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.

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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.

The sponsors of covered studies will be required to maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices. Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
54.6	1,000	1	1,000	.25	250
Total					250

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

Dated: April 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9148 Filed 4–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Parent-Child Assistance Program (P–CAP) in the Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence—New

Since 2001, SAMHSA's Center for Substance Abuse Prevention has been operating a Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence which addresses FASD mainly by providing trainings and technical assistance; and developing and supporting systems of care that respond to FASD using effective evidence based practices and interventions.

Currently the integration of evidence-based practices into service delivery organizations is being accomplished through subcontracts. One such intervention which integrates prevention strategies into service delivery organizations is the Parent-Child Assistance Program (PCAP) targeting pregnant or postpartum women. The PCAP programs uses the following 12 data collection tools.

Description of Instruments/Activity for Parent-Child Assistance Program (P–CAP)

Instrument/activity	Description
At Baseline/Enrollment:	
CRSQ	The Community Referral Screening Questionnaire (CRSQ) is a screening form administered to individuals referred to PCAP. The purpose of the form is to determine eligibility for enrollment in PCAP.
ASI—Part A	The Alcohol Severity Index (ASI) Part A is an intake interview administered at client enrollment. The ASI Part A includes questions about past 30 day alcohol use, lifetime use, age at first use, month and year of last use, range of use (T–ACE), and use during pregnancy, thereby providing a thorough assessment of alcohol consumption.
ASI—Part B & Twin	The Alcohol Severity Index (ASI) Part B is an intake interview administered as soon as possible after the target child birth. The ASI Part B includes questions about the target child at birth and alcohol use during the pregnancy. If the target birth is of twins then the Twins Addendum form is administered.
Demographic Data	The Demographic Questionnaire is administered after client enrollment. The questionnaire includes race, educational attainment, martial status, and an alcohol assessment.
Process Monitoring:	
Weekly Advocate Time Summary	The PCAP Weekly Advocate Time Summary Sheet is administered on a weekly basis. The form tracks time spent on the phone, in person, or providing transportation to each client.
Monthly Updates	The Monthly Update form is administered on a monthly basis. The form records any changes in drug and alcohol use, pregnancy, child custody, and sources of income.