2nd Annual Clinical Trial Methods & Design Workshop for Junior Faculty

May 7-9, 2015
The Houstonian Hotel, 111 N. Post Oak Ln.
Houston, Texas

Sponsored by The Office of the Vice Provost, Clinical Research

Funding support generously provided by the Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy
Workshop Preparation

Workshop participants should come prepared to develop an MD Anderson Protocol Abstract, utilizing the institution’s abstract template, based on the clinical research concept submitted with their application. A thorough literature review of each workshop participant’s concept area is required as preparation for the workshop. Participants should have an updated draft of the concept available for discussion and be prepared to present an overview of their concept at the first small group session (Thursday, May 7th). Participants should bring a laptop computer to the workshop to facilitate completion of their daily assignments and finalization of their protocol template and concept presentation (via powerpoint).

Ground Transportation and Accommodations

The Houstonian is approximately 10 miles from MD Anderson (main building). Participants will be required to arrange for individual transportation to and from the hotel each day of the workshop. Complimentary self-parking is available. **Overnight accommodations will not be provided as a part of your workshop participation.**

Registration Information

The $500 registration fee includes your attendance at all of the sessions on Thursday morning through Saturday afternoon. Included in your registration fee are all workshop materials and meals (breaks, lunches, and dinners) throughout the event. On-site registration packets will be distributed at 7:30 a.m. on Thursday, May 7th and the first session will begin promptly at 8:00 a.m. The conference will adjourn at 4:00 p.m. on Saturday, May 9th. Please refer to the daily program schedule for a detailed summary of the daily workshop activities. To secure your registration, please complete the below information and submit to Mellanie Price at mejprice@mdanderson.org by Friday, April 3rd, 2015 to process the IDT transfer for your workshop registration:

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<tr>
<th>Participant Information:</th>
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<tr>
<td>Last Name</td>
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<td>Emergency Contact</td>
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<td>Special Assistance (If you need any special dietary or ADA accommodations): Please describe</td>
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<tr>
<th>MD Anderson Interdepartmental Transfer (IDT) No.:</th>
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<tr>
<td>Department Code:</td>
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<td>Authorized Signature REQUIRED for IDT</td>
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<td>IDT Approver Name (First/Last) please print</td>
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Questions

For any additional questions regarding the workshop requirements:

- Contact Mellanie Price, associate director, Office of the Vice Provost, Clinical Research, via email at mejprice@mdanderson.org or phone at 713-792-4392.
**THURSDAY, May 7th**

(Continental Breakfast will be provided at 7:30 am)

<table>
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<tr>
<th>Time</th>
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<td>7:00 a.m.</td>
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| 8:00 a.m. - 9:00 a.m. | “Weekend in Review” (Workshop Chairs)  
  • Welcome and Introduction to Workshop Faculty  
  • Review of Workshop Agenda, Designation of Small Groups  
  • Expectations for Participants  
  • 2014 Workshop Participant Perspective, Renata Ferrarotto, MD  
  • Designation of Small Groups |
| 9:00 a.m. - 10:30 a.m. | Study Design Considerations (Bonnie Glisson, MD; Moderator)  
  • Assessing Clinical Trial Impact, Feasibility and Funding: Bruce Minsky (30min)  
  • CTEP and Cooperative Group Trials: Cathy Eng, MD (30min)  
  • CTEP Funding Mechanisms: James Yao, MD (30min)  
  • Industry Sponsored Clinical Trial Collaborations: David Hong, MD (30min) |
| 10:30 a.m. - 12:00 p.m. | Designing Novel Clinical Trials: Statistical Considerations (Kelly Hunt, MD; Moderator)  
  • Essential Statistical Considerations: Kenneth Hess, PhD (30min)  
  • Novel Clinical Trial Designs: J. Jack Lee, PhD (30min)  
  • Bioinformatics: Issues in the Use of High-Throughput ‘Oomics’ Assays: Keith Baggerly, PhD (30min) |
| 12:00 p.m. - 2:00 p.m. | LUNCH w/ Small Groups [Protocol Development Session]  
  • Discussion of Concepts; Assignments  
    - All assigned faculty and participants will discuss draft protocol concepts and participants will present a brief overview of their proposed protocols. Faculty will outline expectations of the participants. |
| 2:00 p.m. - 2:15 p.m. | BREAK |
| 2:15 p.m. - 3:45 p.m. | Biospecimens and Biomarkers Analysis in Clinical Trials (Bruce Minsky, MD; Moderator)  
  • Image-guided Tissue Acquisition: Alda Tam, MD (30min)  
  • The Pathologist as a Study Collaborator: Ignacio Wistuba, MD (30min)  
  • Genomic Resources for Clinical Trials: Funda Meric-Bernstam, MD (30min) |
| 3:45 p.m. - 5:00 p.m. | Individual Work Sessions/ Faculty Office Hours (evening appointments up to 8:30 p.m. may also be scheduled with individual faculty)  
  Participants will meet individually with faculty and Biostat/Radiology/Pathology consults to discuss specific topics (by appointment only) |
| 5:00 p.m. - 6:00 p.m. | Quality of Life and Patient-Reported Outcomes (Bonnie Glisson, MD; Moderator)  
  • Patient-reported Outcomes for Clinical Trial Research: Charles Cleeland, MD (30min)  
  • Quality of Life Assessment in Clinical Trials: Karen Basen-Engquist, MD (30min) |
| 6:00 p.m. - 8:00 p.m. | DINNER w/ Small Groups |
FRIDAY, May 8th

8:00 a.m. - 10:00 a.m. Small Group Meetings [Protocol Development Session]
- Assignments Due
- All assigned faculty and students continue to work on protocol designs.

10:00 a.m. - 11:45 a.m. “Best Practices” for the Principal Investigator (Kelly Hunt, MD; Moderator)
- Basic Principles & Approaches for Investigator Initiated Clinical Trials: Bonnie Glisson, MD (30min)
- Clinical Trial Budget Negotiations and Contract Execution: Jason Love, MHA (15min)
- Study Initiation and Management: Elizabeth Mittendorf, MD, PhD (30min)
- Scientific and Regulatory Reviews: Steven Kornblau, MD (30min)

11:45 a.m. – 12:00 p.m. BREAK

12:00 p.m. – 2:00 p.m. WORKING LUNCH: “Mock” Clinical Research Committee (CRC) Reviews
Participants: Deadline to sign-up for Saturday “Faculty Office Hours” and Biostat/Radiology/Pathology consults
(Scheduled by appointment only from 5:00 p.m. to 8:30 p.m. with individual faculty)

2:00 p.m. – 4:00 p.m. Individual Work Sessions/Faculty Consults [All Participants]
Participants: Individual work on protocols. Biostat/Pathology/Radiology Consultations by appointment only

4:00 p.m. – 5:30 p.m. Innovative Technologies for Novel Clinical Trials
- Novel Clinical Trial Designs to Facilitate Biomarker Discovery: John Heymach, MD, PhD (30min)
- Immunotherapy Platform: Elizabeth Mittendorf, MD, PhD (30min)
- Functional Imaging: Eric Rohren, MD, PhD (30min)

5:30 p.m. – 6:30 p.m. Small Group Meetings [Protocol Development Session]
- Assignments Due
- All assigned faculty and students continue to work on protocol designs.

6:30 p.m. – 8:00 p.m. DINNER
SATURDAY, May 9th  (Continental Breakfast will be provided at 7:30 am)

8:00 a.m. – 10:00 a.m.  Presentations within Small Groups [Powerpoint Presentations]
All Participants present protocols and finalize concept development with faculty.

10:00 a.m. – 11:00 a.m.  BREAK/Group Leaders Meeting

11:00 a.m. – 12:30 p.m.  LUNCH
Participants: Individual Work Sessions/ Faculty Consults [All Participants]

12:30 p.m. – 3:30 p.m.  Selected Protocol Presentations (Bonnie Glisson, MD; Moderator)
Participants present selected protocol presentations to entire group. (30 min each)

3:30 p.m. – 4:00 p.m.  CLOSING REMARKS:
Final Comments and Post-Workshop Evaluations (Workshop Chairs)

4:00 p.m.  Adjourn