ANNUAL BURDEN: CURRENT REQUEST

Activity/respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden hours
Responsible Fatherhood Grantee Impact Evaluation				
(19) RF Follow-up survey Study participants	1,600	1	0.75	1,200
Healthy Marriage Grantee Impact Evaluation				
(20) HM Follow-up survey Study participants	3,200	1	0.75	2,400
Total				3,600

Estimated Total Annual Burden Hours (for instruments previously approved and currently in use, and those associated with this 30-Day Notice): 16,716.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2013–25128 Filed 10–24–13; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1214]

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 12 and 13, 2013, from 8 a.m. to 5 p.m., and on November 14, 2013, 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 November 1, 2013. 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://continuingeducation.dcri.duke.edu/fda-clinical-investigators-training-course-registration* or download a full-size copy of the registration form from the registration site 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 (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 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 14, 2013, 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: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25127 Filed 10–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of a nonvoting industry representative to represent the interests of the tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products, notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancy effective with this notice. Elsewhere in this issue of the **Federal Register**, FDA is publishing a separate document announcing the Request for Notification for Voting Members on the Tobacco Products Scientific Advisory Committee.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of the tobacco manufacturing industry must send a letter stating the interest to FDA by November 25, 2013, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by November 25, 2013.

ADDRESSES: All letters of interest and nominations should be submitted in writing to *TPSAC@fda.hhs.gov,* or by mail to Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850,1–877–287–1373 (choose Option 5), FAX: 240–276–3655, email: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency requests nominations for a nonvoting industry representative on the Tobacco Products Scientific Advisory Committee to represent the interests of the tobacco manufacturing industry.

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

The Committee includes three nonvoting members who represent industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative of the interests of the small business tobacco manufacturing industry may be filled on a rotating basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

With this notice, nominations are sought for one representative of the interests of the tobacco manufacturing industry, and an alternate to this representative.