



Council of Academic Hospitals of Ontario

Clinical Studies Agreement Initiative

Michelle Moldofsky and Karen Arts

CAHO Conference on the Clinical Studies Agreement Initiative –
Toronto: February 22, 2008

Principles

Policy

Guidelines

A Principled Approach

Seeking...

- The ultimate clinical trial agreement
- A better bargaining position
- Faster negotiation timelines
- One standard agreement
- Consensus on the basics of a clinical trial agreement
- A common approach

Negotiation timelines have become a serious
barrier to conduct of research

The CenterWatch Monthly

January 2004

A Thomson CenterWatch Publication

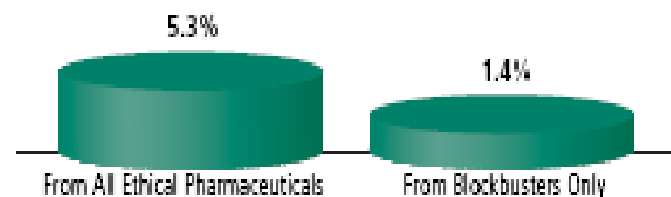
Volume 11, Issue 1

2003 in Review Shifts in the Foundation of Drug Development

► CenterWatch editorial looks back on a year filled with signs of fundamental shifts and changes in the clinical research enterprise. Service providers that are able to survive these fundamental shifts stand to benefit greatly in the long term.

Pharmaceutical Market Losing Steam

Projected annual sales growth 2000–2005



Source: IBM Business Consulting Group

Can Standardization Help the Contract Quagmire?

► Investigative sites are increasingly finding contract negotiations to be one of the largest causes of study conduct delays. Reasons cited include lack of standard terminology and ordering of contract sections, and mutually acknowledged areas of disagreement.

Standard Contract Language?

- Initial question raised in OICR initiative
 - UK & Australia did it!
 - Are we 'fighting' over language?
-
- Context: company-initiated clinical trials

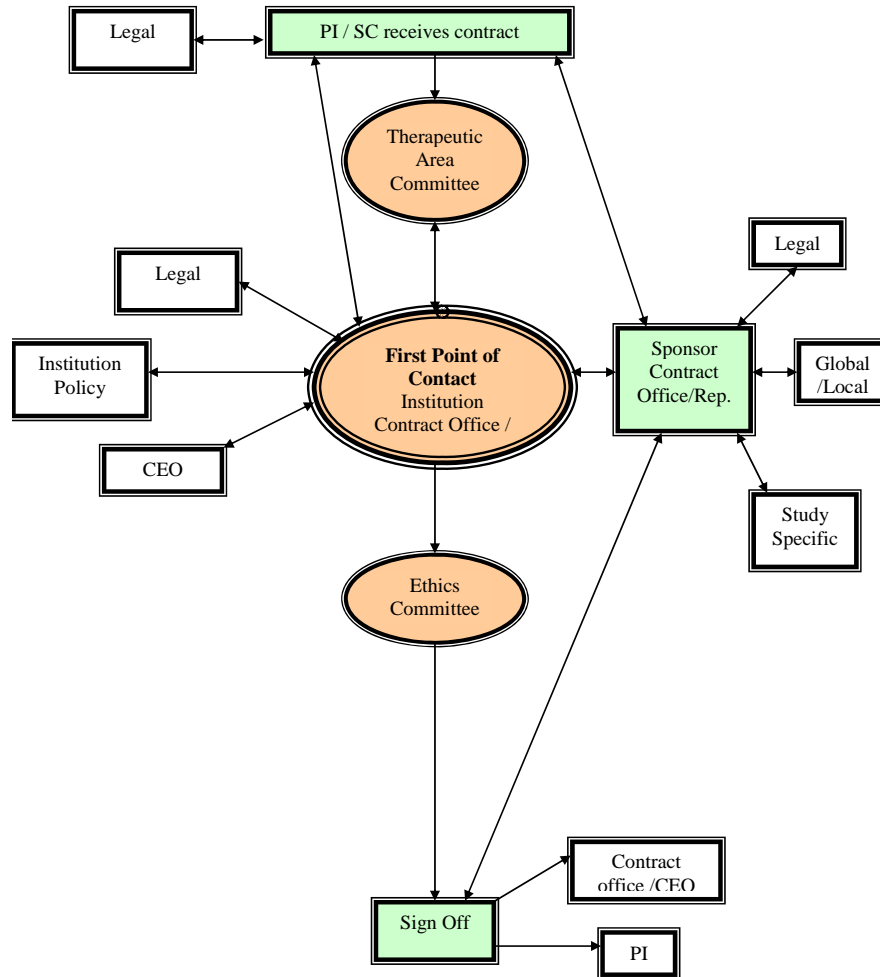
Ontario-wide Principled Approach

- Focus on principles & let companies use own template language
- Need an approach to stand the test of time

OICR Initiative

- Ontario Institute of Cancer Research
 - Industry, academic hospitals & community hospitals
 - Process & content working groups
 - Content stalled at point where needed to commit to principles

Agreement Process Map



OICR Initiative
Process Map,
Nov 2005

UofT Policy Harmonization

- Affiliation Agreement – principles/policy related to clinical trial agreements*
- 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) 453

Conflict With UofT Principles

- Publication delay
 - 18 months (CAHO) vs. 12 months (UofT) for multicentre studies
 - 2 months manuscript review + 2 months IP protection delay (CAHO) vs. 6 month review/delay (UofT)
- Outcome
 - UofT & its affiliated hospitals agreed to adopt CAHO standard as its bottom-line

Phases One - Five

- **Phase One:** Document Development
 - **Phase Two:** Implementation by academic hospitals of Ontario
 - E.g. Policy document to be published on CAHO website & hospitals to hyperlink to official version
 - **Phase Three:** Encourage use as negotiation tool by non-academic sites
 - **Phase Four:** Encourage use by companies as template development & negotiation tool
 - **Phase Five:** Negotiate across Canada to develop a Canada-wide standard
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Statement of Principles to be Considered When Negotiating a Clinical Studies Agreement

- Public statement of expectations
- Meant to limit the number of issues to negotiate
- Policy statement?
- Adopted by academic hospitals in Ontario
- What does it mean to endorse these principles?

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' rights & obligations
- Dispute resolution & governing law/jurisdiction
- Termination
- Additional Principles – for contracts with Contract Research Organizations

Superior Principles

- Study subjects 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.

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Indemnification

- Some institutions will offer on behalf of Institution employees and agents only, excluding licensed physicians and their employees and agents
- Investigators are not expected to provide an indemnification, but each may be asked to provide a statement accepting responsibility for his/her own actions and the actions of those for whom he/she is in law responsible.

Note Regarding Indemnification

Institution insurer (HIROC) and Investigator's defence provider (CMPA) have stated they will not cover for claims brought outside Canada. Institutions will have to make a risk management decision if institutions are asked to defend sponsor.

Some Institutions won't agree to defend sponsors. If Institution does agree to defend sponsor as well as indemnify and hold harmless, Institution may indicate that Institution's obligation to defend applies within Canada only.

Overview of Best Practices

- “Clinical Trial Agreement Best Practices for Agreements with Private Industry Sponsors”
 - Complementary to Principles
 - Living document
 - Internal document
 - Guidance document only
 - Not intended as legal advice

These Best Practices slides are based on slides developed by Laurel Evans for CAURA in May 2007

Why a Best Practice Document?

- Variety of different individuals negotiating clinical trial agreements from varying backgrounds
- Size and sophistication of institutions varies widely
- Very little Canadian specific material to assist someone negotiating and/or reviewing these contracts
- Synthesis of experiences in negotiation by “seasoned” reviewers

Use of Best Practices

- Set up to mirror the Principles Document
- Best Practice vs. Acceptable vs. Not Acceptable
- Helps put Principles into Practice
- NOT to be used as, or intended as fundamental principles that can't be /shouldn't be abrogated.
- Guidance only, as to what is reasonable to ask for, what is reasonable to settle for

Living Documents & Future Improvements

- Mechanism for feedback on the documents
- Frequency of revised versions
- Impact on adoption of documents vs. endorsement of documents

Future Improvements & Living Documents

- Mechanism for revising living documents
- Broadening the scope of applicability
 - Community hospitals
 - Researchers
- Side documents
 - Tackle other related agreements (CDAs)
 - Description of relevant legal issues
- Training/certification of negotiators
- Dynamics of working with industry

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Panel Discussion & Overview
