comments should be received within 30 days of this notice.

Proposed Project

Follow-up Survey of Chronic Fatigue Syndrome in Georgia—New—Coordinating Center for Infectious Diseases (CCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is planning a follow-up study of chronic fatigue syndrome (CFS) in metropolitan, urban and rural communities in Georgia. This is in response to Congressional recommendations that the Centers for Disease Control and Prevention (CDC) utilize advanced surveillance methodologies for CFS to examine its natural history and identify risk factors and biomarkers.

In 2004, OMB approved the information collection. Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia, under OMB Number 0920–0638, which provided baseline information on prolonged fatiguing illness in metropolitan, urban, and rural regions in Georgia. Data from the proposed Follow-up Study of Chronic Fatigue Syndrome in Georgia will be used to describe the clinical course of CFS and evaluate behavioral and biochemical factors associated with outcome. This follow-up study will also determine access to and utilization of health care by persons with CFS and measure direct and indirect economic burden due to the illness. As part of a control strategy, the information from this follow up study will be used in national and pilot region provider education programs.

The proposed study continues the Georgia survey using similar methodology and data collection instruments. This follow-up study begins with a detailed telephone interview to obtain additional data on participant health status during the last twelve month period. Eligible subjects will be asked to participate in clinical evaluations. There will be no cost to respondents other than their time. The estimated total annualized burden hours are 861.

ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Respondents</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden/response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up Study Detailed Interview</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
propose to provide notified workers with a Reader Response postcard for routinely assessing notified study subjects’ responses to individual letter notification materials sent to them by NIOSH. We are requesting approval for three years. Participation is voluntary and there is no cost to respondents except for their time. The total estimated annualized burden hours are 1,333.

ANNUALIZED BURDEN TABLE

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden (in hours)</th>
<th>Total burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reader Response Card</td>
<td>8,000</td>
<td>1</td>
<td>10/60</td>
<td>1,333</td>
</tr>
</tbody>
</table>


Marilyn Radke,  
Reports Clearance Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day–08–07AA]

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 amb@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**


**Background and Brief Description**

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, Section 301, which authorizes “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.” (2) 42 U.S.C. 247b–4, Section 317 C, which authorize the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as “the Children’s Health Act of 2000.” This portion of the code has also been amended by Public Law 108–154, which is also known as the “Birth Defects and Developmental Disabilities Prevention Act of 2003”.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because pre-marketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not have a comprehensive early warning system for major adverse pregnancy or infant outcomes related to medication exposures.

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 adverse effects of medication exposures during pregnancy and lactation. The objective of this project is to conduct a pilot study to assess whether TIS in the United States and Canada can serve as an effective monitoring and early warning system for major adverse effects on (1) pregnancy outcomes (e.g., live birth, stillbirth, premature birth, low birth weight, etc.) and (2) maternal and infant health. 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 adverse 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 conduct 4 telephone interviews: At enrollment; during the third trimester of pregnancy; approximately one month after delivery; and when the infant is about 3 months old. For each