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]

BILLING CODE 4160–01–S

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.

Instrument/activity	Description
Biannual Documentation of Progress (every 6 months).	The Biannual Documentation of Progress is administered every six months. The form documents changes in alcohol/drug treatment, abstinence from alcohol/drugs, birth control and pregnancy, connection to other services, and family stability and client activity.
At Exit:	
Exit ASI	The Exit ASI Follow-Up is administered at the end of the program, at 36 months. The Exit ASI uses a format that is identical to the Addiction Severity Index administered at intake, providing pre- and post-test data for the intervention.
Client Exit Close Out form	The Client Exit Close-Out Form documents the total number of months the client spent in PCAP, number of different advocates who worked with the client, and whether the client ever moved out of the area while enrolled in PCAP.
Ad hoc:	
Advocate Accounting of Tracing Activity on Missing Post-Exit Client.	The Advocate Accounting of Tracing Activity on Missing Post-Exit Client is used to track activity to locate a missing client. When a client is missing, the form is to be completed each month, instead of the Monthly Update form, until the missing post-exit client is brought in for an Exit Interview.
Lost Post-Exit Client Form	The Lost Post-Exit Client Form is used when the client is at least six months past her three year exit date in the program and has not completed the ASI exit interview. The form documents the reason the client has not completed the ASI exit interview.

Two PCAP subcontracts were awarded in February 2008. PCAP uses an intensive paraprofessional home visitation model to reduce risk behaviors in pregnant women with substance abuse problems. The primary goal of PCAP is to prevent future births of alcohol and drug exposed children to women who are at risk. The program uses a holistic case management approach, which is a complement to traditional substance abuse treatment. In addition to addressing alcohol and drug use, the program also aims at reducing other risk behaviors and addressing the health and social well being of mothers and their children.

At the initial client visit, the women receive a comprehensive assessment which includes an assessment for alcohol consumption, contraception use, and use of community services. At-risk women receive case management and every 4 months women are re-evaluated to determine their clinical goals. Counselors complete ''Documentation of Client Progress'' form every 6 months and a final ''Documentation of Client Progress'' at 36 months. In addition, the counselors complete a weekly advocate time sheet, summarizing their activities within the program. All forms are completed online using the Web-portal. All participating subcontractors will maintain identifiable information on clients for service delivery purposes but no identifiable information will be transmitted to SAMHSA.

The data collection is designed to evaluate the implementation of PCAP by measuring whether abstinence from alcohol is achieved and risk for alcohol-exposed births is eliminated.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument/activity	Number of respondents 2 sites	Number of responses per respondent	Average burden per response	Total burden hours per collection
At Baseline/Enrollment:				
CRSQ	190	1	0.08	15
ASI—Part A	190	1	2.75	523
ASI—Part B & Twin	190	1	0.25	47.5
Demographic Data	190	1	0.08	15
Process Monitoring:				
Weekly Advocate Time Summary	190	52	0.50	4,940
Monthly Updates	190	12	0.50	1,140
Biannual Documentation of Progress (every 6 months)	161	2	0.33	106
At Exit:				
Exit ASI	190	1	2.25	428
Client Exit Close Out form	161	1	0.25	40
Ad hoc:				
Advocate Accounting of Tracing Activity on Missing Post-Exit Client	29	1	0.25	7
Lost Post-Exit Client Form	29	1	0.25	7
Total	1,710	74	.....	7,269

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: April 13, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–9193 Filed 4–21–09; 8:45 am]

BILLING CODE 4162–20–P

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: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930–0158)—Extension

SAMHSA's Mandatory Guidelines for Federal Workplace Drug Testing Programs will request OMB approval for the Federal Drug Testing Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644) dated April 13, 2004, and for the information provided by laboratories for the National Laboratory Certification Program (NLCP).

The Federal Drug Testing Custody and Control Form is used by all Federal agencies and employers regulated by the Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination. The Federal Drug Testing Custody and Control Form approved by OMB three years ago is being resubmitted for OMB approval without any revision.

Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the laboratory's testing procedures before arriving at the laboratory.

The NLCP application form has not been revised compared to the previous form.

The annual total burden estimates for the Federal Drug Testing Custody and Control Form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Burden/ response (hrs.)	Number of responses	Total annual burden (hrs.)
Custody and Control Form:			
Donor	.08	7,096,000	567,680
Collector	.07	7,096,000	496,720
Laboratory	.05	7,096,000	354,800
Medical Review Officer	.05	7,096,000	354,800
Laboratory Application	3.00	3	9
Laboratory Inspection Checklist	3.00	100	300
Laboratory Recordkeeping	250.00	50	12,500
Total			1,786,809

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: April 13, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–9187 Filed 4–21–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Nutrition and Aging of Brain.

Date: June 9, 2009.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, National Institutes of Health, Gateway Building, Room 2C/212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, PhD, Scientific Review Officer, National