



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4952]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission and authority of 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 (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; and inspections of clinical investigators, IRBs, and research sponsors.

DATES: The public workshop will be held on November 15 and 16, 2017, from 8 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the Wyndham Lake Buena Vista Resort, 1850 Hotel Plaza Blvd., Lake Buena Vista, FL 32830, 407-828-4444.

FOR FURTHER INFORMATION CONTACT: Kim Prenter, Food and Drug Administration, 15100 NW 67th Ave., suite 400, Miami Lakes, FL 33014, 305-816-1474, Fax: 305-816-1536; or

Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 800-762-7292, Fax 215-822-8633, email: SoCRAMail@aol.com, website: <https://www.socra.org>.

SUPPLEMENTARY INFORMATION:

I. Background

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 clinical investigations, informed consent, and inspections of clinical investigators and IRBs.

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 Food and Drug Administration 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.

II. Topics for Discussion

Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting--Science, Regulation, Error and Safety; (3) Part 11 Compliance--Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings with FDA: Why, When, and How; (9) Investigator

Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working with FDA's Center for Biologics Evaluation and Research; and (12) The Inspection Is Over--What Happens Next? Possible FDA Compliance Actions.

III. Participating in the Public Workshop

Registration: Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of \$129 plus applicable taxes (available until October 16, 2017, or until the SOCRA room block is filled). For additional registration and meeting information, visit <https://www.socra.org/> or <https://www.socra.org/conferences-and-education/live-conferences/fda-clinical-trial-requirements-regulations-compliance-and-gcp-conference/register/>.

Registrations fees are as follows: \$575 for SOCRA members, \$650 for non-members (includes membership), \$450 for Federal Government members, \$525 for Federal Government non-members, and fee waived for FDA Employees.

The registration fee covers expenses including refreshments, lunch, materials, and speaker expenses. Registration for the conference is open through November 14, 2017.

If you need special accommodations due to a disability, please contact Kim Prenter (see FOR FURTHER INFORMATION CONTACT) at least 10 days in advance.

Other Issues for Consideration: Extended periods of question and answer and discussion have been included in the program schedule. This program offers 13.3 hours of Continuing Medical Education (CME) and Continuing Nursing Education (CNE) credit. CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. CNE for Nurses: The Society of Clinical Research Associates is accredited as a

provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. ANCC/PSNA Provider Reference Number: 205-3-A-09.

Dated: September 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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