4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

Summary: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research/Office of Medical Policy and the Duke University Office of Continuing Medical Education are cosponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide clinical investigators with expertise in the design, conduct, and analysis of clinical trials; improve the quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

Date and Time: The training course will be held on November 13 and 14, 2012, from 8 a.m. to 5 p.m., and on November 15, 2012, from 8 a.m. to 4 p.m.

Location: The course will be held at the Holiday Inn College Park, 10000 Baltimore Ave., College Park, MD 20740.

Contact Person: Connie Wisner, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6360, Silver Spring, MD 20993, 301-796-8509.

Registration: Register by October 22, 2012. The registration fee is $400 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration.

Register online for the training course at the registration Web site: http://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIINVEST&eventid=46475 or download a full-size copy of the registration form and mail a check and completed form to: Duke University Conference and Event Services, FDA Investigator Course Box 90841, 101 Bryan Center, Durham, NC 27708. You will receive an email that confirms your registration. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.)

Attendees are responsible for their own accommodations. A block of rooms has been reserved under "FDA Clinical Investigator Course" at the Holiday Inn College Park at a reduced conference rate. Reservations for these accommodations can be made online using the course registration Web site mentioned previously. Click on "registration form." You will see a direct link to the hotel.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site mentioned previously.

If you need special accommodations due to a disability, please contact Connie Wisner at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

I. Background

Clinical trial investigators play a critical role in the development of medical products. They are responsible for ensuring the safe and ethical treatment of study subjects and for collecting adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational drug use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course should do the following:

• Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;

• Promote communication between clinical investigators and FDA;

• Enhance investigators' understanding of FDA's role in experimental medicine; and

• Improve the quality of data while enhancing subject protection in the performance of clinical trials.

B. Proposed Agenda

The course will be conducted over 3 days and comprised of approximately 26 lectures, each lasting between 30 and 45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

The course will address FDA's role in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an "investigator's brochure," i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presenters will discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. The course will also include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 15, 2012, participants will choose among three breakout sessions that will explain how to put together an application to FDA for drugs, biologics, or devices.

C. Target Audience

The course is targeted at health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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