- Termination
- Additional Principles – for contracts with Contract Research Organizations



# Superior Principles

- Study participants are volunteers offering themselves for human experimentation. Their safety must not only be, but must be seen to be, the overriding principle of the contract.
- All parties will comply with all applicable federal and provincial laws, regulations and Health Canada guidelines; with ICH GCP and the Declaration of Helsinki; and the parties to whom it is applicable will comply with the Tri-Council Policy Statement.



# Superior Principles

- The study participants are drawn from the general public and have submitted themselves to experiment in good faith.
- The results, whether positive or negative, should be published within a reasonable time of completion of the study. The trial should be registered in a public registry (which meets the ICMJE criteria) in order to permit publication in peer-reviewed journals.



# Steps to Implementation

- Seek buy-in from academic hospitals of Ontario
- Adopt as policy document & publish on web
- Use as negotiation tool
- Disseminate & request companies to use the document
- Quality assurance & tracking effectiveness
- Seek buy-in from community hospitals of Ontario
- Negotiate across Canada to develop a Canada-wide standard



# Status of Implementation

- Principles document developed
- Input received from academic hospitals across Ontario
- Input received from 4 large pharma companies
- Input sought but not received from Ontario universities
- Principles document revised based on input
- Principles document agreed in principle by academic hospitals



## Input Received - Companies

- 4 responses representing 4 companies
- Positive about approach & quality of document
- 2 companies modified their templates (under negotiation)
- Comments included:
  - Requests for clarifications
  - Document modifications
    - Publication review timelines
      - (1 requested 6-9 mths instead of 120 days)
    - Indemnification



# Input Received - Companies

- Concerns expressed regarding interpretation
  - Access to aggregate data
  - Disclosure of existence of contract & use of sponsor's name
  - Intellectual property rights (although these are flexible in document)
  - Record retention of confidential information
  - Privacy (which legislation is applicable)
  - SAE reporting only when sponsor fails to do so
- Changes made with respect to:
  - Indemnification (PI statement of liability)
  - Multiple clarifications



## Next Steps

- Implementation at Ontario academic hospitals
- Present and publish principles
- Community hospital outreach
- Pharmaceutical company outreach
- Seek input from other Canadian jurisdictions regarding a Canada-wide standard
- Posting of Principles on CAHO web-site as a Living Document



# Seeking Your Input

- Implementation in Ontario
- Quality assurance mechanisms
- How to formulate a Canada-wide standard?



# Contact Information

- Kelly Hill  
Council of Academic  
Hospitals of Ontario  
[khill@caho-hospitals.com](mailto:khill@caho-hospitals.com)

Access the Statement of  
Principles at:

[www.caho-hospitals.com](http://www.caho-hospitals.com)



Council of Academic Hospitals of Ontario



# Credits

- This presentation is an adaptation of a presentation developed by three members of the CAHO working group:
- Michelle Moldofsky, Policy and Legal Advisor, St. Michael's Hospital
- Karen Arts, Director, Business Development Ontario Cancer Research Network
- Laurel Evans, Associate Director Research Ethics, University of British Columbia