

progress towards national public health goals. Participation is voluntary and there is no cost to respondents other

than their time. The total estimated annualized burden hours are 8,735.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Persons Screened Eligible Participants	Eligibility Screener	13,142	1	5/60
	Behavioral Assessment for MSM	3,667	1	30/60
	Behavioral Assessment for IDU	3,667	1	54/60
	Behavioral Assessment for HET	3,667	1	39/60
Peer Recruiters	Recruiter Debriefing	3,667	1	2/60

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity, 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-17-0904; Docket No. CDC-2016-0117]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the "SEARCH for Diabetes in Youth Study," a national multi-center study aimed at understanding more about diabetes among children and young adults in the United States.

DATES: Written comments must be received on or before February 6, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0117 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

SEARCH for Diabetes in Youth Study (OMB Control No. 0920-0904, Expires 8/31/2017)—Revision—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. Type 2 diabetes begins when the body develops a resistance to insulin and no longer uses it 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. 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) produced estimates of the prevalence and incidence of diabetes among youth age <20 years, according to diabetes type, age, sex, and race/ethnicity, and characterized selected acute and chronic complications of diabetes and their risk factors, as well as the quality of life and quality of health care. Phase 3 (2010–2015) built upon the activities in Phase 1 and 2 and added a cohort component to collect information on 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.

SEARCH Phase 4 (2015–2020) continues the activities of the SEARCH

Registry Study via cooperative agreements with the clinical sites, data coordinating center and CDC. Respondents will be youth <20 years of age who have been diagnosed with diabetes. Information will be collected from the study participants by five clinical sites and transmitted to the Coordinating Center for the study, each funded through a cooperative agreement. Information collection will support a case registry that can be used to estimate the incidence and prevalence of diabetes in youth in the U.S. The registry study will continue to collect information from participants related to diabetes diagnosis and will ask participants identified with incident diabetes in 2016 to complete an in-person study examination. CDC is no longer funding the cohort component of the SEARCH for Diabetes in Youth Study.

SEARCH Phase 3 identified an average of 1,361 incident cases of diabetes among youth under 20 years each year of the study and completed an average of 1,088 participant surveys each year (80% participation rate among registry study participants).

Respondents will be the Population-based Diabetes in Youth (SEARCH for Diabetes in Youth Phase 4) study participants. The information collection will include:

1. *Incident diabetes cases:*

- Collection of 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 302 to 303 cases per year, for a total of 1,511 cases across all sites. There are no changes for the Medication Inventory Form. The Initial Participant Survey form has been revised to eliminate questions that were not useful to the researchers and to

improve readability and understanding for the participants. The overall burden for the form has not changed. The total estimated annualized burden for this information collection is 378 hours.

- Physical exam and specimen collection for the 2016 incident cases. CDC estimates that each clinical site will identify and register 1,511 cases during this incident year. Of these cases, CDC anticipants 80% will complete the Initial Participant Survey and be invited for an in-person visit. Of those, we anticipate a 65 to 70% response rate and complete 823 in-person visits. The Physical Exam Form has not changed. There was a change to the Specimen Collection Form since a spot urine will no longer be collected. The total estimated annualized burden for this information collection is 1,371 hours.

2. *Prevalent diabetes cases:*

- Collection of information on prevalent cases of diagnosed diabetes among youth <20 years. CDC estimates that the clinical sites will identify 776 cases. The items collected for each case include an Initial Participant Survey. The total estimated annualized burden for this information collection is 130 hours. This is a new data collection instrument.

The SEARCH for Diabetes in Youth Study was initially approved with 4,248 annualized burden hours. In this Revision, we request approval for 1,878 annualized burden hours (a net reduction of 2,369 annualized burden hours). The estimated annualized burden per participant respondent is reduced by 3.2 hours since the CDC is no longer funding the cohort component. The total annualized burden for this study is 1,878.

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)
Incident cases	Medical Inventory	1,511	1	5/60	126
	Initial Participant Survey	1,511	1	10/60	252
Incident cases in 2016 who complete the survey.	Physical exam	823	1	80/60	1,097
	Specimen collection	823	1	20/60	274
Prevalent cases	Initial Participant Survey	776	1	10/60	129
Total	1,878

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, 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

[CDC-2016-0090; Docket Number NIOSH 288-A]

A Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs; Extension of Comment Period

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and extension of comment period.

SUMMARY: On September 15, 2016 the Director of the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), published a notice in the **Federal Register** [81 FR 63482] announcing a public meeting and request for public comment on a draft testing protocol. Written comments were to be received by December 7, 2016. In response to a request from interested parties, NIOSH has extended the comment period until June 7, 2017. The longer timeframe will allow companies to acquire the proposed challenge agents and test their CSTDs with the proposed universal CSTD performance test protocol.

DATES: NIOSH is extending the comment period on the document published September 15, 2016 [81 FR 63482]. Electronic or written comments must be received by June 7, 2017.

FOR FURTHER INFORMATION CONTACT: Deborah V. Hirst, NIOSH, Alice Hamilton Laboratories, 1090 Tusculum Avenue, MS-R-5, Cincinnati, Ohio 45226, telephone (513) 841-4141 (not a toll free number), Email: DHirst@cdc.gov.

ADDRESSES: You may submit comments, identified by CDC-2016-0090 and Docket Number NIOSH 288-A, by either of the following two methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Dated: December 5, 2016.

Frank Hearl,
Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Family and Child Experiences Survey (FACES).

OMB No.: 0970-0151.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES). Featuring a new "Core Plus" study design, FACES will provide data on a set of key indicators, including information for performance measures. The design allows for more rapid and frequent data reporting (Core studies) and serves as a vehicle for studying more complex issues and topics in greater detail and with increased efficiency (Plus studies).

The FACES Core study will assess the school readiness skills of Head Start children, survey their parents, and ask their Head Start teachers to rate children's social and emotional skills.

In addition, FACES will include observations in Head Start classrooms, and program director, center director, and teacher surveys. FACES Plus studies include additional survey content of policy or programmatic interest, and may include additional

programs or respondents beyond those participating in the Core FACES study.

Previous notices provided the opportunity for public comment on the proposed Head Start program recruitment and center selection process (FR V.78, pg.75569 12/12/2013; FR V.79, pg.8461 02/12/2014), the child-level data collection in fall 2014 and spring 2015 (FR V. 79, pg. 11445 02/28/2014; FR V. 79; pg. 27620 5/14/2014), the program- and classroom-level spring 2015 data collection activities (FR v.79; pg. 73077 12/09/2014), the American Indian and Alaska Native Head Start Family and Child Experiences Survey (AI/AN FACES) child-level data collection activities in fall 2015 and spring 2016 (FR V. 80, pg. 30250 08/07/2015) and AI/AN FACES program- and classroom-level spring 2016 data collection activities (FR V. 80, pg 70231 11/13/2015).

This 30-day notice describes the planned additional data collection activities for FACES program- and classroom-level data collection in spring 2017. Spring 2017 data collection includes site visits to 360 centers in 180 Head Start programs. As in spring 2015, for the Core study teachers, program directors, and center directors will each complete surveys, approximately 25 to 30 minutes in length. Two Plus studies are planned related to program functioning for spring 2017. First, program and center directors in all 180 programs (and 360 centers) will complete a 5-minute survey on how programs are planning for implementing the new Head Start program performance standards. Second, all 720 teachers will complete a survey on program functioning, initially piloted in spring 2015.

The purpose of the Core data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110-134), which calls for periodic assessments of Head Start's quality and effectiveness. As additional information collection activities are fully developed, in a manner consistent with the description provided in the 60-day notice (79 FR 11445) and prior to use, we will submit these materials for a 30-day public comment period under the Paperwork Reduction Act.

Respondents: Head Start teachers and Head Start directors.