2015 Clinical Research Training Institute

2015 Clinical Research Training Institute Summer Workshop Curriculum
Estancia La Jolla Hotel, La Jolla, California
August 1 through August 7, 2015

Saturday, August 1

6:30 pm  Welcome Reception and Dinner – Olive Lawn

Sunday, August 2

7:00 am- 8:00 am  Participant Breakfast - Grande Room
Faculty Breakfast - Magnolia Room

8:00 am- 9:00 am  Learning Theatre
Introductions by CRTI Co-Chairs
Sarah O'Brien, MD, Nationwide Children's Hospital, Columbus, OH
Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic In Arizona, Scottsdale, AZ

9:00 am-10:00 am  The Answer Is the Question
Lillian Sung, MD, PhD, Hospital for Sick Children, Toronto, 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.

10:00 am-10:15 am  Break - Pacifica Pre Function A

10:15 am-12:00 pm  Trainee Presentations (7)
Each trainee will get 15 minutes, 10 minutes to present with five minutes for questions.

12:00 pm-12:30 pm  Lunch - Grande Room

12:30 pm-1:30 pm  Importance of Good Mentorship
Sarah O'Brien, MD, Nationwide Children's Hospital, Columbus, OH

Good mentoring is a critical component of optimizing early success as a clinical investigator. Dr. O'Brien 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. O'Brien will provide hints for how to identify a faculty member at CRTI who would be a good fit to be your personal mentor.
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.

Dr. Welniak 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 describe which NIH grant mechanisms are most appropriate for early-career clinical researchers, specifically, the mentored career development awards (F or K series) and the research grant (R series) as an Early Stage Investigator (ESI). Dr. Welniak 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-10:15 am  Break

10:15 am-11:00 am  Methods in Observational Epidemiology
Allison King, MD, MPH, Washington University, St. Louis, MO

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.

11:00 am-11:45 am  Fundamentals of Interventional Clinical Trials
Kara Kelly, MD, Columbia University, New York, NY

Assessing the quality of clinical research is fundamental to good clinical practice. Describing the strengths of a clinical 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. This lecture will review types of interventional clinical trials (Phase I – IV), and issues of randomization, blinding, and implementation of interventional clinical trials.

11:45 pm-12:45 pm  Lunch Breakout Sessions: Funding Organization Question and Answers (separate rooms)
   a. National Heart, Lung, and Blood Institute – Lis Welniak - Eucalyptus Room
   b. National Cancer Institute – William Merritt - Pepper Room
   c. ASH Awards – TBD
   d. TBD - Dracaena Room

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

Small Group 1 - Dracaena Room
Small Group 2 - Jacaranda Room
Small Group 3 - Eucalyptus Room
Small Group 4 - Juniper Room
Small Group 5 - Pepper Room
Small Group 6 - Olive Room

6:00 pm  Trip to La Jolla

7:30 pm  Dinner in La Jolla

Tuesday, August 4

7:00 am-8:00 am  Breakfast - Grande Room

8:00 am-8:45 am  Systematic Reviews and Meta-Analysis
Adam Cuker, MD, University of Pennsylvania, Philadelphia, PA
Systematic reviews have an increasingly vital role in providing reliable syntheses of research for evidence-based decision-making. This lecture will provide trainees with an understanding of the difference between a systematic review and meta-analysis, as well as an introduction to the principles, interpretation, and critical appraisal of systematic reviews.

8:45 am-9:30 am  
**Incorporating Large Database Analysis Into Your Research Portfolio**  
Ken Carson, MD, Washington University, St. Louis, MO (Oncology)  
Sarah O'Brien, MD, Nationwide Children's Hospital, Columbus, OH (Hematology)

Large administrative databases are research tools that can strengthen any basic, translational, or clinical research program. In this talk, we will discuss several commonly used databases (HCUP, Medicaid, Pediatric Health Information System), as well as their strengths and limitations. Multiple project examples will be described to highlight how administrative data can be used to generate background information or pilot data for grant applications, and keep your publication list steadily growing.

9:30 am-10:00 am  
**Comparative Effectiveness Research**  
Christopher Flowers, MD, MS, Winship Cancer Institute, Atlanta, GA

Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care. CER combines treatment efficacy data with quality of life, outcomes, and other forms of effectiveness data to guide selection of optimal patient management strategies. This lecture will provide a brief summary of the evolution of CER, common methodologies, and its significance and impact on the current research landscape.

10:00 am-10:15 am  
Break - Pacifica Pre Function A

10:15 am-11:00 am  
**Patient Reported Outcome Assessment in Clinical Trials**  
Amanda Brandow, DO, Children’s Hospital 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. In addition, the use of NIH PROMIS for measurement of patient reported outcomes will be discussed.

11:00 am-11:45 am  
**Steps Required to Initiate a Feasibility Study**  
Susan Geyer, PhD, The University of South Florida, Tampa, FL

The purpose of a feasibility study is to determine the viability of a project against factors such as investigator interest, cost, time, and resources as well as
availability of target population, local medical practices, and competing trials. It is important to identify the potential risks and possible solutions before embarking on your project.

11:45 am – 12:15 pm  Searching the Literature – More Effective and More Efficient
Elizabeth Uleryk, E.M. Uleryk Consulting, Toronto, ON

Ms. Uleryk will review the steps in running a successful literature search to find evidence-based literature to support your research and clinical needs. Using her knowledge and experience as a reference librarian, she will provide an overview of search terms, bibliographic management systems, and methods for effective and time efficient searching of the primary and secondary literature.

12:15-1:15 pm  Sessions on Demand - Box Lunch
a.  STATA Statistical Pack - Donna Neuberg - Dracaena Room
b.  Decision Analysis – Chris Flowers - Eucalyptus Room
c.  Interview Skills – Joseph Mikhael- Juniper Room
d.  Funding from NIH/PCORI – Ellen Werner - Pepper Room
e.  Overview of Dose-Finding Studies – George Tomlinson - Olive Room
f.  budget
g.  TBD - Jacaranda Room

1:15 pm-3:00 pm  How to Avoid Conflicts of Interest and Maintain Ethics (Including How to Handle Conflicts with Industry)
Sarah O'Brien, MD, Nationwide Children's Hospital, Columbus, OH
Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic In Arizona, Scottsdale, AZ

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

3:00 pm-6:00 pm  Small Group Breakout Sessions

Small Group 1 - Dracaena Room
Small Group 2 - Jacaranda Room
Small Group 3 - Eucalyptus Room
Small Group 4 - Juniper Room
Small Group 5 - Pepper Room
Small Group 6 - Olive Room
How to Obtain a Career Development Award - Panel Discussion
Adam Cuker, MD, University of Pennsylvania, Philadelphia, PA
Amanda Brandow, DO, Children’s Hospital of Wisconsin, Milwaukee, WI
Allison King, MD, MPH, Washington University, St. 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.

Wednesday, August 5

7:00 am-8:00 am  Participant Breakfast - Grande Room
Faculty Breakfast - Magnolia Room

8:00 am-8:45 am  Using Biomarkers, Profiling and Genomics in Clinical Research
Roland Walter, MD, PhD, MS, Fred Hutchinson Cancer Research Center, Seattle, WA

Biomarkers can be used to predict clinical outcome, understand drug response and resistance, and may be helpful in the selection of patient populations for novel treatments. Genomic profiling appears to be a powerful prognostic tool in various disease states, and is moving toward application in patient care. This lecture will provide a basic introduction to the application of biomarkers and profiling in clinical research.

8:45 am-10:00 am  How to Craft an Effective Research Presentation
Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic In Arizona, 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-11:00 am  **Obtaining the Drugs**  
Ruben A. Mesa, MD, Mayo Clinic, Scottsdale, AZ

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. Other challenges include negotiation with CTEP to obtain a drug that you have been studying and holding an IND when applicable. This talk also includes steps on how to submit an application to CTEP, an overview of the requirements of an IND and how to optimize your chances of success.

11:00 am – 12:00 pm  **The Challenges Facing Junior Faculty**

a. How to Get Hired/Fired  
   David Williams, MD, Boston Children’s Hospital, Boston, MA

b. How to Get Promoted/Demoted  
   Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic In Arizona, Scottsdale, AZ

12:00 pm-1:00 pm  Lunch

1:00 pm-3:00 pm  **Small Group Breakout Sessions**

Small Group 1 - Dracaena Room  
Small Group 2 - Jacaranda Room  
Small Group 3 – Eucalyptus Room  
Small Group 4 - Juniper Room  
Small Group 5 - Pepper Room  
Small Group 6 - Olive Room

4:00 pm  Meet at bus

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

**Thursday, August 6**

7:00 am-8:00 am  Breakfast - Grande Room

8:00 am-8:45 am  **Conducting Clinical Research within Cooperative Groups**

a. **COG** (8:00 am-8:15 am)  
   Kara Kelly, MD, Columbia University, New York, NY

b. **CALGB/Alliance** (8:15 am-8:30 am)  
   Wendy Stock, MD, University of Chicago, Chicago, IL

c. **BMT TCN/CIB** (8:30 am-8:45 am)  
   Navneet Majhail, MD, MS, Cleveland Clinic, Cleveland, OH
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.

8:45 am-9:45 am The ABCs of Running Clinical Trials as a Team: Panel Discussion
Wendy Stock, MD, University of Chicago, Chicago, IL
Kara Kelly, MD, Columbia University, New York, NY
Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic in Arizona, Scottsdale, AZ
Ruben A. Mesa, MD, Mayo Clinic, Scottsdale, AZ
Lillian Sung, MD, PhD, Hospital for Sick Children, Toronto, ON

The protocol is written, but now what? You’ll get tips in this presentation on how to get your study up and running and key items to consider as you begin to enroll subjects on your trial.

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.

9:45 am-10:00 am Break - Pacifica Pre Function A

10:00 am-11:00 am The Publication of Research Data: How To Write, Publish, and Avoid Getting Your Picture into the New York Times for Plagiarism
Ruben Mesa, MD, Mayo Clinic, Scottsdale, AZ

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.

11:00 am-5:30 pm Box lunch and small group time
Rehearsal of Participant Presentations - Learning Theatre
1:00 - 1:45 Group 1
1:45 - 2:30 Group 2
2:30 - 3:15 Group 3
3:15 - 4:00 Group 4
4:00 - 4:45 Group 5
4:45 - 5:30 Group 6

7:00 pm-7:45 pm Dinner with focused topics: Career Advice - La Jolla CD
- Work Life Balance - Sarah O'Brien,
- Work Life Balance – Anita Rajasekhar, Wendy Stock
- Early Clinical Trial Development – Susan Geyer,
- How to be an Effective Mentor - Joseph Mikhael, Sara Vesely
### 2015 Clinical Research Training Institute

**Friday, August 7**

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<th>Time</th>
<th>Event Description</th>
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| 7:45 pm-9:00 pm | Career Retrospective  
Wendy Stock, MD, University of Chicago, Chicago, IL |
| 7:00 am-8:00 am | Breakfast                                                                         |
| 8:00 am-10:00 am | Trainee Presentations (8)  
Each trainee will get 15 minutes, 10 minutes to present with five minutes for questions. |
| 10:00 am-10:15 am | Break - Pacifica Pre Function A  
Review Evaluations with Co-Directors |
| 10:15 am-11:45 am | Trainee Presentations (6) |
| 11:45 am-12:45 pm | Lunch - Grande Room  
Review Evaluations with Co-Directors |
| 12:45 pm-2:45 pm | Trainee presentations (8) |
| 2:45 pm-3:15 pm | Wrap-up and Summary  
Sarah O'Brien, MD, Nationwide Children's Hospital, Columbus, OH  
Joseph Mikhael, MD, FRCPC, MEd, Mayo Clinic In Arizona, Scottsdale, AZ |
| 6:00 pm | Dinner in La Jolla |