www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or *http://www.regulations.gov.*

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17588 Filed 7–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA's) 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 4 and 5, 2014, from 8 a.m. to 5 p.m., and on November 6, 2014, from 8 a.m. to 3:30 p.m.

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

Contact Person: Tomeka Arnett, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6355, Silver Spring, MD 20993, 301–796–8486.

Registration: Register by October 17, 2014. The registration fee is $150 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://continuingeducation.dcri.duke.edu/citc* or download a full-size copy of the registration form from the registration site and mail a check and completed form to Duke Clinical Research Institute (DCRI), Attention—Duke CME/CEE, 300 West Morgan St., Suite 800, Durham, NC 27701. 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 Tomeka Arnett (see *Contact Person*) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring 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 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 accomplish 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 comprises 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 and regulatory considerations for clinical trials and will include a 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 6, 2014, 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 toward health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17589 Filed 7–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: SAMHSA SOAR Web-Based Data Form (OMB No. 0930–0329)—Revision.

In 2009 the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services created a Technical Assistance Center to assist in the implementation of the SSI/SSDI Outreach Access and Recovery (SOAR) effort in all states. SOAR's primary objective is to improve the allowance rate for Social Security Administration (SSA) disability benefits for people who are homeless or at risk of homelessness, and who have serious mental illnesses.

During the SOAR training, the importance of keeping track of SSI/SSDI applications through the process is stressed. In response to requests from states implementing SOAR, the Technical Assistance Center under SAMHSA's direction developed a web-based data form that case managers can use to track the progress of submitted applications, including decisions received from SSA either on initial application or on appeal. This password-protected web-based data form is housed on the SOAR Web site (*https://soartrack.prainc.com*). Use of this form is completely voluntary.

In addition, data from the web-based form can be compiled into reports on decision results and the use of SOAR core components, such as the SSA–1696 Appointment of Representative, which allows SSA to communicate directly with the case manager assisting with the application. These reports will be reviewed by agency directors, SOAR state-level leads, and the national SOAR Technical Assistance Center and SOAR national evaluation team to quantify the success of the effort overall and to identify areas where additional technical assistance is needed. The changes to this form are an added question about the reason for denial, if received and an added ten optional questions about Medicaid and Medicare reimbursement amounts, back payments and applicants' work involvement and earnings. These data provide important tools in local and state sustainability efforts of SOAR. If caseworkers do not have this information, they can simply leave the items blank.

The estimated response burden is as follows:

Information source	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
SOAR Data Form	700	3	2100	.25	525

Written comments and recommendations concerning the proposed information collection should be sent by August 25, 2014 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2014–17521 Filed 7–24–14; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5753–N–03]

60-Day Notice of Proposed Information Collection: Housing Opportunities for Persons With AIDS (HOPWA) Program: Annual Grantee Performance Reporting Requirements and Competitive/Renewal Grant Project Budget Summary

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of proposed information collection.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date: September 23, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400, for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Eric Pfeifer, Management Analyst, CPD, Office of HIV/AIDS Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 7212, Washington, DC 20410–5000; telephone 202–708–1934 (this is not a toll-free number) or email at *eric.m.pfeifer@hud.gov.* This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–