



SRA CLINICAL TRIALS RESEARCH ADMINISTRATION 201 CERTIFICATE PROGRAM

COURSE OUTLINE FOR 2009 ANNUAL MEETING

**You must be a full SRA member to receive a certificate. If you have taken any of the courses in the last three years you do not need to repeat it.*

A sign in sheet will be available in all of the sessions to verify your attendance. Certificates will be issued at the end of the meetings, and may be picked up in the Speaker Ready Room, Room 614 of the Washington Convention Center. To complete this certificate at this meeting, you must register for the meeting and the required workshop.

Course Requirements: 1 workshop, 2 required sessions; 2 elective sessions.

Description:

CLINICAL TRIALS RESEARCH ADMINISTRATION OVERVIEW

The Clinical Trials Research Administration (“CTRA”) series delivers intensive training sessions specifically designed to provide an understanding of the critical elements of successful administration of a clinical trials research program. The program currently has two levels of progressively complex training that must be taken in succession, CTRA 101 then CTRA 201. Each level introduces the student to a curriculum presenting the body of knowledge required to perform as an accomplished clinical trials research administrator. Satisfying the requirements of the CTRA 101 program, or testing out of the CTRA 101 program via an advanced placement test, is required prior to taking CTRA 201. Testing out of CTRA 101 will not provide the member with a CTRA 101 certificate.

The CTRA series examines issues relevant to both National Institutes of Health-sponsored and industry-sponsored clinical trials. Much of the material is explored through case studies. Elements of the curriculum include protocol review, recruitment, negotiation of agreements, development and negotiation of budgets, compliance, billing, international studies, and risk management and analysis. These elements, along with other relevant issues, will be presented in a combination of one full-day workshop and four sessions for each program.

To sign up for CTRA 201, please contact SRA’s Education Coordinator, Tina Johnson at tjohnson@srainternational.org. You will need to verify you have previously taken CTRA 101 or request the CTRA 101 advanced placement test (test requires a \$30 administrative fee.)

Please attend the following courses to complete this program.

Required Workshop (full-day; must register)

Sunday, October 18

9:00 a.m. - 5:00 p.m.

WS18: Fundamentals of Human Research Protections (Required) – you must register for this workshop in addition to registering for the conference.

Sessions (Must take 2 Required Sessions plus 2 Electives)

Monday, October 19

3:45 – 5:15 p.m.

M32: Clinical Trials Rules and More Rules (Required)

Tuesday, October 20

(Electives - chose two):

10:30 a.m. - 12:00 p.m.

T19: Challenges Facing Investigators and Institutional Review Boards when Research Studies are Conducted at Non-US Sites

2:30 - 3:30 p.m.

T33: Office of Human Research Protections (“OHRP”) Update

4:00 - 5:30 p.m.

T46: Ethical Issues in International Human Research Protections

Wednesday, October 21

10:30 a.m. - 12:00 noon

W13: Clinical Trials Budget Negotiations (Required)