Dated: May 4, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9056 Filed 5–9–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0173]

Draft Guidance for Industry on Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators.'' This draft guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. The draft guidance also clarifies FDA's expectations concerning the investigator's responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.

DATES: Submit written or electronic comments on the draft guidance by July 9, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7864.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators.'' Under the regulations in part 312 (21 CFR part 312) (Investigational New Drug Application) and part 812 (21 CFR part 812) (Investigational Device Exemptions), an investigator is responsible for ensuring that a clinical investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs, biological products, and devices under investigation (§§ 312.60 and 812.100). This draft guidance clarifies the responsibilities of investigators in the conduct of clinical investigations conducted under parts 312 and 812, particularly the responsibilities to supervise the conduct of the clinical investigation, and to protect the rights, safety, and welfare of study participants in drug, biologic, and medical device clinical trials. The draft guidance also provides recommendations on how investigators should supervise the study-related actions of persons not in the direct employ of the investigator, including certain study staff and parties conducting associated testing and assessments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the supervisory responsibilities of investigators. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 312 have been approved under OMB Control No. 0910–0014; and the collections of information in part 812 have been approved under OMB Control No. 0910–0078.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or*http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Women's Physical Activity and Healthy Eating Tools Assessment: NEW

The HRSA Office of Women's Health (OWH) developed the Bright Futures for Women's Health and Wellness (BFWHW) Initiative to help expand the scope of women's preventive health activities, particularly related to nutrition and physical activity. An intermediate assessment of the BFWHW

health promotion consumer materials related to physical activity and healthy eating will be conducted in order to assess how the BFWHW materials can stimulate a conversation on physical activity and healthy eating during a clinical encounter, inform future BFWHW programming, and add to the peer-reviewed literature regarding women's health and wellness initiatives.

Towards this end, anonymous assessment forms will be used to collect data from young and adult women clients, health care providers, and administrators of health centers. Data collected will include process and outcome measures. Data domains include: the distribution and use of the materials in the health care setting during wellness and health maintenance/check-up visits; client and provider awareness of physical activity and nutrition behaviors; attitudes about the importance of physical activity and nutrition; self-efficacy; and increase in knowledge and intent to change physical activity and nutrition behaviors.

A total of six organizations, which may include Federally Qualified Health Centers/Community Health Centers, faith-based organizations that offer health care services, worksite health centers, and school-based health clinics, will be selected for the study. Young women will complete anonymous assessment forms at school-based health centers; adult women will be assessed at other health care organizations. The providers at these sites will also be asked to complete a brief one-time anonymous assessment form. Telephone interviews will be conducted with an administrator of each of these sites as well. The data collection period at each site is estimated to last four months. The estimated response burden is as follows:

Data collection activity	Estimated Data Collection Burden Hours				Hourly wage rate	Total cost
	Number of respondents	Hours per response	Responses per respondent	Total burden hours		
Clients	3,000	.81	1	2,430	$5.15	$12,514.50
Administrators	6	4.22	1	25	37.09	927.25
Support Staff	6	63.67	1	382	13.65	5,214.30
Providers	60	5.98	1	359	59.15	21,234.85
Total	3,072			3,196		39,890.90

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Karen Matsuoka, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 4, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–9011 Filed 5–9–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law (Pub. L.) 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on 301–443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Children's Hospital Graduate Medical Education Payment Program (CHGME PP) Annual Report: NEW

The CHGME PP was enacted by Pub. L. 106–129 to provide Federal support for graduate medical education (GME) to freestanding children's hospitals, similar to Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The CHGME PP was reauthorized for a period of five years in October 2006 by Pub. L. 109–307. The reauthorizing legislation requires that participating children's hospitals provide information about their residency training programs in an annual report that will be an addendum to the hospitals' annual applications for funds.

Data are required to be collected on: (1) The types of training programs that the hospital provided for residents such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties including both medical subspecialties certified and non-medical subspecialties; (2) the number of training positions for residents, the number of such positions recruited to fill, and the number of positions filled; (3) the types of training that the hospital provided for residents related to the health care needs of different populations such as children who are underserved for reasons of family income or geographic location, including rural and urban areas; (4) the changes in residency training including changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes and changes for purposes of training residents in the measurement and improvement and the quality and safety of patient care; and