Achieving Excellence in Clinical Research

Scientific, Ethical and Operational Considerations

Friday, September 19, 2014
7:30 am – 4:30 pm

McDonald’s Hamburger University
Oak Brook, Illinois
## Achieving Excellence in Clinical Research

*Scientific, Ethical and Operational Considerations*

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:30 am – 8:15 am</td>
<td><strong>Conference check-in, continental breakfast and exhibit viewing</strong></td>
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| 8:15 am – 8:30 am | **Welcome and Opening Remarks**  
  Denise Angst, PhD, RN, Director, Advocate Center for Pediatric Research  
  Susan Campbell, DNP, RN, NEA-BC, Senior Vice President and Chief Nursing Officer, Advocate Health Care |
| 8:30 am – 9:15 am | **Plenary I**  
  *Back to the Future: Redeveloping Clinical Research in Resource Challenged Environments*  
  Marion Broome, PhD, RN, FAAN, Dean and Vice-Chancellor for Nursing Affairs, Duke University; Associate Vice President for Academic Affairs for Nursing, Duke University Health System; Editor, Nursing Outlook, Official Journal of the American Academy of Nursing |
| 9:15 am – 10:00 am | **Plenary II**  
  *Empowering the Public to Participate in Research*  
  Sharon Terry, MA, President and CEO, Genetic Alliance, Washington, DC |
| 10:00 am – 10:15 am | **Break**  
  · Refreshments and Exhibit Viewing |
| 10:15 am – 11:45 am | **Plenary III**  
  *Comparative Effectiveness Research and the SUPPORT Trial: A Debate and Dialogue*  
  Moderator: Denise Angst, PhD, RN  
  Discussants: Leonard Glantz, JD, Professor of Health Law, Bioethics and Human Rights, Boston University School of Public Health, and David Magnus, PhD, Thomas A. Raffin Professor of Medicine and Biomedical Ethics, and Professor of Pediatrics, Stanford University |
| 11:45 am – 1:00 pm | **Lunch** |
| 1:00 pm – 2:00 pm | **Breakout Session #1**  
  **A. Children as Research Subjects: What (if anything) Makes This Ethical?**  
  Leonard Glantz, JD, Professor of Health Law, Bioethics and Human Rights, Boston University School of Public Health  
  **B. Risk and Consent in Comparative Effectiveness Research: Perspectives of Patients and the IRB Community**  
  David Magnus, PhD, Thomas A. Raffin Professor of Medicine and Biomedical Ethics, and Professor of Pediatrics, Stanford University  
  **C. Show Me the Money: Including Cost Analysis in Research and QI Projects**  
  Surrey Walton, PhD, Associate Professor in Pharmacy Systems Outcomes and Policy, and Assistant Director of the Center for Pharmacoepidemiology and Pharmacoeconomic Research, University of Illinois at Chicago  
  **D. Strategies to Become a Successful Author**  
  Marion Broome, PhD, RN, FAAN, Dean and Vice-Chancellor for Nursing Affairs, Duke University; Associate Vice President for Academic Affairs for Nursing, Duke University Health System; Editor, Nursing Outlook, Official Journal of the American Academy of Nursing |

### Objectives:

At the conclusion of this conference, participants should be able to:

- Describe methods to redevelop clinical research in resource challenged environments
- Identify ways that empower the public to participate in research
- Recognize risks and proper consenting processes when research involves standard of care interventions
- Identify when an IND/IDE application is needed, the necessary contents and the regulatory obligations of the IND/IDE sponsor-investigator
- Examine important legal and ethical considerations when children are involved in research participation decisions
- Identify when and how to use cost analyses in research and QI projects
- Discuss issues related to creating a manuscript and how to respond to publishing decisions and revisions
- Strategize various methods to recruit and retain research subjects
- Comprehend various perspectives related to the meaning of research risks in comparative effectiveness studies
- Describe effective strategies for enhancing the research mentor-mentee relationship
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2:00 pm – 2:15 pm  Break · Refreshments and Exhibit Viewing

2:15 pm – 3:15 pm  Breakout Session #2

A. Meeting Your Enrollment Targets: Effective Strategies to Engage Research Participants
Sharon Terry, MA, President and CEO, Genetic Alliance, Washington, DC

B. Investigator-initiated Research: Navigating the IND/ IDE Process
Sara F. Goldkind, MD, MA, Bioethics Consultant, Potomac, MD; Former Senior Bioethicist, Office of Good Clinical Practice, Office of the Commissioner, Food and Drug Administration

C. Children as Research Subjects: What (if anything) Makes This Ethical?
Leonard Glantz, JD, Professor of Health Law, Bioethics and Human Rights, Boston University School of Public Health

D. Research Mentors and Mentees: Enhancing the Collaborative Relationship
Anne Marie Weber-Main, PhD, Associate Professor, Department of Medicine, Director of Faculty Mentoring, Office of Faculty Affairs, University of Minnesota Medical School

3:15 pm – 3:30 pm  Break · Refreshments and Exhibit Viewing

3:30 pm – 4:30 pm  Breakout Session #3

A. Investigator-initiated Research: Navigating the IND/ IDE Process
Sara F. Goldkind, MD, MA, Bioethics Consultant, Potomac, MD; Former Senior Bioethicist, Office of Good Clinical Practice, Office of the Commissioner, Food and Drug Administration

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D. Research Mentors and Mentees: Enhancing the Collaborative Relationship
Anne Marie Weber-Main, PhD, Associate Professor, Department of Medicine, Director of Faculty Mentoring, Office of Faculty Affairs, University of Minnesota Medical School

Target Audience: Physicians, nurses, research staff, administrators, IRB members, industry professionals and others involved or interested in clinical research.

Format: Lecture, panel discussion

Continuing Education Credits

Physicians: Advocate Health Care is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. Advocate Health Care designates this live activity for a maximum of 6 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses: Advocate Health Care (OH-368, 10/1/2014) is an approved provider of continuing nursing education by the Ohio Nurses Association (OBN-001-91), an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation.

Upon successful completion of this continuing education activity, 6.0 contact hours will be awarded.

Criteria for successful completion: Attendance at entire event and completed evaluation form.

Financial Support: Educational grants and full exhibitor listing will be disclosed on the day of the program.
Registration Form: Achieving Excellence in Clinical Research
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Friday September 19, 2014

Registration Fees

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<th>Before 8/25/14</th>
<th>On or after 8/25/14</th>
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<tr>
<td>Advocate Associates, Residents and Fellows</td>
<td>$100</td>
<td>$125</td>
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<tr>
<td>Advocate Attending Physicians</td>
<td>$150</td>
<td>$175</td>
</tr>
<tr>
<td>Non-Advocate Trainees and Full-Time Students (proof required)</td>
<td>$150</td>
<td>$175</td>
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<tr>
<td>Non-Advocate Attendees</td>
<td>$200</td>
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Intended Breakout Sessions (Circle one choice for each session)

- Breakout Session #1
  - A
  - B
  - C
  - D

- Breakout Session #2
  - A
  - B
  - C
  - D

- Breakout Session #3
  - A
  - B
  - C
  - D

Name ___________________________
Title ___________________________
Institution _______________________
Department / Division _____________
Telephone _________________________
E-mail ___________________________

Preferred Mailing Address:
Street Address _______________________
City, State, Zip _______________________

Special Seating/Mobility Needs: _______________________

Meal Choice:
- Chicken
- Vegetarian

Completion Certificate Requested:
- CME
- Nursing Contact Hours

Check enclosed

Please return this form to:
Sandy Maki
Advocate Center for Pediatric Research
Advocate Children’s Hospital – Park Ridge
1775 Dempster Street – 2 East Pavilion
Park Ridge, IL  60068

Registration Deadline: September 10, 2014
For Additional Information Contact:
847.723.2164 – Advocate Center for Pediatric Research

Faculty Disclosure: Acknowledgement of all disclosures will be made at each session. Conflicts of interests will be identified and resolved prior to the conference.

Location:
Hamburger University
McDonald’s Office Campus
2715 Jorie Boulevard, Oak Brook, IL 60523
630.568.1234

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Registration Deadline: September 10, 2014 (as space allows).
Attendance is limited and registration will be taken on a first come, first served basis; please register early. Fees include program materials, continental breakfast, refreshment breaks and seated lunch.

How to Register:
Register with your credit card via the internet at: advocatehealth.com/seminars

or

Complete the above registration form, include a check payable to “Advocate Health Care” and return to:
Advocate Center for Pediatric Research – Attn: Sandy Maki
Advocate Children’s Hospital – Park Ridge
1775 Dempster Street – 2 East Pavilion
Park Ridge, IL  60068