ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Teachers & Support Personnel	6,450	1	0.5	3,225
Total				3,225

Dated: April 15, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–9156 Filed 4–21–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–0571]

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 or send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an e-mail to *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

Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Many cancer-related deaths in women could be avoided by increased utilization of appropriate screening and early detection tests for breast and cervical cancer. Mammography is extremely valuable as an early detection tool because it can detect breast cancer well before the woman can feel the lump, when the cancer is still in an early and more treatable stage. Similarly, a substantial proportion of cervical cancer-related deaths could be prevented through the detection and treatment of precancerous lesions. The Papanicolaou (Pap) test is the primary method of detecting both precancerous cervical lesions as well as invasive cervical cancer. Mammography and Pap tests are underused by women who have no source or no regular source of health care and women without health insurance.

Despite the availability and increased use of effective screening and early detection tests for breast and cervical cancers, the American Cancer Society (ACS) estimated that 182,460 new cases of breast cancer would be diagnosed among women in 2008, and that 40,480 women would die of this disease. The ACS also estimated that 11,070 new cases of invasive cervical cancer would be diagnosed in 2008, and that 3,870 women would die of this disease.

The CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provides screening services to underserved women through cooperative agreements with 50 States, the District of Columbia, 5 U.S. Territories, and 12 American Indian/Alaska Native tribal programs. The program was established in response to the Breast and Cervical Cancer Mortality Prevention Act of 1990. Screening services include clinical breast examinations, mammograms and Pap tests, as well as timely and adequate diagnostic testing for abnormal results, and referrals to treatment for cancers detected. Awardees collect patient level screening and tracking data to manage the program and clinical services. A de-identified subset of data on patient demographics, screening tests and outcomes are reported by each awardee to CDC twice per year in the Minimum Data Elements (MDE) OMB No. 0920–0571, exp. 1/31/2010). Burden to respondents was significantly reduced in 2008 when the annual requirement to report infrastructure information (System for Technical Assistance Reporting, STAR), previously associated with collection of MDE information, was discontinued.

CDC plans to request OMB approval to collect MDE information for an additional three years. Because awardees already collect and aggregate data at the state, territory and tribal level, the additional burden of submitting data to CDC will be small. CDC will use the information to monitor and evaluate NBCCEDP awardees; improve the availability and quality of screening and diagnostic services for underserved women; develop outreach strategies for women who are never or rarely screened for breast and cervical cancer, and report program results to Congress and other legislative authorities. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents *	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
NBCCEDP Grantees	68	2	4	544

Dated: April 15, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–9155 Filed 4–21–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0637]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 22, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Financial Disclosure by Clinical Investigators—(OMB Control Number 0910–0396)—Extension

Respondents are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. The applicant will incur reporting costs in order to comply with the final rule. Applicants will be required to submit, for example, the complete list of clinical investigators for each covered study, not employed by the applicant and/or sponsor of the covered study, and either certify to the absence of certain financial arrangements with clinical investigators or disclose the nature of those arrangements to FDA and the steps taken by the applicant or sponsor to minimize the potential for bias. The clinical investigator will have to supply information regarding financial interests or payments held in the sponsor of the covered study.

In the **Federal Register** of December 29, 2008 (73 FR 79493), FDA published a 60-day notice requesting public comment on the information collection provisions. Two comments were received, one comment expressed support for this information collection. The second comment raised several issues, first, the issue of the current cost the commenter incurs in the collection of Financial Disclosure and the estimate of substantial operating costs the commenter incurs in operating costs to support the collection of investigator financial information. FDA appreciates the comment and based on this new data, submitted by the commenter, will undertake a new evaluation whether there are capital costs or operating and maintenance costs associated with this collection of information. FDA also appreciates the comment concerning the definition of ''clinical investigator'' and will forward the comment to the FDA office responsible for this collection of information to consider in any future rulemaking. However, these definitions are codified in 21 CFR 54.2.

FDA also appreciates the comment regarding the use of Form FDA 1572 to minimize burden. However, 21 CFR 54.4 requires the use of Form FDA 3454 and Form FDA 3455. This comment will also be forwarded to the FDA office responsible for this collection of information to consider in any future rulemaking.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
54.4(a)(1) and (a)(2)—Form FDA 3454	1,000	1	1,000	5	5,000
54.4(a)(3)—Form FDA 3455	100	1	100	20	2,000
54.4(b)	46,000	.25	11,500	1	11,500
Total					18,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.