

## Sub-Course Abbreviations

**BDC:** Biostatistics and design considerations**AGQ:** Asking good questions**TLC:** Trial logistical considerations**RR:** Responsible research**CENTRAL/FOUNDATIONS TRACK AGENDA**

While we are not requiring 16 hour days, we want the course participants to make as much progress on fully developing protocols during this 3.5 day period. We are recommending working dinners on Tuesday and Thursday within the small groups. In addition, course faculty will be available for one-on-one meetings with trainees within their small groups, and/or with trainees from other small groups.

**Monday, August 7**

- 5:00pm Faculty meeting – *Lindquist Room*
- 6:00 Networking Reception – *Amos Dean Ballroom A, B*
- 7:00 Welcome Dinner – Welcome to Residential Course: **Will Meurer**
- 8:00 Keynote presentation: **Jeff Saver and Roger Lewis**

**Tuesday, August 8**

- 7:30-8:00 Registration and breakfast – *Pre-function area outside of Amos Dean Ballroom A, B*
- 8:00-8:15 Introduction to Course: **Will Meurer** – *Amos Dean Ballroom A, B*
- 8:15-9:00 **Overview of clinical trials:** **Eric Foster** – *Amos Dean Ballroom A, B*
- 9:00-9:45 **Clinical Trial Networks: NeuroNEXT, StrokeNET, SIREN:** **Bill Barsan, Chris Coffey, Robin Conwit, Pooja Khatri** – *Amos Dean Ballroom A, B*
- 9:45-10:00 Break
- 10:00-10:45 **Selecting Outcome Measures for Neuroscience Trials:** **Jeremy Shefner** – *Amos Dean Ballroom A, B*
- 10:45-11:30 **Biomarkers and Surrogate Endpoints:** **Merit Cudkowicz** – *Amos Dean Ballroom A, B*
- 11:30-12:30 **BREAKOUT Small Group Meeting 1** (see topics and locations on page 3)
- 12:30-1:15 Lunch – *Pre-function area outside of Amos Dean Ballroom A, B*
- 1:15-2:00 **Clinical trial case studies from NeuroNEXT:** **Chris Coffey** – *Amos Dean Ballroom A, B*
- 2:00-2:45 **Developing a statistical plan/objectives pertaining to “safety”:** **Jordan Elm** – *Amos Dean Ballroom A, B*
- 2:45-3:00 Break
- 3:00-3:45 **Multiplicity: Incentives and risks of fooling oneself:** **Michelle Detry** – *Amos Dean Ballroom A, B*
- 3:45-4:30 **INDs/IDEs – Perspectives of Sponsor Investigators:** **Pooja Khatri, Jeff Saver** – *Amos Dean Ballroom A, B*

- Evening Small Group work and/or dinner with your small group (*List of area restaurants available at the hotel front desk*)

## Wednesday, August 9

- 7:30-8:00 Networking and breakfast – *Pre-function area outside of Amos Dean Ballroom A, B*
- 8:00-8:15 Introduction to Day 2 (Clinicaltrials.gov): **Will Meurer** – *Amos Dean Ballroom A, B*
- 8:15-9:00 **Recruitment and retention/enrolling representative populations** **Joshua Grill** – *Amos Dean Ballroom A, B*
- 9:00-9:45 **BREAKOUT Small Group Meeting 2** (see topics and locations on page 3)
- 9:45-10:00 Break
- 10:00-10:45 **Career development mechanisms at NINDS**: **Stephen Korn** – *Amos Dean Ballroom A, B*
- 10:45-12:30 **STUDY HALL/Faculty Office Hours** – Meet with recruitment/logistics experts/faculty who are not in your small group. See details on page 4.
- 12:30-1:15 Lunch – boxed lunches will be provided – *Pre-function area outside of Amos Dean Ballroom A, B*
- 1:15-3:00 **STUDY HALL/Faculty Office Hours** – Meet with recruitment/logistics experts/faculty who are not in your small group. See details on page 4.
- 3:00-3:45 **What does an IRB do?** **Roger Lewis** – *Amos Dean Ballroom A, B*
- 3:45-4:30 **DSMBs and the clinical monitoring of trials/role of medical safety monitor**: **Roger Lewis, Robin Conwit**
- 4:30 – 5:00 GROUP PHOTO – Pedestrian Mall outside the Sheraton
- 6:30-8:00 **American Academy of Neurology Sponsored** Group Dinner and Professional Autobiographies of Clinical Trialists: **Erika Augustine, Chris Coffey, Wendy Galpern** – *Joseph's Steakhouse (212 South Clinton Street)*

## Thursday, August 10

- 7:30-8:00 Networking and breakfast – *Pre-function area outside of Amos Dean Ballroom A, B*
- 8:00-8:15 Introduction to Day 3: **Will Meurer** – *Amos Dean Ballroom A, B*
- 8:15-9:00 **Your Date at the PROM: Patient Reported Outcome Measures**: **Brett Kissela, Laurie Gutmann** – *Amos Dean Ballroom A, B*
- 9:00-9:45 **A Brief Introduction to Adaptive Designs /Clinical Trial Simulation**: **Kert Viele** – *Amos Dean Ballroom A, B*
- 9:45-10:00 Break
- 10:00-10:45 **Clinical Trials in Rare Diseases**: **Erika Augustine** – *Amos Dean Ballroom A, B*
- 10:45-11:30 **High yield points for protocols / manuals of procedures: ensuring reproducible research**: **Dixie Ecklund, Marianne Kearney Chase** – *Amos Dean Ballroom A, B*
- 11:30-12:30 **Rotation A through small groups** (see topics and locations on page 4)
- 12:30-1:15 Lunch – *Pre-function area outside of Amos Dean Ballroom A, B*
- 1:15-2:00 **Pragmatic trials**: **Roger Lewis** – *Amos Dean Ballroom B*
- 2:00-3:00 **Rotation B through small groups** (see topics and locations on page 4)
- 3:00-4:00 **Rotation C through small groups** (see topics and locations on page 4)
- 4:00-5:00 **Rotation D through small groups** (see topics and locations on page 4)

- 5:00-6:00 **Biostatistics vs Clinical Neuroscience Knowledge Contest: CTMC course directors** – Amos Dean Ballroom B
- 6:00 Dinner on your own (meet with people outside the course or other faculty/trainees) - *list of area restaurants available at hotel front desk*

**Friday, August 11**

- 7:30-8:00 Networking and breakfast – *Pre-function area outside of Amos Dean Ballroom A, B*
- 8:00-8:15 Introduction to Day 4: **Will Meurer** – Amos Dean Ballroom A, B
- 8:15-9:00 Return of the Jedi – After the CTMC **Andy Southerland** – Amos Dean Ballroom A, B
- 9:00-9:45 **How to be an effective consumer of preclinical data** : **Dietrich Haubenberger, Wendy Galpern** – Amos Dean Ballroom A, B
- 9:45-10:00 Break
- 10:00-10:45 **BREAKOUT Small Group Meeting 3** (*see topics and room locations on page 4*)
- 10:45-11:30 **Partnering with industry/foundations** - **Michael Shy** – Amos Dean Ballroom A, B
- 11:30 – 12:15 Closing remarks and residential course evaluations – Amos Dean Ballroom A, B
- 12:15 Adjourn didactic sessions – Boxed lunches in *Pre-function area outside of Amos Dean Ballroom A, B*
- 1:00 Additional potential office hours for those still in Iowa City / additional protocol writing time

**Breakout Small Group Meeting Topics and Locations**

In each small group meeting, the trainees will report to their peers and small group leaders regarding their current status.

**Breakout Small Group Meeting 1:** Describe current status of protocol and areas for improvement while in Iowa

**Breakout Small Group Meeting 2:** Describe status of plan for IND/IDE, “safety” and human subjects’ protections and areas for development

**Breakout Small Group Meeting 3:** Describe plan for recruitment, retention and enrollment and areas for development, budget, MOP/operations

<b>GROUP 1</b> <i>Dean C</i>	<b>GROUP 2</b> <i>Johnson 3</i>	<b>GROUP 3</b> <i>Carver A</i>	<b>GROUP 5</b> <i>Carver B</i>
<b>GROUP 6</b> <i>Dean C</i>	<b>GROUP 7</b> <i>Dean C</i>	<b>GROUP 9</b> <i>Dean D</i>	<b>GROUP 10</b> <i>Dean D</i>

### **STUDY HALL/Faculty Office Hours (Wednesday, August 9)**

Faculty and other clinical trial experts outside your small group will have 30 minute blocks of time to meet with trainees or groups of trainees regarding their projects on Wednesday, August 9. For example, you might want to meet with a stroke faculty member outside of your small group. Alternatively, you may want to meet with other residential course faculty from NETT/NeuroNEXT/StrokeNET/Berry Consultants.

**Use this link to sign up online. Keep track of who you sign up to meet with and the time.**

<http://bit.ly/CTMCsignup>

Faculty bios and contact information are available in the directory on the course website

<https://nett.umich.edu/training/ctmc/ctmc-directory>

**The central meeting place for appointments will be Amos Dean Ballroom B. If you sign up for multiple meetings, please be sure to return to this room in time to meet your next appointment.**

### **Rotation through Small Groups (Thursday, August 10)**

	<b>GROUP 1,2 Carver A</b>	<b>GROUP 3,5 Carver B</b>	<b>GROUP 6,7 Dean C</b>	<b>GROUP 9, 10 Dean D</b>
<b>ROTATION A 11:30 to 12:30</b>	Recruitment: Joshua Grill	Free Time (Meet with core faculty or work on protocol)	Budget: Maggie Spencer /Kristine Hardin	Logistics: Dixie Ecklund
<b>ROTATION B 2:00 to 3:00</b>	Logistics: Dixie Ecklund	Recruitment: Joshua Grill	Free Time (Meet with core faculty or work on protocol)	Budget: Maggie Spencer /Kristine Hardin
<b>ROTATION C 3:00 to 4:00</b>	Budget: Maggie Spencer /Kristine Hardin	Logistics: Dixie Ecklund	Recruitment: Joshua Grill	Free Time (Meet with core faculty or work on protocol)
<b>ROTATION D 4:00 to 5:00</b>	Free Time (Meet with core faculty or work on protocol)	Budget: Maggie Spencer /Kristine Hardin	Logistics: Marianne Kearney-Chase	Recruitment: Joshua Grill

### **Faculty List**

#### **Course Directors**

Chris Coffey, PhD: Professor of Biostatistics, University of Iowa

Robin Conwit, MD: Program Director, Office of Clinical Research, National Institute of Neurological Disorders and Stroke

Laurie Gutmann, MD: Professor, Vice Chair of Clinical Research, Department of Neurology, University of Iowa

Roger Lewis, MD, PhD: Professor of Emergency Medicine, Harbor-UCLA Medical Center

William Meurer, MD, MS: Associate Professor of Emergency Medicine and Neurology, University of Michigan

### **Core Faculty (Small group leaders)**

Erika Augustine, MD, MS: Assistant Professor of Neurology and Pediatrics, University of Rochester

Bill Barsan, MD: Professor of Emergency Medicine, University of Michigan

Kristine Broglio, MS: Statistical Scientist, Berry Consultants, LLC

Ken Cheung, PhD: Professor of Biostatistics, Columbia University

Michelle Detry, PhD: Statistical Scientist, Berry Consultants, LLC

Valerie Durkalski-Mauldin, PhD, MPH: Professor of Biostatistics, Medical University of South Carolina

Jordan Elm, PhD: Research Associate Professor of Biostatistics, Medical University of South Carolina

Eric Foster, PhD: Clinical Assistant Professor of Biostatistics, University of Iowa

Wendy Galpern, MD, PhD: Medical Director, Neuroscience Clinical Development Group, Janssen Research and Development

Adam Hartman, MD, FAAP, FANA, FAES: Program Director, Division of Clinical Research, NINDS

Dietrich Haubenberger, MD: Director, Clinical Trials Unit, NINDS

Pooja Khatri, MD: Professor of Neurology, University of Cincinnati

Brett Kissela, MD: Professor and Chair of Neurology and Rehabilitation Medicine, University of Cincinnati

Anna McGlothlin, PhD: Statistical Scientist, Berry Consultants, LLC

Jeremy Shefner, MD, PhD: Professor and Chair of Neurology, Associate Director, Barrow Neurological Institute

Kert Viele, PhD: Statistical Scientist, Berry Consultants, LLC

Sharon Yeatts, PhD: Research Associate Professor of Biostatistics, Medical University of South Carolina

### **Residential Course Faculty**

Merit Cudkowicz, MD, MSc: Professor of Neurology, Massachusetts General Hospital (MGH) / Harvard University

Dixie Ecklund RN, MSN, MBA: Associate Director, Clinical Trials Statistical & Data Management Center, University of Iowa

Joshua Grill, PhD: Adjunct Associate Professor of Psychiatry and Human Behavior, Associate Director, Alzheimer's Disease Research Center, UCI

Kris Hardin, MS: Research Administrator, Department of Neurology, University of Iowa

Marianne Kearney Chase: Director of Research Operations, Neurological Clinical Research Institute (NCRI), MGH

Stephen Korn, PhD: Director, Office of Training, Career Development & Workforce Diversity, NINDS

Jeffrey Saver, MD, FAHA, FAAN, FANA: Professor of Neurology, Senior Associate Vice Chair for Clinical Research, Director, UCLA Comprehensive Stroke Center

Michael Shy, MD: Professor of Neurology, University of Iowa

Andy Southerland, MD, MSc: Assistant Professor of Neurology and Public Health Sciences, Adult Neurology, Residency Program Director, University of Virginia

Maggie Spencer: Research Support Specialist, Clinical Trials Statistical Data Management Center, Department of Biostatistics, University of Iowa

Valerie Stevenson, BAS, RRT, CCRP: Administrative Director, Neurological Emergencies Treatment Trials, University of Michigan

**Residential Course evaluation link: [bit.ly/iowa2017](http://bit.ly/iowa2017)**

Please complete an online evaluation for each didactic session. Check off the evaluations which you have completed, below.

Monday, August 7	Tuesday, August 8	Wednesday, August 9
<input type="checkbox"/> Keynote Address: Jeff Saver, Roger Lewis	<input type="checkbox"/> Overview of clinical trials – Eric Foster	<input type="checkbox"/> Recruitment and retention – Joshua Grill
<p><b>NOTES:</b> CME requests must be submitted within 30 days of the residential course. You must complete an overall course evaluation on August 11, at the end of the course, to request CMEs. Please email CME requests to <a href="mailto:ninds-ctmc-info@umich.edu">ninds-ctmc-info@umich.edu</a></p>	<input type="checkbox"/> Clinical Trials Networks (NeuroNEXT, SIREN, StrokeNET): Panel	<input type="checkbox"/> Career development mechanisms at NINDS – Stephen Korn
	<input type="checkbox"/> Selecting outcome measures for neuroscience trials– Jeremy Shefner	<input type="checkbox"/> What does an IRB do? – Roger Lewis
	<input type="checkbox"/> Biomarkers – Merit Cudkowicz	<input type="checkbox"/> DSMBs and medical safety monitors – Robin Conwit/Roger Lewis
	<input type="checkbox"/> Clinical Trials Case studies from NeuroNEXT – Chris Coffey	<input type="checkbox"/> Professional Autobiographies - Panel
	<input type="checkbox"/> Developing statistical plans/objectives for ‘safety’ – Jordan Elm	
	<input type="checkbox"/> Multiplicity – Michelle Detry	
	<input type="checkbox"/> IND/IDEs: perspectives of sponsor investigators – Pooja Khatri, Jeff Saver	
Thursday, August 10	Friday, August 11	
<input type="checkbox"/> Patient reported outcome measures – Laurie Gutmann, Brett Kissela	<input type="checkbox"/> Partnering with industry – Michael Shy	
<input type="checkbox"/> Intro to Adaptive Designs – Kert Viele	<input type="checkbox"/> Using preclinical data – Dietrich Haubenberger/Wendy Galpern	
<input type="checkbox"/> Clinical trials in rare diseases – Erika Augustine	<input type="checkbox"/> Return of the Jedi – After the CTMC – Andy Southerland	
<input type="checkbox"/> High yield points for protocols/manuals for procedures – Dixie Ecklund, Marianne Kearney Chase	<input type="checkbox"/> Overall residential course evaluation – only complete this one on August 11, at the end of the course	
<input type="checkbox"/> Pragmatic trials – Roger Lewis		

**Accreditation Statement:** This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American Academy of Neurology Institute and the University of Iowa, Los Angeles BioMed, and the University of Michigan. The American Academy of Neurology Institute is accredited by the ACCME to provide continuing medical education for physicians.

**AMA Credit Designation Statement:** The American Academy of Neurology Institute designates this live activity for a maximum of 22.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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**Small group evaluation link: [bit.ly/CTMCsmallgroupeval2017](http://bit.ly/CTMCsmallgroupeval2017)**