

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: September 6, 2012.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-12RO]

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 and send comments to Kimberly S. Lane, 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

Anniston Community Health Survey: Follow-up and Dioxin Analyses (ACHS-II)—New—Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (DHHS) Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the past, polychlorinated biphenyls (PCBs) were used as coolants and lubricants in electrical equipment. They didn't burn easily and were good insulators. PCBs are no longer made in the U.S. They were banned in 1977 because they persist in the environment. Concerns grew about harm to health.

The City of Anniston, AL, was the site of the former Monsanto facility. PCBs were made there from 1929 to 1971. For decades, PCBs were released into the local air, soil, and surface water. In 1996, residents found out they were exposed. Concerns grew and led to litigation. In 2003, a settlement in favor of the residents was reached in state and federal courts.

The Anniston Environmental Health Research Consortium (AEHRC) was funded by the Agency for Toxic Substances and Disease Registry (ATSDR). The AEHRC conducted the Anniston Community Health Survey (ACHS) from 2005 to 2007. Serum PCB levels in 766 Anniston adults were

found to be three to seven times higher than in U.S. adults. Also, higher PCB levels were found in Anniston adults who had high blood pressure and diabetes.

The ATSDR and the National Institutes of Health (NIH) plan to continue the work of the first ACHS. These agencies will conduct a follow-up study called the ACHS-II. It will be a repeated cross-sectional study. Data collection will be managed by the University of Alabama at Birmingham (UAB) and the Calhoun County Health Department (CCHD).

A sample of 500 adults will be selected from the first ACHS cohort. After informed consent, clinical assessments will be done. These will be for blood pressure, height, weight, and body girth. A questionnaire will be answered by computer-assisted personal interviews (CAPIs). Questions will be asked for health, demographic, diet, and lifestyle factors. The self-reported responses will be compared to laboratory analytes. For these, blood samples will be drawn and analyzed.

The ACHS-II will measure the same serum PCBs as in the first Anniston survey. In this way, changes in PCB levels can be studied. The ACHS-II will also include serum analytes for dioxins, furans, dioxin-like PCBs, and other similar chemicals. Additional analytes include blood measures of heavy metals. Clinical biomarkers will include measures for thyroid, diabetes, lipids, and immune function. This will give a more complete profile of human exposures and health in Anniston, AL.

The ATSDR is requesting a two-year approval for this information collection.

There are no costs to respondents other than their time. In total, they will spend 2 hours in the study.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden hours
Adults who took part in first Anniston Community Health Survey.	Telephone Recruitment Script.	333	1	2/60	11
	Survey for Refusals	165	1	1/60	3
	Informed Consent	250	1	1/60	4
	Update Contact Information Form.	250	1	1/60	4
	Medications Form	250	1	3/60	12
	Blood Draw Form	250	1	2/60	8
	Questionnaire	250	1	45/60	188
Total	230

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]

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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.