Achieving Excellence in Clinical Research
Scientific, Ethical and Operational Considerations

Friday, September 30, 2016
7:30 am – 4:30 pm
McDonald’s Hamburger University
Oak Brook, Illinois

7:30 – 8:15 am
Conference Check-in, Continental Breakfast and Exhibit Viewing

8:15 – 8:30 am
Welcome and Opening Remarks
Denise Angst, PhD, RN, Director, Advocate Center for Pediatric Research
Rishi Sikka, MD, Senior Vice President, Clinical Operations, Advocate Health Care

8:30 – 9:15 am
Plenary I
Leveraging Big Data for Clinical Research
Connie White Delaney, PhD, RN, FAAN, FACMI, Dean, School of Nursing, University of Minnesota

9:15 – 10 am
Plenary II
How Do You Know What You Think You Know?
Richard Gorman, MD, Associate Director for Clinical Research, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, NIH

10 – 10:15 am
Break - Refreshments and Exhibit Viewing

10:15 – 11 am
Plenary III
The Changing Landscape of Human Subjects Research
P. Pearl O’Rourke, MD, Director, Human Research Affairs, Director, ESCRO, Partners HealthCare

11 – 11:45 am
Panel Discussion with Plenary Speakers
Lunch

11:45 am – 1 pm
Breakout Session #1
A. Using Big Data to Evaluate Clinician-sensitive Outcomes
Connie White Delaney, PhD, RN, FAAN, FACMI, Dean, School of Nursing, University of Minnesota

B. Communicating Results to Research Subjects: Who Should Return What? To Whom? When?
P. Pearl O’Rourke, MD, Director, Human Research Affairs, Director, ESCRO, Partners HealthCare

C. Therapeutic Misconception and the Clinical Investigator: Beyond Protocol Deviations
Kristen Grace, MD, PhD, Director, Human Research Integrity and Education, Weill Cornell Medicine, New York-Presbyterian

D. Health Literacy: Fostering Comprehension for Research Subjects
Laurie Myers, MBA, Global Health Literacy Director, Merck & Co., Inc.

2 – 2:15 pm
Break - Refreshments and Exhibit Viewing

2:15 – 3:15 pm
Breakout Session #2
A. Using Big Data to Evaluate Clinician-sensitive Outcomes
Connie White Delaney, PhD, RN, FAAN, FACMI, Dean, School of Nursing, University of Minnesota

B. Building Successful Academic, Corporate and Clinical Partnerships to Advance Your Research
Nancy M. Albert, PhD, CCNS, CCRN, NE-BC, FAAN, Associate Chief Nursing Officer, Nursing Research and Innovation - Nursing Institute and Clinical Nurse Specialist-Kaufman Center for Heart Failure, Cleveland Clinic

C. Therapeutic Misconception and the Clinical Investigator: Beyond Protocol Deviations
Kristen Grace, MD, PhD, Director, Human Research Integrity and Education, Weill Cornell Medicine, New York-Presbyterian

D. Keeping the Spark Alive During Long-term Clinical Trials
Marianne Gildea, RN, BSN, MS, CCRC, Program Director of THAPCA Trials, University of Utah and Sally Jo Zuspan, RN, MSN, DCC Program Director, University of Utah

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

3:30 – 4:30 pm
Breakout Session #3
A. Building Successful Academic, Corporate and Clinical Partnerships to Advance Your Research
Nancy M. Albert, PhD, CCNS, CCRN, NE-BC, FAAN, Associate Chief Nursing Officer, Nursing Research and Innovation - Nursing Institute and Clinical Nurse Specialist-Kaufman Center for Heart Failure, Cleveland Clinic

B. Keeping the Spark Alive During Long-term Clinical Trials
Marianne Gildea, RN, BSN, MS, CCRC, Program Director of THAPCA Trials, University of Utah and Sally Jo Zuspan, RN, MSN, DCC Program Director, University of Utah

C. Clinical Research in Pregnant Women: Process, Promise and Perils
Richard Gorman, MD, Associate Director for Clinical Research, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, NIH

D. Health Literacy: Fostering Comprehension for Research Subjects
Laurie Myers, MBA, Global Health Literacy Director, Merck & Co., Inc.
Objectives
At the conclusion of this conference, participants will be able to:

• Comprehend the reasons for and implementation of information review systems (GRADE) that reduce the possibility of bias in recommendations
• Discuss benefits and boundaries of inter- and intra-professional collaborations
• Identify both the need and challenges of executing clinical research in pregnant women
• Discuss the need for health literacy principles in research, using a case study on returning results to patients
• Demonstrate interactive training and motivational techniques to keep study personnel engaged during a multi-year study
• Describe how human subject research has changed over recent history and the realities and challenges we can expect in the near future
• Identify challenges and best practices when it comes to communicating results to research subjects
• Discuss how investigators can use big data from electronic medical records and other data sources to address important clinical research questions
• Identify, in this more “nuts and bolts” session, key strategies and tactics that investigators should consider in using big data to evaluate clinician-sensitive outcomes
• Define “therapeutic misconception” and understand its role in clinical study data integrity, specifically as it relates to the clinician-researcher

Nurses will apply knowledge of scientific, ethical and operational considerations when participating in clinical research.

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 is an approved provider of continuing nursing education by the Ohio Nurses Association an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation (OBN-001-91), (OH-368, 10/1/2017).

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: Acknowledgement of educational grants and full exhibitor listing will be made on the day of the program.

Faculty Disclosure: Acknowledgement of all disclosures, i.e., nothing to disclose or the existence of relevant financial relationships, will be made at the activity. Conflicts of interest will be identified and resolved prior to the conference.

Location
Hamburger University
McDonald’s Office Campus
2715 Jorie Boulevard, Oak Brook, IL 60521
630.568.1234

Registration Fees:

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<tr>
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<th>Before September 1, 2016:</th>
<th>On or after September 1, 2016:</th>
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<tr>
<td>Advocate Associates, Residents, Fellows and Attending Physicians</td>
<td>$125</td>
<td>$175</td>
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<tr>
<td>Non-Advocate Trainees and Full-time Students (proof required)</td>
<td>$125</td>
<td>$175</td>
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<tr>
<td>Non-Advocate Attendees</td>
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Registration Deadline: September 23, 2016 (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: https://www.eventbrite.com/e/achieving-excellence-in-clinical-research-2016-registration-26283404370
or
Complete the adjacent registration form, include a check payable to Advocate Health Care and return to:
Advocate Center for Pediatric Research – Attn: Sandy Maki, MAT
Advocate Children’s Hospital – Park Ridge
1775 Dempster Street – 2 East Pavilion
Park Ridge, IL 60068
or
Advocate employees can contact Sandy Maki directly at 847.723.2164 regarding a cost center transfer.
Registration Form

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Registration Fees:

- Advocate Associates, Residents, Fellows and Attending Physicians $125 $175
- Non-Advocate Trainees and Full-time Students (proof required) $125 $175
- Non-Advocate Attendees $200 $250

Intended Breakout Sessions (Circle one choice for each session)

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<th>Breakout Session #1</th>
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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
- Generic Continuing Education

Check enclosed

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

Registration Deadline: September 23, 2016
(as space allows)

For Additional Information Contact:
847.723.2164 – Advocate Center for Pediatric Research

Advocate Health Care