Achieving Excellence in Clinical Research
Scientific, Ethical and Operational Considerations
Wednesday, September 27, 2017
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, Vice President, Research, Advocate Health Care
Thomas Hansen, MD, Chief Academic Officer, Advocate Health Care

8:30 – 9:15 am
Plenary I
Improving Health Care Quality and Patient Safety through Research*
Carolyn Clancy, MD, MACP, Deputy Under Secretary for Health for Organizational Excellence, Department of Veterans Affairs

9:15 – 10 am
Plenary II
How Sex Differences Influence the Brain and Body: An Issue Whose Time Has Come*
Larry Cahill, PhD, Professor, Neurobiology and Behavior, School of Biological Sciences, University of California, Irvine

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

10:15 – 11 am
Plenary III
Implementation Science at the Frontline: Design and Lessons Learned*
Mary A. Dolansky, PhD, RN, FAAN, Associate Professor at the Frances Payne Bolton School of Nursing, Case Western Reserve University, Director of the QSEN Institute (Quality and Safety Education for Nurses)

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

11:45 am – 1 pm
Lunch

1– 2 pm
Breakout Session #1
A. Translational Research and Use of Collaboratives to Expedite Standards of Care*
Carolyn Clancy, MD, MACP, Deputy Under Secretary for Health for Organizational Excellence, Department of Veterans Affairs

B. Medical Device Trials: Rethinking Informed Consent*
E. Haavi Moreim, JD, PhD, Professor, Department of Internal Medicine College of Medicine, University of Tennessee Health Science Center

C. Countdown to the Common Rule Changes: How Should We Prepare?*
Ryan Meade, JD, Director, Regulatory Compliance Studies, Beazley Institute for Health Law and Policy, Loyola University Chicago School of Law

D. ‘You’ve Gotta Be a Soldier’: Experiences of the Professional ‘Lab Rat’ in Pharmaceutical Studies*
Jill A. Fisher, PhD, Associate Professor of Social Medicine and Bioethics, University of North Carolina at Chapel Hill

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

2:15 – 3:15 pm
Breakout Session #2
A. Continuing Dialogue on the Influences of Sex: Considerations for the Clinic and Research Protocols*
Larry Cahill, PhD, Professor, Neurobiology and Behavior, School of Biological Sciences, University of California, Irvine

B. Medical Device Trials: Rethinking Informed Consent*
E. Haavi Moreim, JD, PhD, Professor, Department of Internal Medicine College of Medicine, University of Tennessee Health Science Center

C. The 10 Commandments for Principal Investigators*
Randall R. Stoltz, MD, CPI, Medical Director, Covance Clinical Research Unit, Evansville, Indiana

D. Beyond Audit Survival: The Busy Clinical Research Professional’s Guide to Audit Preparation*
Lisa Haney, BS, Clinical Operations Manager, Lutonix, Inc., A subsidiary of C.R. Bard

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

3:30 – 4:30 pm
Breakout Session #3
A. Successful Implementation and Evaluation of Innovative Strategies to Improve Nursing Care
Mary A. Dolansky, PhD, RN, FAAN, Associate Professor at the Frances Payne Bolton School of Nursing, Case Western Reserve University, Director of the QSEN Institute (Quality and Safety Education for Nurses)

B. Beyond Audit Survival: The Busy Clinical Research Professional’s Guide to Audit Preparation*
Lisa Haney, BS, Clinical Operations Manager, Lutonix, Inc., A subsidiary of C.R. Bard

C. ‘You’ve Gotta Be a Soldier’: Experiences of the Professional ‘Lab Rat’ in Pharmaceutical Studies*
Jill A. Fisher, PhD, Associate Professor of Social Medicine and Bioethics, University of North Carolina at Chapel Hill

D. The 10 Commandments for Principal Investigators*
Randall R. Stoltz, MD, CPI, Medical Director, Covance Clinical Research Unit, Evansville, Indiana

*Approved for AMA PRA Category 1 Credit™
Objectives
At the conclusion of this conference, participants will be able to:

• Discuss strategies to incorporate research evidence to inform and improve quality of care and patient safety
• Recognize the need to consider sex influences to provide equal medical treatment for women and men
• Discuss the similarities and differences among research, quality improvement and implementation science in developing study protocols
• Describe the benefits of participating in research collaborative partnerships in order to guide changes in patient care based on evidence
• Comprehend the multiple ways that sex influences can impact the etiology of disease
• Identify the “typical” participants who enroll in Phase I trials as healthy volunteers, focusing on demographic trends, patterns of participation, and their perceptions of the risks and benefits, and discuss how this relates to participants enrolling in Phase II and III studies
• Discuss examples of specific implementation strategies and plans for evaluation
• Describe strategies to formulate a plan to be audit ready at all times
• Discuss the purposes of informed consent when enrolling into a medical device study
• Comprehend changes to the Common Rule scheduled to be effective in January 2018 and manage compliance with the changes
• Discuss the responsibilities of the PI and other key players in the drug and device development industry in studies involving human subjects
• Design ethical research studies that improve safety and quality of patient care

Desired Nurse Learner Outcome: 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 (ONB-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>
<th>Before September 1, 2017:</th>
<th>On or after September 1, 2017:</th>
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<tr>
<td>Advocate Associates, Residents, Fellows and Attending Physicians</td>
<td>$125</td>
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<tr>
<td>Non-Advocate Trainees and Full-Time Students (proof required)</td>
<td>$125</td>
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<tr>
<td>Non-Advocate Attendees</td>
<td>$200</td>
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Registration Deadline: September 15, 2017 (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-2017-tickets-35204173631

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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Wednesday, September 27, 2017

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September 1, 2017: September 1, 2017:
☐ 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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<tr>
<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  ☐ Chicken (gluten free)

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 15, 2017
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For Additional Information Contact:
847.723.2184 – Advocate Center for Pediatric Research