

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Quarterly Allocation Estimate, ACF-535 .....	55	1	0.25	13.75

Estimated Total Annual Burden Hours: 13.75.

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@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, *Fax:* 202-395-7285, *E-mail:* [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov), *Attn:* Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011-19229 Filed 7-28-11; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families****Submission for OMB Review; Comment Request**

*Title:* Adoption and Foster Care Analysis and Reporting System (AFCARS), Title IV-B & IV-E.

*OMB No.:* 0980-0267.

*Description:* Section 479 of title IV-E of the Social Security Act (the Act) directs States to establish and

implement an adoption and foster care reporting system. Federal regulations at 45 CFR 1355.40 sets forth the requirements of section 479 of the Social Security Act for the collection of uniform, reliable information on children who are under the responsibility of the State title IV-B/IV-E agency for placement, care, and adoption. The respondents are child welfare agencies in the 50 States, the District of Columbia, and Puerto Rico.

The data collected will inform State/Federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data are used for short/long-term budget projections, trend analysis, child and family service reviews, and to target areas for improved technical assistance. The data will provide information about foster care placements, adoptive parents, length of time in care, delays in termination of parental rights and placement for adoption.

*Respondents:*

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS .....	52	2	2,581	268,424

Estimated Total Annual Burden Hours: 268,424.

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**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2011-19192 Filed 7-28-11; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2011-N-0523]

**Clinical Investigator Training Course**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Critical Path Programs and the Clinical Trials Transformation Initiative (CTTI) 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 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 7 and 8, 2011, from 8 a.m. to 5 p.m., and on November 9, 2011, from 8 a.m. to 3:30 p.m.

**Location:** The course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20903-0002.

**Contact Person:** Leonard Sacks, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4174, Silver Spring, MD 20993, 301-796-8502.

**Registration:** Register by October 21, 2011. 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/information Web site at <https://www.trialstransformation.org/fda-clinical-investigator-training-course> or by FAX to 919-660-1769. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. A block of rooms has been reserved under "FDA Clinical Investigator Course" at the National Labor College at a reduced conference rate. Reservations can be made at [https://www.supportnlc.org/Room\\_Reservations.html](https://www.supportnlc.org/Room_Reservations.html) or by calling 301-431-6400. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at <https://www.trialstransformation.org/fda-clinical-investigator-training-course>.

If you need special accommodations due to a disability, please contact Leonard Sacks 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 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 will comprise 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.

On November 7, 2011, the course will address the role of FDA 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. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. On November 8, 2011, the course will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 9, 2011, participants will choose among three breakout sessions that 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: July 25, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2011-19149 Filed 7-28-11; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

#### **Request for Nominations for Members on a Public Advisory Committee; Medical Imaging Drugs Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for 12 members to serve on the Medical Imaging Drugs Advisory Committee in the Center for Drug Evaluation and Research.

FDA has a special interest in ensuring that women, minority groups, and individuals with physical disabilities are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically challenged candidates. Final selection from each vacancy will be determined by the expertise required to meet specific Agency needs and in a manner to ensure appropriate balance on membership.