

Dated: February 26, 2010.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-10-0736]

#### 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 or send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto: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

Human Smoking Behavior Study (OMB No. 0920-0736, exp. 3/31/2010)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Cigarettes are currently ranked as full-flavor, light or ultralight on the basis of machine-measured levels of smoke toxins (yield categories). The machine-based methods approximate human smoking patterns under controlled conditions but may not accurately reflect conditions of actual use, moreover, public health data have not consistently shown differences in health outcomes among smokers of cigarettes of different machine-smoked yield categories. Comparison of cigarette smoke emissions using machine-smoking methods will continue until something superior is developed, therefore, machine-smoking must be adequately informed to yield results that better reflect human smoking behavior.

In 2007, the Centers for Disease Control and Prevention (CDC) received OMB approval for a study designed to elucidate patterns of human smoking behavior, quantify biomarkers of exposure to smoke toxins under conditions of actual use, and determine how smoking behavior modifies the relationship between cigarette yield category, biomarkers of exposure, and measures of cardiovascular reactivity. The study has been a collaborative endeavor involving the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and the National Center for Environmental

Health (NCEH). Information has been collected from adult smokers of full-flavor, light and ultralight cigarettes, however, the target number of respondents was not achieved during the initial approval period.

CDC requests OMB approval to reinstate the information collection after the expiration date (OMB No. 0920-0736, exp. 3/31/2010) in order to meet recruitment goals and complete the data analysis as outlined in the original approval. Respondents will be asked to participate in a laboratory-based descriptive study of smoking behavior and analysis of biomarkers of exposure. Respondents will make two visits to a laboratory for measurements and complete a brief smoking diary during the one-day interval between the two laboratory visits. Indicators of smoking behavior such as ventilation pore-blocking behavior, puff volume, puff duration, puff velocity and inter-puff interval will be assessed. Measures of exposure to be assessed include expired-air carbon monoxide boost, carcinogens, nicotine and its metabolites in urine, cotinine in saliva and solanesol in cigarette butts as an indicator of total smoke exposure.

The goals of this project are to characterize the range of human smoking behavior for a variety of cigarette categories and machine-smoked yields, and to estimate the levels of biomarkers of exposure with the various cigarette styles.

CDC Requests OMB approval for two years. During this period there will be a reduction in total burden due to the limited number of respondents needed to complete the study. No changes to the data collection instruments or the estimated burden per response are proposed. Participation in the study is voluntary. There are no costs to 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)
Adult Smokers .....	CATI Screener .....	150	1	5/60	13
	Visit 1 Screener .....	70	1	5/60	6
	Smoking Diary .....	61	1	10/60	10
	Laboratory Visit .....	61	2	1	122
Total .....	.....	.....	.....	.....	151

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Centers for Disease Control and Prevention**  
**[30Day-10-0009]**

**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](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington,

DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

National Disease Surveillance Program I—Case Reports (OMB No. 0920-0009, exp. 3/31/2010)—Revision—National Center for Zoonotic, Vector-borne, and Enteric Diseases (NCZVED), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Formal surveillance of 16 separate reportable diseases has been ongoing to meet the public demand and scientific interest in accurate, consistent, epidemiologic data. These ongoing disease reports include: Creutzfeldt-Jakob Disease (CJD), Cyclospora, Dengue, Hantavirus, Kawasaki Syndrome, Legionellosis, Lyme disease, Malaria, Plague, Q Fever, Reye Syndrome, Tickborne Rickettsial Disease, Trichinosis, Tularemia, Typhoid Fever, and Viral Hepatitis. The Active Bacterial Surveillance (ABCs) forms were removed in 2007 and were

approved as separate documents under OMB control number 0920-0802. Case report forms from state and territorial health departments enable CDC to collect demographic, clinical, and laboratory characteristics of cases of these diseases. This revision incorporates the removal of the ABCs surveillance forms and minor changes to the Malaria surveillance form.

The purpose of the proposed study is to direct epidemiologic investigations, identify and monitor trends in reemerging infectious diseases or emerging modes of transmission, to search for possible causes or sources of the diseases, and develop guidelines for prevention and treatment. The data collected will also be used to recommend target areas most in need of vaccinations for selected diseases and to determine development of drug resistance. Because of the distinct nature of each of the diseases, the number of cases reported annually is different for each. There is no cost to respondents other than their time. The estimated annualized burden for this data collection is 11,441 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Epidemiologist .....	Typhoid fever .....	55	6	20/60
	Viral hepatitis .....	55	200	25/60
	CJD .....	20	2	20/60
	Cyclosporiasis .....	55	10	15/60
	Dengue .....	55	182	15/60
	Hantavirus .....	40	3	20/60
	Kawasaki Syndrome .....	55	8	15/60
	Legionellosis .....	23	12	20/60
	Lyme Disease .....	52	385	10/60
	Malaria .....	55	20	15/60
	Plague .....	11	1	20/60
	Q Fever .....	55	1	10/60
	Reye Syndrome .....	50	1	20/60
	Tick-borne Rickettsia .....	55	18	10/60
	Trichinosis .....	25	1	20/60
	Tularemia .....	55	2	20/60

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**Maryam I. Daneshvar,**  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)**

**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 Cancer Institute (NCI), 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:* The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI) (OMB#: 0925-0406). *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* The purpose of this information collection is to