

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent per year	Average burden per response (in hrs)
Potential participant	Eligibility Consent	3,333	3	2/60
Potential participant	Eligibility Screener	3,333	20	2/60
Potential participant	Study Consent	1,333	2	4/60
Potential participant	Registration contact information	1,267	7	2/60
Enrolled participant	Baseline Survey	1,200	107	20/60
Enrolled participant	Initial HIV Test Result Survey	1,000	43	5/60
Enrolled participant	Follow-up Survey	1,000	187	30/60
Enrolled participant	Final HIV Test Result Survey	1,000	18	5/60
Enrolled participant	Product ordering	400	12	3/60
Guest	Guest Consent	667	1	2/60
Guest	Guest HIV Test Result Survey	667	24	5/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-1129; Docket No. CDC-2019-0058]

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 the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection titled, Improving Fetal Alcohol Spectrum Disorders (FASD) Prevention and Practice through Practice and Implementation Centers and National Partnerships (PICs). The purpose of FASD PICs is to collect training evaluation data from healthcare practitioners and staff in health systems where FASD-related practice and systems changes are implemented, and from grantees of Practice and Implementation Centers and national partner organizations related to prevention, identification, and

treatment of fetal alcohol spectrum disorders (FASDs).

DATES: CDC must receive written comments on or before September 9, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0058 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments 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 Jeffrey M. Zirger, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs

Proposed Project

Improving Fetal Alcohol Spectrum Disorders (FASD) Prevention and Practice through Practice and Implementation Centers and National Partnerships” project (OMB Control No. 0920-1129, Exp. 8/31/2019)—Revision — National Center for Birth Defects and Developmental Disability (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Prenatal exposure to alcohol is a leading preventable cause of birth defects and developmental disabilities. The term ‘fetal alcohol spectrum

disorders' describes the full continuum of effects that can occur in an individual exposed to alcohol in utero. These effects include physical, mental, behavioral, and learning disabilities. All of these have lifelong implications.

Since 2002, CDC funded FASD Regional Training Centers (RTCs) to provide education and training to healthcare professionals and students about FASD prevention, identification, and treatment. In July 2013, CDC convened an expert review panel to evaluate the effectiveness of the RTC program overall and to make recommendations about the program.

The panel highlighted several accomplishments of the RTCs and proposed several changes for future programming: (1) The panel identified a need for more comprehensive coverage nationally with discipline-specific trainings, increased use of technology, greater collaboration with medical societies, and stronger linkages with national partner organizations to increase the reach of training opportunities, and (2) The panel suggested that the training centers focus on demonstrable practice change and sustainability and place a stronger emphasis on primary prevention of FASDs. In addition, it was recommended that future initiatives have stronger evaluation components.

Based on the recommendations of the expert review panel, CDC is placing

increased focus on prevention, demonstrating practice change, achieving national coverage, and strengthening partnerships between FASD Practice and Implementation Centers, or PICs (the newly redesigned RTCs), and medical societies and national partner organizations. The National Organization on Fetal Alcohol Syndrome (NOFAS) also participates in this project as a resource to the PICS and national partners. The PICs and national partners are asked to closely collaborate in discipline-specific workgroups (DSWs) and identify strategies that will increase the reach of the program on a national level. While a major focus of the grantees' work will be national, regional approaches will be used to develop new content and test feasibility and acceptability of materials, especially among healthcare providers and medical societies. In addition, CDC is placing a stronger emphasis on evaluation, with both individual DSW/NOFAS evaluations and a cross-site evaluation.

CDC requests OMB approval to collect program evaluation information from (1) healthcare practitioners from disciplines targeted by each DSW, including training participants, (2) health system staff, and (3) cooperative agreement grantees over a three-year period.

Healthcare practitioners will complete surveys to provide information on

whether project trainings impacted their knowledge and practice behavior regarding FASD identification, prevention, and treatment. The information will be used to improve future trainings and assess whether knowledge and practice changes occurred. Some participants will also complete qualitative key informant interviews to gain additional information on practice change. Health system employees will be interviewed or complete surveys as part of projects to assess healthcare systems change, including high impact evaluation studies and DSW systems change projects. The high impact evaluation studies will be primarily qualitative assessments of two to three specific grantee efforts that seem likely to result in achievement of program objectives. The DSW systems change projects will employ online surveys to assess systems change in selected health systems across the U.S.

Grantees will complete program evaluation forms to track perceptions of DSW collaboration and perceptions of key successes and challenges encountered by the DSW. It is estimated that 29,573 respondents will participate in the evaluation each year, for a total estimated burden of 3790 hours annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Project Grantee Staff	DSW Report	90	2	10/60	30
Project Grantee Staff	High Impact Study: Discipline Specific Workgroup Discussion Guide for Project Staff.	10	2	60/60	20
Health Care System Staff	High Impact Study: Key Informant Interview—Health Care System Staff.	10	2	60/60	20
FASD Core Training Participants	FASD Core Training Survey—Pre-Test.	4013	1	9/60	602
FASD Core Training Participants	FASD Core Training Survey—Post-Test.	4013	1	5/60	335
FASD Core Training Participants	FASD Core Training Survey—6 Month Follow-Up.	4013	1	6/60	402
Nurses	Pre-Training Survey for Nursing	667	1	9/60	101
Nurses	Post-Training Survey for Nursing	550	1	9/60	83
Nurses	Six Month Follow-Up Training Survey for Nursing.	440	1	9/60	66
Nurses	Nursing DSW Polling Questions	417	1	5/60	35
Nurses	Key Informant Interviews with Champions.	14	2	45/60	21
Nurses	Brief Questionnaire for Nursing Organization Memberships.	2,934	1	10/60	489
Nurses	Friends & Members of the Network Survey.	34	2	10/60	12
Healthcare Organization Representatives.	Healthcare Organization Utilization Survey.	234	1	30/60	117

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Obstetrician-Gynecologists and students in allied health professions.	OBGYN SBI Knowledge & Agency ..	600	1	2/60	20
Obstetrician-Gynecologists	OBGYN BI-MI Proficiency Rating Scale—Provider Skills Training Baseline.	600	1	3/60	30
Students in allied health professions	OBGYN BI-MI Proficiency Rating Scale—Standardized Patient Version.	600	1	3/60	30
Obstetrician-Gynecologists	OBGYN BI-MI Proficiency Rating Scale—Provider Follow Up (3m & 6m).	600	2	3/60	60
Obstetrician-Gynecologists and students in allied health professions.	OBGYN Telecom Training Satisfaction Survey.	480	1	5/60	40
Obstetrician-Gynecologists and students in allied health professions.	OBGYN Avatar Training Satisfaction Survey.	120	1	5/60	10
Obstetrician-Gynecologists	OBGYN FASD-SBI Training Event Evaluation.	124	1	2/60	5
Residency Directors, Training Coordinators, Clinical Directors, Obstetrician-Gynecologists.	OBGYN Qualitative Key Informant Interview—Pre-Training.	34	1	25/60	15
Residency Directors, Training Coordinators, Clinical Directors, Obstetrician-Gynecologists.	OBGYN Qualitative Key Informant Interview—Post-Training.	34	1	25/60	15
Certified Medical Assistants and students.	Medical Assistant—Pre-Test Survey	334	1	10/60	56
Students in allied health professions	Medical Assistant—Pre-Test Survey (Academic).	67	1	10/60	12
Certified Medical Assistants and students.	Medical Assistant—Post-Test Survey.	334	1	10/60	56
Students in allied health professions	Medical Assistant—Post-Test Survey (Academic).	67	1	10/60	12
Certified Medical Assistants and students.	Medical Assistant Follow Up Survey	200	1	10/60	34
Students in allied health professions	Medical Assistant Follow Up Survey (Academic).	17	1	10/60	3
Certified Medical Assistants and students.	Medical Assistants Change in Practice Survey.	250	1	15/60	63
Pediatricians	Survey of Pediatricians—Baseline and Follow Up.	534	2	10/60	178
Pediatricians	AAP Post-Training Evaluation Survey.	120	1	7/60	14
Pediatricians	AAP Pre-Training Evaluation Survey	120	1	7/60	14
Pediatricians	AAP Three Month Follow Up Evaluation Survey.	120	1	2/60	4
Pediatricians	AAP Six Month Follow Up Evaluation Survey.	120	1	5/60	10
Pediatricians	FASD Toolkit User Survey	50	1	15/60	13
Pediatricians	FASD Toolkit Evaluation Focus Group/Guided Interview.	10	1	30/60	5
Pediatricians	Pediatric FASD Regional Education and Awareness Liaisons Work Plan.	10	1	20/60	4
Pediatricians	Pediatric FASD Regional Liaison/Champion Training Session Evaluation.	10	1	4/60	1
Family Medicine Physicians	Family Medicine Evaluation Questions Addendum for Practice or Individual Provider.	62	1	8/60	9
Family medicine physicians, social workers, social work students.	Social Work and Family Physicians Pre-training Survey.	1167	1	8/60	156
Family medicine physicians, social workers, social work students.	Social Work and Family Physicians Post-training Survey.	1167	1	5/60	98
Family medicine physicians, social workers, social work students.	Social Work and Family Physicians 6-Month Follow Up Survey.	1167	1	8/60	156
NOFAS webinar attendees	NOFAS Webinar Survey	601	1	2/60	20
NOFAS webinar attendees	NOFAS Three Month Follow-Up Webinar Questionnaire.	601	1	2/60	20
NOFAS training participants	NOFAS Pre-Test Survey	551	1	3/60	28
NOFAS training participants	NOFAS Post-Test Survey	551	1	3/60	28

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Systems change project participants	Clinical Process Improvement Survey.	246	2	10/60	82
Systems change project participants	TCU Organizational Readiness Survey.	246	2	10/60	82
Systems change project participants	Organizational Readiness to Change Assessment.	220	2	10/60	74
TOTAL	29,573	3,790

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-19ABV]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Information Collection on Soil-transmitted Helminth Infections in Alabama and Mississippi” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on April 2, 2019 to obtain comments from the public and affected agencies. CDC did not receive any comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Information Collection on Soil-transmitted Helminth Infections in Alabama and Mississippi—New—Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Soil-transmitted helminths (STH) are intestinal worms transmitted through contaminated soil. They include roundworms (*Ascaris lumbricoides*), whipworms (*Trichuris trichiura*), hookworms (*Ancylostoma duodenale* and *Necator americanus*) and the worm *Strongyloides stercoralis*. These infections were widespread across the American South through the early 20th century, yet despite the historically high burden of STH infections in these endemic areas of the United States, few resources have been devoted to surveillance, prevention, and treatment of STH infections in recent years and

they are missed by routine information collection systems. As a result, the current prevalence of STH infections in previously endemic areas is unknown, but socioeconomic and environmental conditions favorable to ongoing transmission persist in areas of the south, including Alabama and Mississippi. Collecting this data, along with biological specimens to document infection, is critical to determine the prevalence of STH infections, their distribution, and risk factors associated with infection. This data will be used to inform the development and implementation of effective and sustainable prevention and control measures in affected areas.

The core data elements were developed with input from community advocates, and local, state, and federal public health and environmental health partners in both Alabama and Mississippi. The questionnaires have been designed for self-completion by respondents. The data that are collected will be pooled and analyzed by university partners and CDC, to generate hypotheses about potential risk factors for infection.

CDC requests OMB approval to collect critical information, not available otherwise, on the prevalence and distribution of disease and on risk factors, knowledge, attitudes and/or practices related to STH infections among residents in at-risk areas in Alabama and Mississippi. This information is critical for planning and implementation of disease prevention and control strategies targeting STH infections in the southeastern United States.

This data collection is not expected to entail substantial burden for respondents. The estimated total annualized burden associated with this data collection is 220 hours (approximately 958 individuals interviewed × 10 minutes/response). There will be no costs to respondents other than their time.