2012 Clinical Research Training Institute Summer Workshop Curriculum
Estancia La Jolla Hotel, La Jolla, California
July 28 - August 3, 2012

Saturday, July 28

6:30 pm Welcome Reception and Dinner – Garden Courtyard

Sunday, July 29

7:00 am Participant Breakfast - Grande Room
Faculty Breakfast – Magnolia Room

8:00 am Learning Theatre
Introductions by CRTI Co-Chairs
Mark A. Crowther, MD, MSc, St. Joseph's Hospital, Hamilton, ON
Julie Panepinto, MD, MSPH, Medical College of Wisconsin, Milwaukee, WI

9:30 am Importance of Good Mentoring
Joseph R. Mikhael, MD, FRCPC, MEd, Mayo Clinic, Scottsdale Campus, Scottsdale, AZ

Good mentoring is a critical component of optimizing early success as a clinical investigator. Dr Mikhael will explain the role of the mentor and provide some examples of excellent mentorship and examples of poor mentorship. He will discuss not only optimal attributes of an excellent mentor but also include what the scholar can do to improve the mentor-mentee relationship. Finally, Dr. Mikhael will provide hints for how to identify a faculty member at CRTI who would be a good fit to be your personal mentor.

10:15 am Break - Pacifica Pre Function A

10:30 am The Answer Is the Question
Nancy Heddle, MSc, McMaster University, Hamilton, ON

Defining the question that will define your research project is the most important (and often most difficult) component of a research project. A carefully developed question will reduce the amount of work required to complete a project and will facilitate the analysis and publication of the results. A poorly defined question will often lead to a difficult study course, complex analysis, and a publication that lacks clarity, and therefore impact. This presentation will review some of the characteristics of a well designed research question. It will set the groundwork for much of the work to be done in the week.

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11:30 am	Trainee Presentations (6) Each trainee will get fifteen minutes. Ten minutes to present with five minutes for questions.
1:00 pm	Lunch - Grande Room
1:30 pm	Trainee Presentations (6)
3:15 pm	Break
3:30 pm	Trainee Presentations (8)
5:30 pm	Group Photo - Olive Lawn
6:30 pm	Small Group Get Acquainted Dinner - Grande Room

Monday, July 30

7:00 am	Breakfast – Grande Room
8:00 am	<u>Introduction to Biostatistics</u> Donna Neuberg, ScD, Dana - Farber Cancer Institute, Boston, MA Statistical analyses can take many diverse forms, but there are underlying principles common to most of them. It is essential that clinicians entering the world of clinical research have a solid understanding of these basic statistical principles. They will prove useful whether designing research projects or reading the results of research done by others. This presentation will provide a review of several basic concepts: hypothesis tests, p-values, power, sample size, and regression analysis. This will provide a framework for many topics that will be discussed during the week in small groups and also in the lectures by other CRTI faculty members.
9:00 am	<u>Introduction to NIH Funding Mechanisms and Grant Submission</u> Ellen Werner, PhD, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD Dr. Werner will represent the National Institutes of Health and she will discuss the structure, functions and mission of the different NIH organizational units (e.g., Institutes, Center for Scientific Review). She will also determine which NIH grant mechanism is most appropriate for early-career clinical researchers; specifically, a mentored career development award (K series) or a research grant (R series) as an Early Stage Investigator (ESI). She will review the steps that should be taken to apply for NIH funding, including how to find the necessary information on the NIH website and/or the specific institute websites and the process of how to submit an application.

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10:00 am Break

10:15 am <u>Inside the NIH Grant Review Process - Video and Discussion</u>
Ray Wu, PhD, National Cancer Institute, National Institutes of Health, Bethesda, MD
Ellen Werner, PhD, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD

CRTI participants will view two videos that give an inside look at how NIH grant applications are reviewed for scientific and technical merit. The first video shows a mock study section evaluating applications based on the NIH review criteria. The second video includes information on what applicants can do to improve the chances their applications will receive a positive review. The NIH panel will review the NIH study section review process, and scoring system. A Q&A discussion will follow.

Video Mock Study Section: http://www.youtube.com/watch?v=HMO3HoLJuJY

Tips to applicants:
http://www.youtube.com/watch?v=9cNRMsCGfHo&feature=channel

11:15 am <u>Overview of Other Granting Agencies Relevant to Hematology</u>
Linda Burns, MD, University of Minnesota, Minneapolis, MN
Armand Keating, MD, Princess Margaret Hospital, Toronto, ON

This session will provide an overview of grants and awards available from the American Society of Hematology, the Leukemia Lymphoma Society, FDA, ACS, and the Doris Duke Foundation.

12:00 - 1:00 pm Lunch Breakout Sessions: Funding Organization Question and Answers (separate rooms)

a. National Heart, Lung, and Blood Institute and the National Institute of Diabetes and Digestive and Kidney - Dr. Werner - Cypress Room
b. National Cancer Institute - Dr. Wu - Pepper Room
c. Foundation Funding (American Society of Hematology, the Leukemia Lymphoma Society, American Cancer Society, and the Doris Duke Foundation) – Drs. Burns and Keating - Olive Room
d. Canadian Funding Mechanisms - Drs. Crowther and Heddle - Dracaena Room

1:00 - 5:00 pm Small Group Breakout Sessions

Small Group Breakout #1 - Dracaena Room
Small Group Breakout #2 - Jacaranda Room
Small Group Breakout #3 - Cypress Room
Small Group Breakout #4 - Juniper Room
Small Group Breakout #5 - Pepper Room
Small Group Breakout #6 - Olive Room

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6:00 - Trip to La Jolla
7:30 - Dinner in La Jolla

Tuesday, July 31

7:00 am Breakfast - Grande Room

8:00 am <u>Methods in Observational Epidemiology</u>
Kathryn Webert, MD, McMaster University, Hamilton, ON

An overview of the design, conduct, analysis, and interpretation of epidemiologic studies of diseases in humans (in particular, cancer) with focus on the use of epidemiologic methods to learn about disease causation and techniques useful in carrying out epidemiologic studies.

9:00 am <u>Introduction to the Fundaments of Randomized Controlled Trials and How To effectively Teach Evidence Based Medicine</u>
Wendy Lim, MD, MSc, St. Joseph's Hospital, Hamilton, ON

Assessing the quality of clinical research is fundamental to good clinical practice. Describing the strengths of a randomized trial helps to provide insight into ways observational studies and randomized trials may be biased and ways that such types of bias could be avoided or minimized. Excellent quality publications are uncommon; most publications have significant, although hard to detect, biases that might influence either the results or the interpretation of the results. Use of validated tools during the assessment of the literature will increase the confidence of the reader in the results.

10:00 am Break - Pacifica Pre Function A

10:15 am <u>Patient Reported Outcome Assessment in Clinical Trials</u>
Julie Panepinto, MD, MSPH, Medical College of Wisconsin, Milwaukee, WI

Patient-reported outcomes (PROs) are increasingly being used as an alternative outcome measure in clinical trials. This talk will focus on the PRO of health-related quality of life (HRQL) and will provide an overview of the rationale for using HRQL in clinical trials - including how and when to incorporate measurement of HRQL - and will review HRQL results from prior research studies.

11:15 am <u>ABC's of Genomics as Applied to Clinical Research</u>
James Bradner, MD, Dana-Farber Cancer Institute, Boston, MA

Understanding the relationship between the genome and clinical outcomes is in its infancy; however, genomic research is becoming central to all aspects of clinical research, both because it provides insight into disease states, but also

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because it may predict response to treatment. This lecture will provide a basic introduction to genomics as it can be applied in clinical research.

12:15 - 1:15 pm Lunch - Grande Room

1:15 - 3:00 pm <u>How to Avoid Conflicts of Interest and Maintain Ethics (Including How to Handle Conflicts with Industry)</u>
John P. Leonard, MD, Weill Medical College, New York, NY
Linda J. Burns, MD, University of Minnesota, Minneapolis, MN

Conflicts of interest can occur frequently for clinical investigators. This talk will focus on the most common sources of conflict of interest; discuss how to recognize them, and some strategies for how to deal with them when they occur. In particular, a focus on dealing with industry and possible conflicts in such relationships will be discussed.

3:00 - 5:30 pm Small Group Proposal Refinement
Breakout Room #1 - Dracaena Room
Breakout Room #2 - Jacaranda Room
Breakout Room #3 - Cypress Room
Breakout Room #4 - Juniper Room
Breakout Room #5 - Pepper Room
Breakout Room #6 - Olive Room

7:00 pm Dinner with mentors and mentees – La Jolla CD

7:45 – 8:30 pm <u>What We're Looking for When We Hire</u>
Armand Keating, MD, Princess Margaret Hospital, Toronto, ON
Janis L. Abkowitz, MD, University of Washington, Seattle, WA

Interactive after-dinner session exploring the characteristics department chairs look for in faculty candidates, including training background, commitment to academic career, predictors of success, references from mentors, and personal qualities such as ambition, drive, collegiality, communication skills (written and verbal), and leadership potential. The speakers will also cover questions to ask chairs (and other faculty hosts) during interviews and what candidates should look for before accepting an offer for a faculty position.

Wednesday, August 1

7:00 am Participant Breakfast – Grande Room

8:00 am <u>Steps Required to Initiate a Feasibility Study</u>
Susan Geyer PhD, The Ohio State University, Columbus, OH

The purpose of a feasibility study is to determine the viability of a project against factors such as investigator interest, cost, time, resources and availability of target population, local medical practices and competing trials. It

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is important to identify the potential risks and possible solutions before embarking on your project.

9:00 am

How to Craft an Effective Research Presentation
Joseph R. Mikhael, MD, FRCPC, MEd, Mayo Clinic, Scottsdale Campus, Scottsdale, AZ

The single most important characteristic of any successful research presentation is that it encompasses a coherent, linear story. Like successful storytelling in many cultures, matching the story to the audience, drawing the audience in with a compelling raison d'être, clearly presenting why and how you did what you did, and finishing with an explanation of how your results address the reason for doing the study in the first place, will result in success. For CRTI trainees, translational beginnings and ending seem highly appropriate, including weaving in patient issues and relevance. This presentation will address reasons for giving an effective research presentation and will apply to both oral and poster presentations. Examples of good and not so good slides and posters will be discussed.

10:15 am

Break - Pacifica Pre Function A

10:30 am

How Does Basic Science Investigation Interface with Clinical Investigation and Steps Required to Obtain Drugs from CTEP
Jennifer R. Brown, MD, PhD, Dana-Farber Cancer Institute, Boston, MA

One of the challenges in performing translational research is the long timeline required to get a clinical trial off the ground, open, accruing, and successfully completed – a timeline that can be inconsistent with academic requirements for research productivity. Good trial-related biology and strong interactions with basic science colleagues can keep you publishing before the definitive paper describing the trial comes out - and keep your academic pipeline filled. The next stage may include negotiation with CTEP to obtain a drug that you have been studying. This talk also will include steps on how to submit an application to CTEP and how to optimize your chances of success.

11:30 am

How to Obtain a Career Development Award - Panel Discussion
Robert Liem, MD, Children's Memorial Hospital, Chicago, IL
Allison King, MD, MPH, Washington University, Saint Louis, MO

Perspectives and advice from trainees and mentors will be provided during this interactive discussion on how to be successful in obtaining your career development award. In addition to the NIH, other funding agencies including ASH and foundations will be highlighted.

12:30 pm

Sessions on Demand – Box Lunch

a) STATA Statistical Pack – Donna Neuberg - Dracaena Room
b) Biomarkers – Jennifer Brown - Jacaranda Room

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c) Decision Analysis – Sarah O'Brian - Cypress Room
d) How to Recruit Under Represented Minorities to a Clinical Trial – Christopher Flowers - Juniper Room
e) Navigating the FDA to Get Approval for a Drug – Drs. Leonard and Liem – Pepper Room
f) TBD – Olive Room

1:30 - 3:00 pm — Small Group Discussion
Breakout Room #1 - Dracaena Room
Breakout Room #2 - Jacaranda Room
Breakout Room #3 - Cypress Room
Breakout Room #4 - Juniper Room
Breakout Room #5 - Pepper Room
Breakout Room #6 - Olive Room

3:30 pm — Meet at bus

4:00 - 7:00 pm — Group Outing - Beach Cookout at Torrey Pines

8:30 pm — Overview of Dose-Finding Studies (attendance is optional)
George A Tomlinson, PhD, Toronto General Hospital, Toronto, ON

Thursday, August 2

7:00 am — Breakfast - Grande Room

8:00 am — Conducting Clinical Research within Cooperative Groups
James A. Whitlock, MD, The Hospital for Sick Children, Toronto, ON – Children's Oncology Group - ALL - 15 minutes
John P. Leonard, MD, Weill Medical College, New York, NY - CALGB - 15 minutes
Sara Vesely, PhD, MPH, The University of Oklahoma, Oklahoma City, OK - Transfusion Network – 15 minutes.

Cooperative groups are powerful research tools, but are also complex. This presentation will outline some of the major cooperative groups and will provide insight on how to maximize the research opportunities provided by working within such a group.

9:00 am — Protocol, Approval, Accrual
John P. Leonard, MD, Weill Medical College, New York, NY

The protocol is written, but now what? You'll get tips in this presentation on how to obtain IRB approval and activate your study in the shortest amount of time. This session will include a discussion of FDA processes.

10:00 am — Break - Pacifica Pre Function A

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10:15 am

The Publication of Research Data: How To Write, Publish and Avoid Getting Your Picture into the *New York Times* for Plagiarism
Mark A. Crowther MD, MSc, St. Joseph's Hospital, Hamilton, ON

This talk will discuss the "do's and don'ts" pertaining to writing a paper for a scientific journal. It will cover important pre-submission, submission, and post-submission issues. It will also discuss style issues related to writing a scientific articles; differentiating scientific writing from the Great American Novel will be discussed in depth

11:15 - 4:00 pm

Afternoon refinement of proposals (box lunch included).

Rehearsal of Participant Presentations – Learning Theatre
11:30 – 12:15 Group 1
12:15 – 1:00 Group 2
1:00 – 1:45 Group 3
1:45 – 2:30 Group 4
2:30 – 3:15 Group 5
3:15 – 4:00 Group 6

7:00 pm

Dinner with focused topics: Career Advice - La Jolla CD

- Work Life Balance (Sarah O'Brien, Mark Crowther)
- Work Life Balance (Julie Panepinto, John Leonard)
- Early Clinical Trial Development (Jennifer Brown)
- Establishing a Collaborative Relationship with a Statistician (Lauren Griffith)
- How to be an Effective Mentor (Joe Mikhael)

7:45 - 9:00 pm

Career Retrospective
Nancy Heddle, MSc, McMaster University, Hamilton, ON

Friday, August 3

7:00 am

Breakfast – Grande Room
Faculty Breakfast

8:00 am

How to Initiate a Research Program
Nancy Heddle, MSc, McMaster University, Hamilton, ON

Clinical investigation has become more complex requiring interaction with multiple investigators from different sites and in different disciplines. This presentation will focus on describing practical guidelines for forming and sustaining a multi-disciplinary clinical research team at the junior faculty level.

9:00 am

Trainee presentations (7)

10:45 am

Break - Pacifica Pre Function A

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11:00 am	Trainee presentations (6)
12:30 pm	Lunch - Grande Room
1:30 pm	Trainee presentations (7)
3:15 pm	<u>Wrap - up and Summary</u> Mark A. Crowther, MD, MSc, St. Joseph's Hospital, Hamilton, ON Julie Panepinto, MD, MPH, Medical College of Wisconsin, Milwaukee, WI
6:00 pm	Dinner out

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