

Tennessee). The network consists of environmental health specialists (EHSs), epidemiologists, and laboratorians. The EHS-Net has developed a standardized protocol for identifying, reporting, and analyzing data relevant to foodborne illness outbreak environmental assessments.

While conducting environmental assessments during outbreak investigations is routine for food safety program officials, reporting information from the environmental assessments to CDC is not. Thus, state, local, tribal, and territorial food safety program officials are the respondents for this data collection—one official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies. There are approximately 3,000 such agencies in the United States.

Thus, although it is not possible to determine how many programs will choose to participate, as NVEAIS is voluntary, the maximum potential number of program respondents is approximately 3,000.

These programs will be reporting data on outbreaks, not their programs or personnel. It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. However, we can estimate, based on existing data, that a maximum of 1,400 foodborne illness outbreaks will occur annually. Only programs in the jurisdictions in which these outbreaks occur would report to NVEAIS. Thus, not every program will respond every year. Consequently, the respondent burden estimate is based on the number of outbreaks likely to occur each year. Assuming each outbreak

occurs in a different jurisdiction, there will be one respondent per outbreak.

There are two activities associated with NVEAIS that require a burden estimate. The first is entering all requested environmental assessment data into NVEAIS. This will be done once for each outbreak. This will take approximately 2 hours per outbreak.

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate that a maximum average of 4 manager interviews will be conducted per outbreak. Each interview will take about 20 minutes.

The total estimated annual burden is 4,667 hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Food safety program personnel	Reporting environmental assessment data into electronic system.	1,400	1	2	2,800
Food safety program personnel	Manager interview	1,400	4	20/60	1,867
Total	4,667

Dated: April 20, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub.

L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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.

Proposed Project: Poison Help General Population Survey—(NEW)

The “Poison Help General Population Survey” is a 10-minute telephone survey designed to assess the campaign's effects among 2,000 households in the United States. The survey will be conducted with an adult household member and will address topics related to the types of individuals or organizations they would contact for information, advice, and treatment related to a poisoning. Survey results will be used to guide future communication, education and outreach efforts.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Survey Respondents	2000	1	2000	.167	334
Screened households	2353	1	2353	.0167	39
Total	4353	373

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 21, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Environmental Science Formative Research Methodology Studies for the National Children's Study

SUMMARY: 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 National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Environmental Science Formative Research Methodology Studies for the National Children's Study (NCS)

Type of Information Collection

Request: Generic Clearance

Need and Use of Information

Collection: The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) **PURPOSE.**—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) **IN GENERAL.**—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental

factors, both risk and protective, that influence health and developmental processes.

(c) **REQUIREMENT.**—The study under subsection (b) shall—

(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of environmental sample collection procedures and technology, storage procedures, accompanying questionnaires, and assays, and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain an OMB generic clearance to collect environmental samples from homes and child care settings, and conduct accompanying short surveys related to the physical and chemical environment.

The NCS has obtained an OMB generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, recruitment and retention (0925–0590; requesting renewal). Under separate notice, the NCS is also requesting an OMB generic clearance to conduct formative research featuring biospecimen and physical measures, neurodevelopmental, and study logistic information collection. These separate and distinct generic clearances will facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs.

Background

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines “environment” broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better

able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: The U.S. Department of Health and Human Services (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this request, the NCS is requesting a generic clearance from OMB for formative research activities relating to the collection, storage, management, and assay of environmental samples and accompanying questionnaires. The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study environmental sample and information collection in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

The NCS has obtained generic clearance for formative research activities pertaining to outreach, recruitment and retention (0925–0590). Under separate notice, the NCS also requests an OMB generic clearance for formative research featuring biospecimen and physical measures, neurodevelopmental measures, and study logistic information collection. These separate and distinct generic clearances are requested to facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs.