

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-10-0217]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (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. Written comments should be received within 60 days of this notice.

**Proposed Project**

Vital Statistics Training Application, (OMB No. 0920-0217 exp. 7/31/2010)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

In the United States, legal authority for the registration of vital events, *i.e.*, births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics System (NVSS), depends on a cooperative relationship between the

States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

NCHS assists in achieving the comparability needed for combining data from all States into national statistics, by conducting a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a). In order to offer the types of training that would be most useful to vital registration staff members, NCHS requests information from State and local vital registration officials about their projected needs for training. NCHS also asks individual candidates for training to submit an application form containing name, address, occupation, work experience, education, and previous training. These data enable NCHS to determine those individuals whose needs can best be met through the available training resources. NCHS is requesting 3 years of OMB clearance for this project.

There is no cost to respondents in providing these data.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State, local, and Territory Registration Officials .....	57	1	20/60	19
Training applicants .....	100	1	15/60	25
<b>Total .....</b>				<b>44</b>

Dated: January 7, 2010.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0605]

**Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled,

“Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval.” The draft guidance announced in this notice is intended to assist institutional review boards (IRBs) in carrying out their continuing review responsibility by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review.

**DATES:** Although comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers a comment on this draft guidance before it begins work on the final version of the guidance, written or electronic comments on the draft guidance should be submitted by March 15, 2010. 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**ADDRESSES:** Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., White Oak (WO) Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 (1-888-463-6332 or 301-796-3400); or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448 (1-800-835-4709 or 301-827-1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave. (WO Bldg. 66, rm. 4622), Silver Spring, MD 20993 (1-800-638-2041 or 301-796-7100). Send one self-addressed adhesive label to assist the office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:** Sara Goldkind, Office of Good Clinical Practice (HF-34), Food and Drug Administration, 5600 Fishers Lane, rm. 16-85, Rockville, MD 20857, 301-827-3340.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval." This guidance is intended to assist IRBs in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators

and sponsors better understand their responsibilities related to continuing review. When finalized, this guidance will supersede the Information Sheet, "Continuing Review After Study Approval" (September 1998, Office of Health Affairs, Food and Drug Administration).

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research. This draft guidance document was developed as part of these efforts.

FDA is issuing this as a draft guidance because it has been substantially revised in response to numerous questions about the continuing review process from the IRB and research communities. Changes include more detailed discussion about what should be submitted to assist the IRB in conducting continuing review, discussion of the circumstances in which expedited review procedures may be used for continuing review, and guidance about how continuing review dates should be determined.

This draft guidance is part of the Information Sheet Guidance Initiative, announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as "Information Sheets," these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are updated, consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue guidances that address current issues, and develop new guidance documents as needed.

The draft guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520) (PRA). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, which include the requirements for records of continuing review, have been approved under OMB Control No. 0910-0130; the collections of information in part 312 (21 CFR part 312) have been approved under OMB control number 0910-0014; and the collections of information in part 812 (21 CFR part 812) have been approved under OMB control number 0910-0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment, and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

##### **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. 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 <http://www.regulations.gov>, or <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm>

Dated: January 7, 2010.

**David Dorsey,**

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

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