

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 regional 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

Respondents	Number of respondents	Number of responses per respondent	Average burden/response (in hours)
Follow-up Study Detailed Interview	2,870	1	18/60

Dated: November 15, 2007.
Marilyn Radke,
Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0566]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Use of a Reader Response Postcard for Workers Notified of Results of Epidemiologic Studies Conducted by the National Institute for Occupational Safety and Health (NIOSH)—

Reinstatement—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Section 20(a)(1), (a)(4), (a)(7)(c), and Section 22 (d), (e)(5)(7) of the Occupational Safety and Health Act (29 U.S.C. 669), has the responsibility to “conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.” NIOSH also has the responsibility to “conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health [e.g., worker notification], which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of the Act.” .

Since 1977, the National Institute for Occupational Safety and Health (NIOSH) has been developing methods and materials for the notification of subjects of its epidemiological studies. NIOSH involvement in notifying workers of past exposures relates primarily to informing surviving cohort members of the findings of retrospective

cohort studies conducted by NIOSH. Current policy within NIOSH is to notify subjects of the results of its epidemiologic studies. The extent of the notification effort depends upon the level of excess mortality or the extent of the disease or illness found in the cohort. Current notification efforts range from posting results at the facilities studied to mailing individual letter notifications to surviving cohort members and other stakeholders. The Industry-wide Studies Branch (IWSB) of NIOSH, Division of Surveillance, Hazard Evaluation, and Field Studies (DSHEFS), usually conducts about two or three notifications per year, which typically require individual letters mailed to cohorts ranging in size from 200–20,000 workers each. In order to assess the effectiveness of the notification materials received by the recipients and to improve future communication of risk information, the evaluation instrument proposed was developed.

The NIOSH Institute-wide Worker Notification Program routinely notifies subjects about the results of epidemiologic studies and the implications of the results. The overall purpose of the proposed project is to gain insight into the effectiveness of NIOSH worker notification in order to improve the quality and usefulness of the Institute’s worker notification activities. Researchers from the NIOSH Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS)

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

Form name	Number of respondents	Number of responses per respondent	Average burden response (in hours)	Total burden (in hours)
Reader Response Card	8,000	1	10/60	1,333

Dated: November 15, 2007.

Marilyn Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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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 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

Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

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 authorizes 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 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 then 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