Dated: September 14, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12–12RP]

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 404–639–7570 or send comments to Kimberly S. Lane, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email 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

Assessment of the Psychosocial Impact of Newborn Screening for Congenital Cytomegalovirus (CMV) Infection—New—National Center for Immunization and Respiratory Diseases (NCIRD) and National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year in the United States, more than 30,000 children are born with congenital CMV infection. Approximately 80% develop normally, while the remaining 20% are born with or subsequently develop disabilities such as hearing loss or mental retardation. A similar number of children are affected by serious CMV-related disabilities than by several better-known childhood conditions, including Down syndrome and spina bifida.

The birth prevalence of congenital CMV infection is several times higher than the combined birth prevalence of all metabolic or endocrine disorders in the core U.S. newborn screening panel. Because newborn CMV screening is rarely performed, and because a definitive diagnosis of congenital CMV requires access to urine, saliva, or blood collected soon after birth, most infected children are never diagnosed. Newborn CMV screening offers some clear potential benefits, but few studies have assessed the potential for harm (e.g., increased parental anxiety, ''fragile child syndrome'').

CDC is requesting OMB approval for one year to collect information about newborn CMV screening. The purpose of this information collection is to understand the psychosocial impact of newborn screening on parents whose infants underwent CMV screening as part of a routine infant CMV screening program in Houston, Texas. The potential study population includes approximately 70 CMV-infected children who were symptomatic at birth, 100 CMV-infected children who were asymptomatic at birth (20 of whom developed sequelae), and 50 controls that were CMV-uninfected. The goals of this information collection are to: (1) Document the positive and negative psychosocial impacts of newborn CMV screening on parents and their children; (2) identify modifiable factors that might increase positive psychosocial impacts and decrease negative psychosocial impacts of newborn CMV screening; (3) use what is learned about psychosocial impacts to identify key messages that parents need relative to newborn CMV screening and follow-up; and (4) to learn what challenges are associated with obtaining a congenital CMV diagnosis in the absence of CMV newborn screening.

Much of the potential study population is unique in that their children experienced newborn CMV screening as part of a previous research study. Universal CMV screening has not been recommended by medical associations or state or federal governments and as a result newborn CMV screening is not typically performed. The parents' experience with CMV screening and follow-up will help inform decisions about whether newborn CMV screening would be good public health policy. This study represents the first assessment of the experiences of parents whose children were screened for CMV at birth.

Respondents fall into four categories depending on the past experiences of their child who was screened for CMV:

- Parent Group 1 (PG1)—Child screened positive for congenital CMV at birth, asymptomatic at birth, but *did not* develop sequelae.
- Parent Group 2 (PG2)—Child screened positive for congenital CMV at birth, asymptomatic at birth, but *did* subsequently develop sequelae (e.g., hearing loss).
- Parent Group 3 (PG3)—Child was diagnosed with congenital CMV and had symptoms at birth.
- Parent Group 4 (PG4)—Child screened negative for congenital CMV at birth.

Information will be collected from PG1 via focus groups, from PG2 and PG3 via interviews, and from all four parent groups via a mail survey. The focus group, interview and survey respondents will be asked to participate only once. It is estimated that 71 parents will participate in either individual interviews or focus groups and that 230 will participate in the mail survey. The interviews are planned to take 60 minutes while the focus groups will be held for 90 minutes. The survey is estimated to take 10 minutes per respondent to complete and mail based on previous administrations reported in the literature. Reading and responding to the focus group and interview recruitment letters is estimated to take 5 minutes each. There is no cost to respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Parent category	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Parent Group 1	Focus Group Guide	36	1	1.5	54
	Focus group recruitment letter	50	1	5/60	4
Parent Groups 2 and 3	Interviewer guide	35	1	1	35
	Interview recruitment letter	50	1	5/60	4
Parent Groups 1, 2, 3, and 4	Survey	230	1	10/60	38
Total Burden Hours					135

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Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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Proposed Project

Exposure Assessment and Epidemiological Study of U.S. Workers Exposed to Carbon Nanotubes and Carbon Nanofibers—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act of 1970, Public Law 91–596 (Section 20[a][1] authorizes NIOSH to conduct research to advance the health and safety of workers. In this capacity, NIOSH will conduct an exposure assessment and epidemiological study of U.S. carbon nanotube (CNT) and carbon nanofiber (CNF) workers.

At present, because of the newness of the technology, much of the occupational exposure to engineered nanomaterials occurs at the research and development (R&D) or pilot scale. There have been few reliable surveys of the size of the workforce exposed to nanomaterials. Health effects from exposure to nanomaterials are uncertain, but may be more severe than from larger-sized particles of the same material. This is due to the small size, high surface area per unit mass (i.e., specific surface area) or (in some cases) high aspect ratio of nanomaterials. Carbon nanotubes and nanofibers are among the nanomaterials of greatest interest from a public health perspective because of their potentially asbestiform properties (e.g., high aspect ratio) and toxicological evidence of possible fibrogenic, inflammatory, and clastogenic damage resulting from exposures at occupationally relevant levels. In addition, the useful properties of CNT and CNF have rendered them among the first nanomaterials to be commercially exploited in manufacturing settings. Thus, an epidemiologic study to determine whether early or late health effects occur from occupational exposure to CNT and CNF is warranted.

The proposed research is a cross-sectional study of the small current U.S. workforce involved with CNT and CNF in manufacturing and distribution, to be conducted in the following phases: 1) Industrywide exposure assessment study to evaluate worker exposure and further develop and refine measurement methods for CNT and CNF. This component will refine sampling and analysis protocols previously developed for the detection and quantification of CNT and CNF in US workplaces. 2) A cross-sectional study relating the best metrics of CNT and CNF exposure to markers of early pulmonary or cardiovascular health effects. After the sampling and analysis protocols have been established to measure CNT and CNF, an industrywide study of the association between exposure and health effects will be conducted. Medical examinations will be conducted and several biomarkers of early effect (for pulmonary fibrosis, cardiovascular disease, and genetic damage) will be measured in blood and sputum for workers exposed to a range of CNT and CNF levels.

The study will include a questionnaire with a three-fold purpose: (1) To determine whether study participants have any contraindications for certain medical procedures to be conducted (spirometry and sputum induction), (2) to assist in interpretation of the biomarker results, and (3) to inquire about current and past exposure to CNT, CNF, and other chemicals, dusts, and fumes. The questionnaire will be given by NIOSH personnel as a computer-assisted personal interview (CAPI). After administration of the CAPI, medical examinations will be conducted to evaluate pulmonary function (via spirometry) and blood pressure, and sputum and blood will be collected. Statistical analyses will be conducted to determine the nature of the relation between exposure to CNT