SEARCH FOR DIABETES IN YOUTH STUDY

OMB SUPPORTING STATEMENT: PART A

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Abstract

CDC is submitting a new Information Collection Request to obtain OMB approval for the first three years of a five-year project known as the SEARCH for Diabetes in Youth Study ("SEARCH") (Phase 3). The new Phase 3 of SEARCH builds upon activities initiated in 2000 through a multi-center collaborative research project. OMB approval was not requested in previous phases of SEARCH. At that time, all SEARCH awardees were funded through cooperative agreements and did not provide data directly to CDC.

In Phase 3, changes in data collection methodology are being initiated which alter the status of SEARCH under the Paperwork Reduction Act. As in previous phases, five clinical sites will be funded through cooperative agreements, however, in Phase 3 CDC plans to collect de-identified information from the sites through a Coordinating Center, funded by CDC through a contract mechanism. The de-identified information collected by CDC through the Coordinating Center will support 1) a case registry that can be used to estimate the incidence of diabetes in youth in the U.S., and 2) a cohort study of youth with diabetes to estimate the prevalence and incidence of risk factors and complications, including chronic microvascular (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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 develops when the body's immune system destroys pancreatic cells that make the hormone insulin that regulates blood sugar. It normally strikes children and young adults. People with type 1 diabetes must have daily insulin injections to survive.
In the last two decades, type 2 diabetes, 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, there was very limited data on how diabetes among children in the U.S. may have changed over time, or even how many children in the U.S. had type 1 or type 2 diabetes. There was no survey or study large enough to document either the change in incidence and prevalence of diabetes among youth or to distinguish between different types of diabetes. 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 (Kaiser Permanente of Southern California, Los Angeles, California; Cincinnati Children's Medical Center, Cincinnati, Ohio; University of Colorado Denver, Denver, Colorado; Seattle Children's Hospital, Seattle, Washington; South Carolina coordinated at University of North Carolina, Chapel Hill, North Carolina; Kaukini Medical Center, Hawaii) 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. During Phases 1 and 2, a Coordinating Center, funded through a cooperative agreement, worked collaboratively with clinical sites to conduct data collection and analysis. Major strengths of SEARCH include: 1) race/ethnic diversity within the large cohort of youth with type 1 diabetes; and 2) size and diversity of the cohort of youth with type 2 diabetes. In addition, SEARCH has substantially contributed to the understanding of the etiologic and clinical dimensions of childhood diabetes that relate to classification of diabetes. The SEARCH study 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.

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. SEARCH is exceptionally strongly positioned to address these questions through its established infrastructure and surveillance system, and its highly experienced, collaborative and multi-disciplinary investigative team.

Phase 3 of the SEARCH for Diabetes in Youth study will build on previous efforts, with some changes to the data collection and management procedures development during Phases 1 and 2. As in the initial phases, clinical and observational protocols will be determined collaboratively by the principal investigators from five study sites, and guided by experience gained during Phases 1 and 2. However, information collected at each site will then be transmitted to a Coordinating Center, funded by CDC through a contract mechanism, for aggregation and analysis. In this Information Collection Request, CDC seeks OMB approval to receive information through the data collection contractor. These activities are authorized by section 301 of the Public Health Service Act (42 USC 241, Part A, Research and Investigation; see **Attachment 1**).

Privacy Impact Assessment

Overview of the Data Collection

Phase 3 will involve five geographically dispersed study sites and a Coordinating Center (see **Attachment 3).** Data collection will consist of two components:

1. The Registry Study will collect information on newly diagnosed incident diabetes cases in youth age < 20 years.
2. The Phase 3 Cohort Study will collect information about SEARCH participants whose diabetes was incident in 2002 or later, with duration of diabetes > 5 years, who completed a baseline study visit (expected n=3550) in a previous phase of SEARCH. The Phase 3 Cohort Study is based on a previous epidemiological study consisting of the largest and most culturally diverse population of youth with diabetes ever assembled.

De-identified, encrypted study data will be transmitted to the Coordinating Center via the study webpage. Personal health information will not be transmitted to the Coordinating Center or to CDC, but will be kept locally at the clinical sites. All study personnel will be trained in the appropriate management of study data.

Items of Information to be Collected

The information collected from the clinical sites will include information about the clinical study site, and information about cases including diabetes type, date of diabetes diagnosis, risk factors, clinical assessment, and measurements for micro and macro vascular risk factors.

Identification of Website(s) and Website Content Directed at Children under 13 Years of Age

Study data will be transmitted to the Coordinating Center via the secured study webpage https://search.phs.wfubmc.edu/index.cfm. There is no website content directed at children under 13.

A.2. Purpose and Use of Information Collection

SEARCH provides the foundation for childhood diabetes surveillance efforts in public health, clinic, and research settings. SEARCH data will be used to design and implement public health efforts to prevent both type 1 and type 2 diabetes in youth. The data that are acquired by SEARCH regarding the natural history, risk factors of diabetes complications, quality of care and quality of life will also to be used to assist with the design and implementation of interventions that can reduce the risk for both acute and chronic diabetes complications.

Examples of information generated through previous phases of SEARCH include:

- SEARCH prevalence data indicate that in the U.S., at least 154,000 children/youth have DM. DM prevalence varies across major racial/ethnic groups:
    - In children 0–9 years of age non-Hispanic whites have the highest prevalence (about 1/1,000). In this age group across all race/ethnic groups, type 1 DM is the

most common form of diabetes. The study found that type 2 DM is extremely rare in children of all races younger than 10 years of age.
    - Among adolescents and young adults (age 10–19 years), African American and non-Hispanic white youth have the highest burden of DM (about 1 of 315) and Asian/Pacific Islanders have the lowest (about 1 of 746). Type 1 diabetes prevalence is 2.3/1,000 and it is the most common form of DM in all racial/ethnic groups except in American Indian youth. Type 2 prevalence is 0.4/1,000 and it represented 6% of the cases of diabetes in Non-Hispanic White, 33% in African American, 40% in Asian/Pacific Islander, and 76% among American Indian youth.

- Based on 2002 and 2003 data, the overall incidence is estimated to be 24.3 per 100,000 per year. Annually, an estimated 15,000 youth are diagnosed with type 1 diabetes, and about 3,700 youth are diagnosed with type 2.
    - Among youth aged <10 years, most diabetes cases are type 1, regardless of race/ethnicity. In this age group the highest incidence of type 1 diabetes is observed in non-Hispanic whites (19/100,000 for 0– to 4– years-old and 28/100,000 for 5– to 9– years-old)
    - Among older youth (ages 10–14 and 15–19 years), the highest incidence of type 1 diabetes is in non-Hispanic white youth (33/100,000 per year for 10– to 14– years-old and 15/100,000 for 15– to 19– year olds), followed by African American (19.2 and 11.1) and Hispanic (17.6 and 12.1), and lowest among American Indian (7.1 and 4.8) and Asian/Pacific Islanders (8.3 and 6.8).
    - The incidence of type 2 DM is the highest among American Indians (25.3 and 49.4 for ages 10–14 and 15–19 years, respectively), followed by African Americans (22.3 and 19.4), Asian/Pacific Islanders (11.8 and 22.7) and Hispanics (8.9 and 17.0), and is low (3.0 and 5.6) among non-Hispanic whites.

- SEARCH has shown that nutritional intake in adolescents with DM is poor and does not follow current recommendations. Recommendations for total dietary fat intake are met by only 10 percent of youth with DM and recommendations for saturated fat intake by only 7 percent.

- SEARCH found that about 9 percent of adolescents with DM have moderate or severely depressed mood symptoms, with more girls than boys being affected. Depressed mood is associated with poor glycemic control and a higher likelihood of emergency room visits.

- About half of the SEARCH participants had an LDL-C concentration above the optimal level of 100 mg/dL. In older youth (≥ 10 yrs of age), the prevalence of abnormal lipids was higher in those with type 2 (33%) than in those with type 1 diabetes (19%). Moreover, worse glycemic control was associated with a worse lipid profile, regardless of diabetes type.

- The prevalence of multiple cardiovascular disease (CVD) risk factors is high in children and adolescents with DM. CVD risk factors are present in both youth with type 1 or type 2 DM, but were more common in adolescents with type2.

- Higher Body Mass Index (BMI) is associated with younger age at diagnosis of type 1 diabetes but, only in children with reduced beta cell function. These data suggest that, only among individuals with already compromised beta-cell function or high rate of beta cell loss, obesity accelerates type 1 diabetes onset. In addition, low birth weight may be a factor in accelerating the onset of type 1 diabetes. These data suggest that the intrauterine environment may be an important determinant of age of onset for type 1 diabetes.

Additional information about uses of SEARCH Phase 1 and Phase 2 data is provided in the References section of this Information Collection Request (see **Attachment 5**).

In Phase 3, the specific aims of the SEARCH Registry Study are:

Aim 1: To ascertain newly diagnosed (2010 - 2014) incident diabetes cases in youth age < 20 years in order to assess temporal trends in diabetes incidence and temporal trends in presentation of diabetes for the period 2002-2014, by age, sex, race/ethnicity, and diabetes type.

Aim 2: To provide consultation and support to inform the development of low-cost sustainable public health surveillance systems of childhood diabetes in the U.S., with a focus on challenges in ascertainment of cases with T2D and cases among older youth (ages 15 years or older) with any form of non-gestational diabetes.

Aim 3: To conduct surveillance of mortality including cause of death on the incident cases from September 30, 2010 to September 29, 2015.

In Phase 3, the specific aims of the SEARCH Cohort Study are:

Aim 4: To assess the prevalence and incidence of, and risk factors for chronic microvascular degeneration (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.

Aim 5: To assess the incidence of, and risk factors for, serious acute complications of diabetes including severe hypoglycemia and diabetic ketoacidosis (DKA).

Aim 6: To determine the degree to which barriers to care, quality of care, and the process of transition from pediatric to adult health care impact disease factors, including dimensions of diabetes type, and diabetes-related outcomes (acute and chronic complications, quality of life, diabetes-related mortality).

Aim 7: To maintain and supplement the SEARCH repository for biological specimens, and promote access to SEARCH for conduct of scientifically and logistically appropriate ancillary studies.

Privacy Impact Assessment

The SEARCH clinical sites will collect information in identifiable form (IIF) on each registered diabetes case and cohort study participant (personal identifiers such as name, address, age, race/ethnicity) along with information about the youth's medical history and results of in-person visits. The collection of personal information is necessary in order for the clinical sites to contact registered cases for inclusion in the study and to conduct follow-up. While the SEARCH clinical sites will use a number of different methods to collect data (telephone and in-person interviews, medical record abstraction, laboratory and physical examination measurements, each collected on separate forms), all the data submitted to the Coordinating Center will be entered into a database. The data collection method for the Coordinating Center is the database that has been developed to capture the information collected by the SEARCH clinical sites. Each clinical site will enter the data collected on the forms into an Access database that is then transmitted to the CDC through the Coordinating Center. Each SEARCH Clinical Site will maintain the data for 7 years after the end of the study. At the close out of SEARCH the Coordinating Center will provide CDC with a de-identified data set. This data will also be made publically available through the NIH data repository or similar site.

Case-level information undergoes two levels of de-identification prior to transmission to CDC. First, each clinical site assigns a unique identifier (ID) code to each participant identified or followed at that site. The site-specific ID code is used to manage transmission of records from the clinical site to the Coordinating Center (data collection contractor). The information transmitted to the Coordinating Center does not include names or addresses of SEARCH participants. The Coordinating Center will not accept a method of record identification, such as social security number, that may be linked to other databases. The identifying information provided to Coordinating Center will include the site-specific patient ID code, county of residence, state of residence, month and year of birth, and Hispanic origin. The clinical site is solely responsible for maintaining the unique list linking the site-specific ID code with the client's name, as well as the encryption information associating their unique ID codes with the personal identifiers maintained by the site. Neither the encryption scheme nor identifying information, other than the variables noted, will ever be provided to the Coordinating Center or to CDC.

Upon receipt of de-identified, coded data, the Coordinating Center will create a new, randomly generated ID code for each diabetes case, which will be used to manage the records transmitted to CDC. The ID codes assigned by the Coordinating Center cannot be linked back to the ID codes assigned by the clinical sites, or the names of patients. Research entities such as the SEARCH clinical sites have successfully used the two-step de-identification process to protect the identities of research participants and to guard against inadvertent disclosure of personal information in identifiable form.

The aggregate data provided to the Coordinating Center is archived on secure network servers with user ID and password restricted access at the location of the Coordinating Center. Access rights and restrictions to network resources are determined by user ID. Network systems are maintained in a locked room with access strictly limited to essential employees.

The proposed data collection by CDC will not impact the respondent's privacy. CDC will not receive any identifying information. All identifying information will be maintained at the SEARCH Clinical Sites and will not be transmitted to the Coordinating Center or to the CDC. CDC has also obtained a Certificate of Confidentiality for each SEARCH Clinical Site. The current certificate is valid through October 2011 and CDC is currently in the process of obtaining Certificate of Confidentiality for each SEARCH site for the remainder of the study (**Attachment 8**).

A.3. Use of Information Technology and Burden Reduction

Clinical sites will submit 100% of the information to the Coordinating Center electronically by entering updates on the SEARCH study website. The electronic submission system will include tracking features to facilitate data management and follow-up with SEARCH study participants. The electronic submission system will also facilitate data analysis and transmission of information to CDC. Although records are due for transmission to the Coordinating Center once per year, the web-based entry system permits clinical sites to enter the data at their convenience, and allows analysts to generate ongoing summary information and estimates. (**see Attachment 4D**).

A.4. Efforts to Identify Duplication and Use of Similar Information and Efforts to De-Identify Information

These data are available exclusively from the SEARCH grantees, and no other source of data exists that would allow for national estimates of the incidence of diabetes in youth or for the incidence and prevalence of risk factors and complications among youth with diabetes. Although data-sets with questions and measures related to diabetes currently exist [e.g., the National Health and Nutrition Examination Survey, OMB No. 0920-0237, exp. 11/30/2012], the number of youth with diabetes in the U.S. is too small to allow accurate estimates from NHANES or other general-purpose information collections. Since the estimates of the incidence or prevalence of diabetes among youth are not available from these data sets, SEARCH will supplement the existing information to provide this information. Further, the alternative data sources only allow the tracking of prevalence of diabetes and do not allow estimates of incidence.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting Information Less Frequently

Ongoing data collection is a necessary component of the SEARCH study in order to calculate incidence of diabetes among youth and to obtain estimates of the prevalence and incidence of complications among youth with diabetes on an on-going basis. The respondent (the SEARCH clinical sites) will respond to the data collection annually for 5 years. Annual response allows for on-going monitoring of the study and estimates of the incidence of diabetes in youth. This allows the tracking of trends in the population. The reporting periods established for SEARCH are frequent enough to allow for ongoing evaluation, but not too frequent to be overly burdensome. The current reporting periods allow CDC and grantees to assess performance at regular intervals, and to make adjustments as necessary. Less frequent data collection would compromise the ability to successfully conduct the SEARCH study.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments to the Federal Register Notice and Efforts to Consult with Outside Agency

A. A 60-day Notice was published in the Federal Register on February 11, 2011, Vol. 76, No. 29, pp. 7859-7860 (Attachment 2). No comments were received in response to publication of the Notice.
B. In 2006, CDC and NIH formed a working group of experts, the External Scientific Evaluation Committee (ESEC), to provide on-going outside consultation to the SEARCH Study. The ESEC meets annually. In 2009, the National Institutes of Health, National Institute for Diabetes, Digestive and Kidney Disease, formed a group of experts (External Evaluation Committee) to advise NIH on recommendations for the future direction of SEARCH. There were major problems that could not be resolved during the consultations. Members of both the ESEC and the NIH External Evaluation Committee, along with scientists at both the CDC and NIH, are listed in **Attachment 6**.

A.9. Explanation of Any Payment or Gift to Respondents

No payment to respondents, i.e. the SEARCH clinical sites, is made directly by the Coordinating Center.

A.10. Assurance of Confidentiality Provided to Respondents

The SEARCH Phase 3 information collection has been approved by the IRB at each participating site and at the Coordinating Center (see **Attachment 7**).

Privacy Impact Assessment Information

A. Privacy Act Determination. This submission has been reviewed by CDC's Information Collection Review Office, which determined that the Privacy Act does/does not apply. The de-identified patient-level information received by CDC cannot be retrieved by name or other direct identifiers, as the information goes through a two-step de-identification and re-coding process prior to receipt by CDC.

   In the first step, the clinical site removes patient name and other direct identifiers from the records, and assigns site-specific patient ID codes before transmitting the records to the Coordinating Center. To maintain confidentiality, materials will be sent to the central location with a study number but no personal information (such as name, social security number, medical record number, contact information, etc). The unique participant ID is generated randomly at the site when a participants' information is entered into the tracking database. This site-specific ID is then submitted to the Coordinating Center. All identifiable information linking the participant and the unique study ID are maintained at the clinical site and can not be linked by the CDC or the Coordinating Center. These Patient-level identifiers will be maintained in a separate file, which is maintained and protected locally.

   In the second step, the Coordinating Center replaces each record's site-specific ID code with a new, randomly generated patient ID code. Information reported to CDC includes only ID codes generated by the Coordinating Center. Patient names and other direct identifiers cannot be reconstructed from the ID code that is randomly generated by the Coordinating Center.

B. Administrative Safeguards. The information collected during prior phases of the SEARCH project was protected by a Certificate of Confidentiality at each site (**Attachment 8**). The 301(d) confidentiality certificates provide legally effective barriers to disclosure for individually identifiable data residing at the clinical sites and as needed, protection to data residing at laboratories, and other subcontractors with study data. These certificates will protect individual data from sources not connected with this study. CDC is seeking updated Certificates of Confidentiality 301(d) for Phase 3. Sensitive individually identified patient data which require the continuous confidentiality protection granted under the earlier certificates will be covered under the updated certificates, as well as new data to be collected in Phase 3. All study personnel will be trained in the appropriate and sensitive means of data collection.

Physical and Electronic Safeguards. Information will be obtained from multiple sources: Medical Records, In Person Survey, In Person Visit (including physical exam, questionnaires, laboratory studies of blood and urine). Forms used for data collection will be distributed to the clinical sites by the Coordinating Center. Data will be transmitted electronically via a password protected website to the Coordinating Center for data analysis. The Coordinating Center employs a digital server certificate from Verisign, Inc. This certificate allows the communications between the web server and the client system to be encrypted. This encryption is as advanced as is now allowable by the United States Government, and the mechanism is the same as is used by the banking industry and for electronic commerce. The Coordinating Center's web system is protected by a Cisco firewall that limits the source and type of traffic coming into the institution, and remains under constant monitoring and control. In addition, the institution is currently implementing a suite of Net Ranger products that will assist in the detection and circumvention of certain well-known attacks. Using attack signatures, the products monitor incoming traffic, looking for data streams that match the signature of attacks. If found, information is collected about the attack and the transmission is terminated.

Restricted areas of the SEARCH web site are protected by user login. Prior to gaining access to the restricted area, the user is required to enter a username and password that is checked against a database of authorized system users. The organization of the SEARCH authorization database is such that it allows the Coordinating Center to restrict functions of an individual user by their login. The Coordinating Center can restrict their ability to view entire sections of the web site, reports, data elements and more. For security purposes, once a user has successfully logged into the system, inactivity for a period of 15 minutes will automatically force the user to re-authenticate prior to using the system again. Users are recommended to log out of the system before leaving their work area for any extended period.

C. Consent. The research at each clinical site is overseen by its Institutional Review Board. As required by 45 CFR 46, each site obtains assent from the youth who participate in the research, and permission from their parent(s) or guardian(s).

D. Nature of Response. Respondents are the five sites participating in the research. Transmission of information to CDC via the Coordinating Center is required under the terms of the cooperative agreements that provide funding for the research.

A.11. Justification for Sensitive Questions

SEARCH grantees collect potentially sensitive questions on baseline forms. The justification for each item is detailed below.

- Racial/ethnic group - necessary for subgroup analysis by ethnic group to evaluate differences in prevalence and incidence of diabetes and outcomes,

- Total family income, parental and participant education and finance questions - an important measure of socioeconomic status and predictor of disease development, medical care use, and longevity.
- Other medical issues – questions and measures pertaining to acute and chronic health conditions related to diabetes, such as diabetes ketoacidosis, severe hypoglycemia, retinopathy, nephropathy, neuropathy, vascular dysfunction, depressive symptoms, quality of life; necessary to determine the effects of diabetes on acute and chronic complication.
- Health behaviors – alcohol use, tobacco use, dietary intake; important for understanding the impact of these behaviors on diabetes complications.
- Quality of health care questions – adherence to standards of care for patients with diabetes; changes in diabetes care from adolescent to young adults; important to understanding the factors that affect health care for patients with diabetes during this vulnerable time period.

As described in Section A.10 of this submission, steps have been taken to ensure confidentiality of data and to safeguard patient-level information. Information is protected by a Certificate of Confidentiality (**Attachment 8**).

A. 12. Estimates of Hour Burden Including Annualized Hourly Costs

A.12 Estimates of Annualized Burden and Costs

Respondents will be five clinical sites participating in the SEARCH for Diabetes in Youth Study (Phase 3). All information will be transmitted to the Coordinating Center (CDC's data collection contractor) for aggregation and analysis. Information will be transmitted electronically through a secure web site dedicated to the project. 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). Copies of the data collection instruments are included in **Attachment 4a**. 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, and Family Conflict Survey, Pediatric Quality of Life Scale, Physical Exam, and Specimen Collection. Copies of the data collection

instruments are included in **Attachment 4b**. The total estimated annualized burden for this information collection is 1,383 hours.

- Information will also be collected for the purpose of monitoring Unanticipated Occurrences and Conditions (see **Attachment 4c**). CDC estimates that each site will report an average of 13 unanticipated occurrences per year. The total estimated annualized burden for this information collection is five hours.

The estimated annualized burden per clinical site (respondent) is 426.4 hours. The total estimated annualized burden for all sites is 2,132 hours, as shown in Table A.12-A.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Information Collection	Form Name	Average Burden per Response	Total Burden (in hours)
SEARCH Clinical Sites	5	255	Registry Study	Extended Core	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	5	142	Cohort Study	Health Questionnaire-Youth	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
				Specimen Collection	5/60	59
SEARCH Clinical Sites	5	13	Monitoring	Unanticipated Occurrence /Condition Reporting Form	5/60	5
					Total	2,132

Costs to respondents are based on an average hourly wage of $32.64, which is the average hourly wage for nurse coordinators (check – it's also ok to insert a citation if this available). The total estimated annualized cost to respondents is $69,792, as shown in Table A.12-B.

Table A.12-B. Estimated Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Information Collection	Form Name	Total Burden (in hours)	Total Cost
SEARCH Clinical Sites	5	255	Registry Study	Extended Core	213	$6,952
				Medication Inventory	106	$3,460
				Inpatient Survey	213	$6,952
				Specimen Collection (Registry)	106	$3,460
				Physical Exam (Registry)	106	$3,460
SEARCH Clinical Sites	5	142	Cohort Study	Health Questionnaire-Youth	178	$5,910
				Health Questionnaire-Parent	178	$5,910
				CES-Depression	47	$1,534
				Medical Record Validation	118	$3,852
				Quality of Care	154	$5,027
				Peds QL	59	$1,926
				SEARCH MNSI Neuropathy	59	$1,926
				Diabetes Eating Survey	59	$1,926
				Low Blood Sugar Survey	59	$1,926
				Supplemental	118	$3,852
				Tanner Stage	59	$1,926
				Retinal Photo	59	$1,926
				Family Conflict	59	$1,926
				Pediatric Diabetes QOL Scale	59	$1,926
				Physical Exam	59	$1,926
				Specimen Collection	59	$1,926
SEARCH Clinical Sites	5	13	Monitoring	Unanticipated Occurrence /Condition Reporting Form	5	$163
					Total	$69,792

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital costs, operating costs or maintenance costs to report.

A.14. Annualized Cost to the Federal Government

For the SEARCH for Diabetes in Youth Study, the estimated average annual contract costs (including direct and indirect costs) in this 5 year submission for coordinating center are as follows:

Coordinating Center	$1,469,580.00
Subcontractors	$729,364.00
Annual Contract Costs	$2,198,945.00

The Coordinating Center is responsible for coordinating data collection, data analysis, and providing general study support to the SEARCH clinical sites.

The Coordinating Center will identify subcontractors to complete the tasks of laboratory measurement, subclinical measurements, and development of recruitment materials.

CDC costs for staff time for project development, implementation and monitoring are estimated at 0.5 FTE for $40,000 annually. The average annualized cost to the Federal Government for the SEARCH study in this submission period is estimated at $2,198,985.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

CDC will use the registry and cohort data reported by grantees to produce and provide national estimates on the incidence of diabetes among youth and the incidence and prevalence of micro and macro-vascular complications. This information will be included in CDC reports such as the Diabetes Fact Sheet which is updated every two years and will also be reported in peer reviewed journals in collaboration with the SEARCH grantees and the contractor. The SEARCH Clinical Sites are funded under cooperative agreements, therefore decisions on specific publications and time tables is determined by the SEARCH Clinical Site Principal Investigators with input and suggestions by CDC. CDC and the Coordinating Center provide support to the SEARCH Clinical Sites in the efforts but do not develop specific timelines. The Coordinating Center will work with SEARCH Clinical Site investigators to develop detailed analysis plans and timelines for each publication. We are seeking OMB approval for the first three years of the five year study and plan to seek and plan to submit an Extension request to cover data collection for the remainder of the project period.

A.17. Reason (s) Display of OMB Expiration Date is Inappropriate

For the purposes of this clearance request, respondents are five clinical sites. The OMB expiration date is displayed on the web-based interface that each clinical site uses to transmit de-identified information to CDC's data collection agent, i.e., the Coordinating Center. The OMB expiration date is not displayed on forms administered to research participants at the clinical sites. Research participants are not considered respondents for this data collection..

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

Collection of information encompassed by this OMB request complies with 5 CFR 1320.9.