NEW INVESTIGATOR CLINICAL TRIALS COURSE
August 28-31, 2007
Donald Gordon Centre
Queen's University
Kingston Ontario

Day 1 Tuesday August 28 2007
16:30 Opening Remarks and Welcome Reception
17:30 Keynote Speaker : Clinical Research in Academic Medicine
20:00 Faculty Meeting/Dinner

Day 2 Wednesday August 29 2007
07:00 Breakfast at Donald Gordon Centre
09:00 Plenary Session 1: Translating Laboratory Observations into the Clinic
Prerequisites for therapeutic studies
Prerequisites for development of biomarker studies and other translational lab studies
10:30 Break
10:45 Plenary Session 2: Phases of Clinical Development of Therapeutics Phase I, II, III
Phase I trials
Phase II Trials
Phase III Trials
12:00 Lunch
13:00 Workshop 1: Sample Size: Determination, Methodology, Analysis and Philosophy
Workshop 2: Phase II Design
Workshop 3: Correlative Studies in Early Phase Trials
13:45 Break
14:00 Workshop 4: Statistical Analysis - Stopping Rules
Workshop 5: Clinical Trials Infrastructure in Centres
Workshop 6: Effective Presentations of Study Results
14:45 Break
15:00 Plenary Session 3: Special Topics in Trial Design
Surrogate efficacy endpoints
Quality of life analysis
Economic evaluation
17:00 Office Hours: 30 minutes one-on-one with a faculty member
19:00 Dinner (Kingston Dinner Cruise)

Day 3 Thursday August 30 2007
07:00 Breakfast at Donald Gordon Centre

08:00 **Plenary session 4: Biomarkers in Clinical Studies**

Tumour banking

Hypothesis generating studies/validation studies

Statistical analyses of correlative studies

Lois Shepherd

Janet Dancey

Chris O'Callaghan

10:00 Break

10:15 **Plenary session 5: Ethical, Legal and Regulatory Aspects of Clinical Trial Conduct**

Oversight of safety

International and Canadian standards

Contracts: negotiation and key elements

Lesley Seymour

Lesley Seymour and Alison Urton

Belinda Vandersluis

12:00 Lunch

13:00 **Workshop 7: QOL Analysis**

**Workshop 2: Phase II Design** (repeat)

**Workshop 3: Correlative Studies in Early Phase Trials** (repeat)

Michael Brundage

Kim Chi

Lillian Siu

13:45 Break

14:00 **Workshop 8: Challenges in Design and Conduct of Prevention Studies**

**Workshop 5: Clinical Trials Infrastructure in Centres** (repeat)

**Workshop 6: Effective Presentations of Study Results** (repeat)

Harriet Richardson

Kathleen Pritchard

Kim Chi

15:00 - 17:00 **Plenary session 6: Data Collection, Database and Analysis: Privacy, Security, Accuracy, Validity**

Data collection

Database creation

Database analysis and interpretation

Wendy Parulekar

Lam Pho

Chris O'Callaghan

17:00 Office Hours: 30 minutes one-on-one with a faculty member

19:00 Dinner (at your own leisure)

Day 4 Friday August 31 2007

07:00 Breakfast at Donald Gordon Centre

09:00 **Friday August 31 2007**

**Canadian Cancer Trials Group Collaborations:** Academic, Regulatory and Industry

Ralph Meyer

Kathleen Pritchard

10:00 **Panel Discussion: Mentorship in Academic Medicine**

11:00 Adjourn