exposure as a condition of new drug approval. However, registries such as these monitor only a small number of medications, and many suffer from methodologic limitations including high loss to follow-up rates and incomplete or nonspecific outcome information.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the effects of medication exposures during pregnancy and lactation. The objective of this project is to assess the quality of information on (1) pregnancy outcomes (*e.g.*, live birth, stillbirth, premature birth, low birth weight, *etc.*) and (2) maternal and infant health following medication use during pregnancy and lactation that can be obtained from maternal interviews conducted by TIS in the U.S. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (up to a maximum of 250 enrollees per TIS) who have used any prescription or over-the-counter medication, vitamin, herbal, or other dietary supplement during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will then conduct 4 telephone interviews: (1) At enrollment; (2) during the third trimester of pregnancy; (3) approximately one month after delivery; and (4) when the infant is about 3 months old. For each breastfeeding woman who agrees to participate, the TIS will then conduct 3 telephone interviews: (1) At enrollment; (2) approximately one month after enrollment; and (3) 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, and maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time. The total estimated annualized burden is 516 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
All Respondents	Telephone script	294	1	3/60
Screened Eligible Respondents-	Tracking	250	1	5/60
Pregnancy Exposure (Group 1)/Lactation Exposure (Group 2)/Pregnancy and Lactation Exposure (Group 3).	Consent	250	1	20/60
Groups 1, 2 and 3	Enrollment	250	1	10/60
Group 1 and 3	Initial Pregnancy	200	1	30/60
	Follow-up Pregnancy	200	1	20/60
	Initial Infant	200	1	20/60
	Follow-up Infant	200	1	15/60
Groups 2 and 3	Initial breastfeeding	100	1	20/60
	Follow-up breastfeeding	100	1.5	15/60

Dated: September 18, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–23309 Filed 9–25–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects:

Title: Project LAUNCH Cross-Site Evaluation.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data as part of a cross-site evaluation of a new initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health): Project LAUNCH is intended to promote the healthy development and wellness of children ages birth to eight years. A total of 18 Project LAUNCH grantees will be funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees will also implement a range of public health strategies to support young child wellness in a designated locality.

Data for the cross-site evaluation of Project LAUNCH will be collected through: (1) Interviews conducted during annual site visits to Project LAUNCH grantees, and (2) semi-annual reports that will be submitted electronically on a Web-based data-entry system. Information will be collected from all Project LAUNCH grantees.

During annual site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in States/Tribes and local communities of focus. Site visitors will ask program administrators questions about all Project LAUNCH activities, including: infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports on State/Tribal and local

systems development and on services that children and families receive. The electronic data reports also will collect data about other Project LAUNCH-funded service enhancements, such as trainings, Project LAUNCH systems change activities, and changes in provider settings. Information provided in these reports will be aggregated on a quarterly basis, and reported semi-annually.

Respondents: State/Tribal Child Wellness Coordinator, State/Tribal Wellness Council Members, State ECCS Project Director, Local Child Wellness Coordinator, Local Wellness Council Members, Local Evaluator, and Local Service Providers.

ANNUAL BURDEN ESTIMATES'>

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Site Visit Interview Guide	216	1	1.25	270
Electronic Data Reporting: Systems Measures	18	2	4	144
Electronic Data Reporting: Services Measures	18	2	8	288

Estimated Annual Burden Hours: 702 hours.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocol1ection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974. *Attn:* Desk Officer for the Administration for Children and Families.

Dated: September 17, 2009.

Seth F. Chamberlain,

OPRE Reports Clearance Officer.

[FR Doc. E9–23242 Filed 9–25–09; 8:45 am]

BILLING CODE M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health;

Notice of Closed Meeting

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 meeting.

The meeting 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 of Mental Health Special Emphasis Panel. K99.

Date: October 29, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852–9609. 301–402–6807. *libbeym@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: September 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23337 Filed 9–25–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel. Pharmacodynamic Assays for Cancer Therapeutics.

Date: October 6, 2009.

Time: 11 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Room # 210, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Thomas M Vollberg, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7142, Bethesda, MD 20892. 301–594–9582. *vollbert@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Name of Committee: National Cancer Institute Special Emphasis Panel. R13 Conference Grants Review.

Date: October 29, 2009.

Time: 1 p.m. to 5 p.m.