4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration Clinical Trial Requirements, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Baltimore District Office, in cosponsorship with the Society of Clinical Research Associates (SoCRA), is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of the FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulation, relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRB, and research sponsors.

Date and Time: The public workshop will be held on November 14 and 15, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Radisson Plaza Lord Baltimore Hotel, 20 West Baltimore St., Baltimore, MD 21201, 410-539-8400. Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $129.00 plus applicable taxes (available until October 13, 2012, or until the SoCRA room block is filled).

Contact: Cynthia A. Harris, Food and Drug Administration, 6000 Metro Dr., suite 101, Baltimore, MD 21215, 410-779-5133, FAX: 410-779-5705; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 800-762-7292 or 215-822-8644; FAX: 215-822-8633, email: SoCRAmail@aol.com, Web site: http://www.socra.org.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. The cost of the registration is as follows:

Cost of Registration

SoCRA member	$575.00
SoCRA nonmember (includes membership)	$650.00
Federal Government SoCRA member	$525.00
Federal Government SoCRA nonmember	$450.00
FDA Employee	Fee Waived

If you need special accommodations due to a disability, please contact SoCRA or Cynthia Harris (see Contact) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this educational activity for a maximum of 13.3 American Medical Association Physician's Recognition Award Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC /PSNA Provider Reference Number: 205-3-1-09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to "SoCRA". Mail to: SoCRA (see Contact for address). To register via the Internet, go to http://socra.org/html/FDA_Conference.htm. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA (see Contact).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with

information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) Are We There Yet?; (2) What FDA Expects in a Pharmaceutical Clinical Trial; (3) Medical Device Aspects of Clinical Research; (4) Adverse Event Reporting--Science, Regulation, Error and Safety; (5) Working With FDA's Center for Biologics Evaluation and Research; (6) Ethical Issues in Subject Enrollment; (7) Keeping Informed and Working Together; (8) FDA Conduct of Clinical Investigator Inspections; (9) Investigator Initiated Research; (10) Meetings with FDA--Why, When and How; (11) Part 11 Compliance--Electronic Signatures; (12) IRB Regulations and FDA Inspections; (13) Informed Consent Regulations; and (14) The Inspection Is Over--What Happens Next? Possible FDA Compliance Actions.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarify of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) as outreach activities by Government Agencies to small businesses.

Dated August 8, 2012

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19851 Filed 08/15/2012 at 8:45 am; Publication Date: 08/16/2012]