4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Society of Clinical Research Associates – Food and Drug Administration; "Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance and Good Clinical Practice"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Public Workshop

SUMMARY: The Food and Drug Administration (FDA) is announcing the following conference: Educational Conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The public workshop 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 the FDA and clinical trial staff, investigators and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices and biologics, as well as inspections of clinical investigators, of IRB, and of research sponsors.

Date and Time: The conference will be held on March 11 and 12, (Wednesday and Thursday) 2015, from 8:00 a.m to 5 p.m..

Location: The conference will be held at the Holiday Inn Golden Gateway Hotel, 1500 Van Ness Ave., San Francisco, CA 91409, 415-441-4000.

Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $159.00 plus applicable taxes (available until February 13, 2015, or until the SOCRA room block is filled).

Contact Person: Jane Kreis, Food and Drug, Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739 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: **Office@socra.org** Web site: www.socra.org. (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).

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 workshop will receive confirmation. The cost of the registration is as follows: SOCRA member - $575, SOCRA nonmember (includes membership)- $650, Federal Government member - $450.00, Federal Government nonmember - $525.00, FDA Employee – (free) Fee Waived

If you need special accommodations due to a disability, please contact SOCRA (see Contact Person) 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 Credits for SOCRA continuing education (CE) and Nurse continuing nurse education (CNE), SOCRA designates this live 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. Continuing medical education (CME) for Physicians: SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide CME for physicians. CNE for Nurses: Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

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 Person for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SOCRA (see Contact Person).

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 workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related informed consent, clinical investigation requirements, institutional review board inspections, electronic record requirements, and investigator initiated research Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the

Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials / BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial: (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting – Science, Regulation, Error and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with the FDA - Why, When and How; (12) Part 11 Compliance - Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over - What Happens Next? Possible FDA Compliance Actions; (16) Question and Answer Session / Panel Discussion.

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 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 clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by Government Agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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