

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Hours per response
Office-based physicians/CHC providers/staff.	Patient Record form (NAMCS-30) .....	1,017	30	11/60
Office/CHC staff .....	Pulling, re-filing Patient Record form (NAMCS-30).	893	30	1/60
Office-based physicians/CHC providers/staff.	Asthma Supplement .....	669	1	15/60
Office-based physicians .....	EMR/EHR Mail Survey .....	5,460	1	20/60
Office-based physicians .....	Physician Workflow Survey .....	2,982	1	20/60
Pretest NAMCS forms:				
Office-based physicians .....	Physician Induction Interview (NAMCS-1) ....	100	1	35/60
Office-based physicians .....	Asthma Supplement .....	100	1	15/60
Office-based physicians/staff .....	Patient Record form (NAMCS-30) .....	100	30	14/60

Dated: February 7, 2011.

**Carol E. Walker,**

*Acting 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-11-11CB]

#### 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 Carol E. Walker, 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

SEARCH for Diabetes in Youth Study—New—Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Diabetes is one of the most common chronic diseases among children in the United States. When diabetes strikes during childhood, it is routinely assumed to be type 1, or juvenile-onset, diabetes. Type 1 diabetes (T1D) develops when the body's immune system destroys pancreatic cells that make the hormone insulin that regulates blood sugar. People with type 1 diabetes must have daily insulin injections to survive. In the last two decades, type 2 diabetes (T2D), formerly known as adult-onset diabetes, has been reported among U.S. children and adolescents with increasing frequency. Type 2 diabetes begins when the body develops a resistance to insulin and no longer uses the insulin properly. As the need for insulin rises, the pancreas gradually loses its ability to produce sufficient amounts of insulin to regulate blood sugar.

Reports of increasing frequency of both type 1 and type 2 diabetes in youth have been among the most concerning aspects of the evolving diabetes epidemic. Unfortunately, reliable data on changes over time in the U.S., or even how many children in the U.S. had type 1 or type 2 diabetes, were lacking. In response to this growing public health concern, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH)

funded the SEARCH for Diabetes in Youth Study.

The SEARCH for Diabetes in Youth Study began in 2000 as a multi-center, epidemiological study, conducted in six geographically dispersed Study Centers that reflected the racial and ethnic diversity of the U.S. Phases 1 (2000–2005) and 2 (2005–2010) were designed collaboratively by the research sites to produce estimates of the prevalence and incidence of diabetes among youth age < 20 years, according to diabetes type, age, sex, and race/ethnicity, and to characterize selected acute and chronic complications of diabetes and their risk factors, as well as the quality of life and quality of health care. Phases 1 and 2 of SEARCH have contributed substantially to understanding of the etiologic and clinical dimensions of childhood diabetes that relate to classification of diabetes. However, critical questions remain regarding ongoing trends in incidence of childhood diabetes, as well as the rationale and sustainability of public health surveillance systems for diabetes in youth.

Phase 3 of the SEARCH for Diabetes in Youth Study will build on previous efforts, with some changes to the data collection procedures developed during Phases 1 and 2. Phase 3 brings together major and timely facets of childhood diabetes research: An epidemiologic component that assesses temporal trends in the incidence of diabetes in youth; a pathophysiologic component addressing the natural history of diabetes in youth; a health services research component to evaluate the processes and quality of care for youth with diabetes; and a public health perspective on case classification of diabetes in youth.

As authorized by section 301 of the Public Health Service Act (42 U.S.C. 241), CDC seeks OMB approval to collect de-identified case-level information from SEARCH study sites.

Information will be collected for three years through a data collection contractor, which will serve as the SEARCH study Coordinating Center. Data will be transmitted electronically to the Coordinating Center through a secure, dedicated Web site. Information can be entered and transmitted at any time. The information collection has three components:

The Registry Study will collect information on newly diagnosed incident diabetes cases in youth age < 20 years. CDC estimates that each clinical site will identify and register an average of 255 cases per year. The items collected for each case include an Extended Core, Medication Inventory, Inpatient Survey, Specimen Collection (Registry version), and Physical Exam (Registry version). The total estimated

annualized burden for this information collection is 744 hours.

The Cohort Study is a longitudinal research study about SEARCH cases whose diabetes was incident in 2002 or later. CDC estimates that each clinical site will conduct follow-up on an average of 142 cases per year. The items collected for each case include a Health Questionnaire (Youth version), an additional Health Questionnaire (Parent version), CES—Depression, Medical Record Validation, Quality of Care, Peds QL, SEARCH MNSI Neuropathy, Diabetes Eating Survey, Low Blood Sugar Survey, Supplemental Survey, Tanner Stage, Retinal Photo, Family Conflict Survey, Pediatric Quality of Life Scale, Physical Exam, and Specimen Collection.

Information will also be collected for the purpose of monitoring unanticipated occurrences and conditions. CDC estimates that each site will report an average of 13 unanticipated occurrences per year.

Respondents will be the five study sites funded for SEARCH Phase 3. Participation in the data collection is required for the study sites, but participation in the SEARCH study is voluntary for individuals who are followed at those sites. The estimated annualized burden per study site is 426.4 hours. The total estimated annualized burden for all sites is 2,132 hours.

There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response	Total burden (in hours)
SEARCH Clinical Sites (Registry Study).	Extended Core .....	5	255	10/60	213
	Medication Inventory .....			5/60	106
	Inpatient Survey .....			10/60	213
	Specimen Collection (Registry) .....			5/60	106
	Physical Exam (Registry) .....			5/60	106
SEARCH Clinical Sites (Cohort Study).	Health Questionnaire—Youth .....	5	142	15/60	178
	Health Questionnaire—Parent .....			15/60	178
	CES—Depression .....			4/60	47
	Medical Record Validation .....			10/60	118
	Quality of Care .....			13/60	154
	Peds QL .....			5/60	59
	SEARCH MNSI Neuropathy .....			5/60	59
	Diabetes Eating Survey .....			5/60	59
	Low Blood Sugar Survey .....			5/60	59
	Supplemental .....			10/60	118
	Tanner Stage .....			5/60	59
	Retinal Photo .....			5/60	59
	Family Conflict .....			5/60	59
	Pediatric Diabetes QOL Scale .....			5/60	59
	Physical Exam .....			5/60	59
SEARCH Clinical Sites (Monitoring)	Specimen Collection .....			5/60	59
	Unanticipated Occurrence/Condition Reporting Form.	5	13	5/60	5
<b>Total .....</b>					<b>2,132</b>

Dated: February 7, 2011.

**Carol E. Walker,**

*Acting 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-11-11CD]**

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