

FACULTY

Faculty for the course includes some of the leading surgeons and biostatisticians with expertise in clinical trials research, led by Kamal F. Itani, MD, FACS, course chair.

- Waddah B. Al-Refaie, MD, FACS
- Lawrence T. Kim, MD, FACS
- Robert J. Anderson, PhD
- Eric L. Lazar, MD, FACS
- William R. Clarke, PhD
- Peter R. Nelson, MD, MS, FACS
- Joseph F. Collins, ScD
- David M. Ota, MD, FACS
- Dorothy D. Dunlop, PhD
- Domenic J. Reda, PhD
- William G. Henderson, PhD
- Layton F. Rikkers, MD, FACS

ENROLLMENT

The course is limited to 50 participants and preference is given to members of the American College of Surgeons. **All participants are expected to attend the entire course and remain until the conclusion.** Letters of notification regarding acceptance into the course will be sent by Monday, October 31, 2011.

Dress will be business casual and participants are **strongly encouraged** to bring their own laptop, *preferably with a working USB port and wireless Internet capabilities.*

FEE

The course fee includes tuition, course materials, and most daily meals, including continental breakfast, lunch, and one group evening meal. Early registration is available until Friday, October 14, 2011 with a course fee of \$2,250. The course fee is \$2,495 for registration forms received after October 14, 2011.

REGISTRATION

Register online, by fax, or by mail by completing the registration form. Space is limited to 50 participants.

Online www.facs.org/cqi/src/clintrial.html

Fax 312-202-5003

Mail American College of Surgeons
Attn: Registration Services
633 N. Saint Clair St.
Chicago, IL 60611

CANCELLATIONS AND REFUNDS

Participants who find it necessary to cancel their registrations will receive a full refund, less a fee of \$250, provided the cancellation is received in writing no later than Friday, October 21, 2011. Registrants who cancel after October 21, 2011 will not receive a refund unless an alternate from the course's official wait list can be confirmed.

Cancellations may be sent via e-mail, fax, or mail.

LOCATION

Course activities will take place at the American College of Surgeons Headquarters and Wyndham Chicago Hotel, 633 N. Saint Clair St., Chicago, IL.

HOTEL ACCOMMODATIONS

Hotel accommodations can be made by contacting the Wyndham Chicago Hotel, 633 N. Saint Clair St., directly at 312-573-0300. To obtain the "Clinical Trials Methods" group rate of \$179, plus tax per night, for a single or double room, you must make your reservations no later than Tuesday, November 8, 2011. The hotel will honor this rate only until the room block fills or until November 8, 2011.

QUESTIONS

For registration-related questions, please contact Registration Services at registration@facs.org or 312-202-5244.

For course-related questions, please contact Ms. Alexandra Marchel, Division of Research and Optimal Patient Care, at amarchel@facs.org or 312-202-5319.

ACCREDITATION

The American College of Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AMA CREDIT DESIGNATION

The American College of Surgeons designates this live activity for a maximum of 38.0 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Clinical Trials Methods Course

December 2–6, 2011
Chicago, IL



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*



AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:
Highest Standards, Better Outcomes*

Sponsored by the Surgical Research Committee,
Division of Research and Optimal Patient Care



2011

Clinical Trials Methods Course

SCHEDULE

COURSE DESCRIPTION AND OBJECTIVES

The Clinical Trials Methods Course provides a five-day intensive course based on four successfully conducted and published clinical trials. Expert faculty will use a combination of didactic lectures and hands-on approaches, including breakout sessions, to apply concepts learned throughout the course.

The course is designed to provide surgical investigators with the concepts necessary to:

- Develop a protocol for a clinical trial that is fundable by a peer-reviewed agency,
- Understand the statistical concepts necessary to design a clinical trial,
- Understand the design and implementation issues unique to performing surgical trials, and
- Foster collaborative efforts necessary to conduct a clinical trial.

COURSE CONTENT

The course features lectures and small group breakout sessions to address the following topics:

- Design and types of clinical trials
- Determining the research hypothesis and research components
- Statistical concepts, inference, hypothesis testing, and sample size
- Developing a study proposal
- Experimental design for a randomized clinical trial
- Publication—dissemination of results, who owns the data
- Interventions and endpoints
- Planning measurements
- Trial management
- Clinical trials methods analysis
- Industry-funded trials
- Ethics issues
- Peer review and funding sources
- Presentation of proposals and critiques

DAY 1—FRIDAY, DECEMBER 2	
7:00–8:00 am	Continental Breakfast
8:00–9:30 am	Review of Four Clinical Trials <i>Kamal F. Itani, MD, FACS</i>
9:30–10:30 am	Statistics I <i>William G. Henderson, PhD</i>
10:30–11:00 am	Break
11:00 am–12:00 noon	Statistics II <i>Domenic J. Reda, PhD</i>
12:00 noon–1:00 pm	Lunch
1:00–2:00 pm	Overview of Design Options for Clinical Trials <i>Waddah B. Al-Refaie, MD, FACS</i>
2:00–3:00 pm	The Question and End Points <i>Peter R. Nelson, MD, FACS</i>
3:00–5:00 pm	Group Breakout Sessions

DAY 2—SATURDAY, DECEMBER 3	
7:00–8:00 am	Continental Breakfast
8:00–9:00 am	Patient Selection <i>Lawrence T. Kim, MD, FACS</i>
9:00–10:00 am	Experimental Design for a Randomized Clinical Trial <i>Robert J. Anderson, PhD</i>
10:00–10:30 am	Break
10:30–11:30 am	Statistical Inference, Hypothesis Testing, and Sample Size <i>Dorothy D. Dunlop, PhD</i>
11:30 am–12:30 pm	Interventions <i>David M. Ota, MD, FACS</i>
12:30–1:30 pm	Lunch
1:30–5:30 pm	Group Breakout Sessions
5:30–6:30 pm	Break
6:30–8:00 pm	Group Dinner

DAY 3—SUNDAY, DECEMBER 4	
7:00–8:00 am	Continental Breakfast
8:00–9:00 am	Statistical Concepts in Clinical Trials <i>Joseph F. Collins, ScD</i>
9:00–10:00 am	Publication of Results <i>Layton F. Rikkers, MD, FACS</i>
10:00–10:30 am	Break
10:30–11:30 am	Ethics of Clinical Trials <i>Kamal F. Itani, MD, FACS</i>
11:30 am–12:30 pm	Clinical Trials Analysis Methods <i>Domenic J. Reda, PhD</i>
12:30–1:30 pm	Lunch
1:30–5:30 pm	Group Breakout Sessions

DAY 4—MONDAY, DECEMBER 5	
7:00–8:00 am	Continental Breakfast
8:00–9:00 am	Putting It All Together: How to Get a Clinical Trial Paid For <i>Eric L. Lazar, MD, FACS</i>
9:00–10:00 am	Trial Management and Planning Measurements <i>William R. Clarke, PhD</i>
10:00–11:00 am	Mistakes in Clinical Trials <i>William G. Henderson, PhD</i>
11:00 am–12:30 pm	Group Breakout Sessions
12:30–1:30 pm	Lunch
1:30–5:30 pm	Continue Group Breakout Sessions

DAY 5—TUESDAY, DECEMBER 6	
6:00–7:00 am	Continental Breakfast
7:00 am–12:00 noon	Proposal Presentations and Discussions
12:00 noon–1:00 pm	Wrap-Up and Closing Remarks <i>Kamal F. Itani, MD, FACS</i>

** course schedule may be subject to change