



RISK MANAGEMENT ISSUES IN HEALTH RESEARCH

(ONE-DAY INTENSIVE CONFERENCE)

MONDAY MAY 27, 2013 - 9:00 A.M. TO 4:30 P.M. (EST)

St. Andrew's Club & Conference Centre

150 King St. West (at University)

Conservatory One – 16th Floor

8:30-9:00 REGISTRATION

9:00-9:30 WELCOME AND INTRODUCTION TO THE CONFERENCE

Mary Jane Dykeman, Dykeman Dewhirst O'Brien LLP

Cindy Lee Heinz, Dykeman Dewhirst O'Brien LLP

- Key players in Canadian health research
- Overview of risk management issues in health research
- Legal context for research and its regulation
- Issues that keep research administrators, lawyers and researchers up at night

9:30-10:30 USA/CANADIAN RELATIONSHIPS: RESEARCH THAT CROSSES BORDERS

Christopher Viney, Director of Legal Services, The Hospital for Sick Children

- Comparing the Canadian and US context in health research
- HIPAA v. PHIPA
- Challenges in negotiating with US sponsors and collaborators
- U.S. anti-corruption and bribery requirements in the US, and their effect on Canadian hospitals

10:30-10:45 BREAK

10:45-12:15 ARE WE THERE YET?: TIMELY REVIEW OF RESEARCH CONTRACTS

Terry Donaghue, Director, Technology Transfer & Industry Liaison, Mount Sinai Hospital

Delilah Ofosu-Barko, Research Consultant, Trillium Health Partners

Katie Porter, Clinical Research Agreements and Contracts Specialist, Hamilton Health Sciences

- Balancing turnaround times and efficiency with thoroughness and risk mitigation
- Effectiveness of templates and master agreements
- Lessons learned of how to run a research contracts office

Moderated by: Kate Dewhirst, Dykeman Dewhirst O'Brien LLP



12:15-1:15 NETWORKING LUNCH

1:15-2:45 HOT TOPICS IN RESEARCH

Dr. Lorraine Ferris, Professor, Dalla Lana School of Public Health and Associate Vice Provost, Health Sciences Policy and Strategy, University of Toronto

Dr. Raphael (Rafi) Hofstein, President and CEO, MaRS Innovation

Richard Kirchner, Supervisor BTOX/GCP Unit, Health Canada

Kathy O'Brien, Dykeman Dewhirst O'Brien LLP

- Procurement rules as they pertain to research
- Sponsor-investigator duties and responsibilities in investigator-initiated trials
- Investigator-initiated trials and off label uses
- Commercialization in research

Moderated by: Candi Gogar, Dykeman Dewhirst O'Brien LLP

2:45-3:00 BREAK

3:00-4:00 INSURANCE AS A RISK MANAGEMENT STRATEGY

Aaron Leahy, Legal Counsel, The Hospital for Sick Children

James Penafiel, Senior Underwriter, Healthcare Insurance Reciprocal of Canada

Khalid Sabihuddin, Manager, Business Operations, Applied Health Research Centre at St. Michael's Hospital

- Hospital insurance issues in research endeavours
- Physician/researcher risks and risk management tips
- Foreign clinical trials insurance coverage

Moderated by: Mary Jane Dykeman, Dykeman Dewhirst O'Brien LLP

4:00-4:30 PRIVACY UPDATE FOR RESEARCH

Kate Dewhirst, Dykeman Dewhirst O'Brien LLP

Mary Jane Dykeman, Dykeman Dewhirst O'Brien LLP

- Latest privacy issues in research
- European data protection treaty issues

CONFERENCE REGISTRATION FORM

Register by mail, e-mail with PDF attachment, telephone or fax (see below)

Early Bird Price: \$450 + HST (\$58.50) = **\$508.50** (if registered and paid by May 7th)

Regular Price: \$495 + HST (\$64.35) = **\$559.35**

Attending course in person Attending course via webcast

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Fees

Fees include course attendance, continental breakfast, lunch, refreshment breaks and course materials. Webcast fees are per individual participant. Please contact us to discuss volume discounts for additional participants – we offer one free registration with every three registrations paid by the same organization.

Cancellations, Substitutions & Course Changes

A substitute is welcome to attend in your place. Cancellations are accepted with refund (less a \$60 administrative fee) up to 10 days prior to the event, otherwise no refund is available. It may be necessary for us to change the date, venue, content and/or speakers with little or no notice. Dykeman Dewhirst O'Brien LLP will reimburse paid fees for course cancellation only, and assumes no further liability for course changes.

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