

**Information Collection on Soil-transmitted Helminth Infections in Alabama and
Mississippi**

Request for OMB Approval for Data Collection

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Statement A

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- **Goal of the study:** Determine if STH infections represent an unrecognized problem in communities in this region and to understand risk factors associated with infection.
- **Intended use of the resulting data:** This information is critical for planning and implementation of disease prevention and control strategies targeting STH infections in the southeastern United States.
- **Methods to be used to collect:** Information collections from parents/legal guardians of enrolled children will consist of small, focused questionnaires. Specimens will be collected from enrolled children and will include one to three stool specimens (separated by at least 24 hours) and a dried blood spot collected via finger prick.
- **The subpopulation to be studied:** Participants from selected at-risk counties in Alabama will be children between the ages of 2 and 18 years of age (specimens) and their parent/legal guardian (information). Participants from selected at-risk counties in Mississippi will be children between the ages of 2 and 18 years of age (specimens) and their parent/legal guardian (information).
- **How data will be analyzed:** Generating descriptive statistics and performing regression analysis.

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Information Collection on Soil-transmitted Helminth Infections in Alabama and Mississippi

Request for OMB Approval for Data Collection

This is a request for a new information collection. CDC is requesting a three year approval to collect data.

PART A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Center for Global Health (CGH), Division of Parasitic Diseases and Malaria (DPDM) requests approval of a new information collection to better understand risk factors, attitudes and practices related to soil-transmitted helminth (STH) infection among residents of Alabama and Mississippi in the southeastern United States. The information collection for which approval is sought is in accordance with DPDM's mission to reduce death, illness, and disability from parasitic diseases in the United States and to advance research to detect, prevent, and eliminate parasitic diseases.

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 worms live in the intestines of infected persons and their eggs or larvae are shed in the stool. If an infected person defecates outside, or has inadequate sewage facilities that result in human waste being deposited into the environment, then the eggs or larvae are deposited in the soil. People are infected with roundworm and whipworm when they ingest the eggs from the soil, as can happen when dirty hands or fingers are put in the mouth or by consuming fruits and vegetables that have not been carefully washed, peeled, and/or cooked. Hookworm and *Strongyloides* infection are transmitted primarily by walking barefoot or working with bare hands in contaminated soil where the larvae can penetrate the skin. People with light STH infections (e.g. caused by only a few worms) may not have any symptoms. Heavy infections can result in abdominal pain, diarrhea, blood and protein loss, rectal prolapse, and physical and cognitive growth retardation. *Strongyloides* infections can sometimes result in severe life-threatening forms called hyperinfection syndrome and disseminated strongyloidiasis; these forms of disease are more common in people who are on immunosuppressive therapies.

STH infections were widespread across the southeastern United States through the early 1900s. In 1909, the Rockefeller Sanitary Commission began conducting a widespread research survey and deworming campaign across the American South, and they subsequently identified between 43–90% of individuals surveyed were infected with hookworm, depending on the location [1]. STH infections are both a result of poverty and a contributing cause of poverty – infected individuals may suffer from chronic anemia, malnourishment, and growth and developmental delays, which decrease worker vitality and productivity over the long run [2, 3].

In the early 20th century chronic hookworm infection was responsible for an estimated 43% reduction in earning potential among workers in the American South, and contributed to the widespread notion at the time of the “lazy Southerner” [2, 3]. Following the eradication campaigns of the early 1900s, school enrollment, school attendance, and literacy increased significantly in areas that previously had high rates of hookworm infection [3]. In 1937 in Alabama, the prevalence rate was still elevated at 32% of those surveyed [4]. By 1954, the last time a large prevalence study was done in Alabama, the prevalence was reported at 17%.

Despite the historically high burden of STH infection in endemic areas of the United States the last reported high-quality study examining endemic transmission in the U.S. was done in 1982 in Kentucky and found that infection persisted among children in previously endemic areas [5]. The current prevalence of STH infections is unknown, but socioeconomic and environmental conditions favorable to ongoing transmission of STH infections persist in some areas of the southeastern United States, including Alabama and Mississippi. Environment and socioeconomic status are the most important determinants of STH infection [6]. The Alabama study locations are in the Black Belt region, which are largely rural counties where many residents live below the poverty line, making these some of the poorest counties in the United States. The Black Belt region of Alabama is largely undeveloped: a majority of counties within the area lack public sewage systems and the type of specialized septic systems required because of the soil are expensive, beyond the financial reach of many residents to install and maintain. Residents instead must rely on individual home systems, like “straight-piping” which involve crudely constructed piping systems and ditches to carry human waste from the home; however, these systems often fail during rain storms and allow sewage to creep back into the home [7]. The proposed Mississippi study locations are also in impoverished, rural areas in the Delta and elsewhere. Many residents living in poverty in Mississippi still lack closed sewage operations, putting them at-risk of STH infections. For example, Rankin County, a proposed site in Mississippi, has historically had high rates of hookworm infection and the soil type pervasive in the county is optimum for hookworm survival. Conditions such as these noted in Alabama and Mississippi are highly favorable for continued transmission of STH infections.

This data collection is needed by DPDM to determine if STH infections represent an unrecognized problem in communities in this region and to understand risk factors associated with infection. Relatively 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 in the United States [8, 9]. As a consequence, limited information is available about the health status, health beliefs, practices and risk factors for STH infections amongst communities at risk in the southeastern United States, including Alabama and Mississippi [10]. Additionally, physicians may not be as familiar with parasitic infections as these diseases are typically not emphasized during medical training, which leads to underdiagnoses and underreporting [8, 11-13].

This OMB clearance will allow DPDM 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.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

Overview of Data Collection System

DPDM will engage with academic collaborators from both the University of Alabama at Birmingham (UAB) and the University of Mississippi Medical Center (UMMC) to conduct this information collection in their respective states.

Alabama

Participants from selected at-risk counties in Alabama will be children between the ages of 2 and 18 years of age. Participants will be enrolled through schools, after school programs, and through sharing investigation information at community gatherings (e.g. churches, school events, or beauty salons). Information collections from parents/legal guardians of enrolled children will consist of small, focused questionnaires. Specimens will be collected from enrolled children and will include one to three stool specimens (separated by at least 24 hours) and a dried blood spot collected via finger prick. Parents/legal guardians will be informed of the risks and benefits and provide permission for their children to participate in specimen collection. Informed consent will be obtained from parents/legal guardians prior to collection of information

Mississippi

Participants from selected at-risk counties in Mississippi will be children between the ages of 2 and 18 years of age (specimens) and their parent/legal guardian (information). Participants will be enrolled through health fairs and during well-child visits at UMMC Regional Outpatient Centers (ROCs). Specimens collected from each child will include one to three stool specimens (separated by at least 24 hours) and a dried blood spot collected via finger prick. Information collections from parents/guardians of participating children will consist of small focused questionnaires. Parents/guardians will be informed of the risks and benefits and provide permission for their children to participate in the specimen collection. Informed consent will be obtained from parents/legal guardians prior to collection of information.

Information collection will take place using self-completed questionnaires, in-person interviews, or by phone.

Items of Information to be Collected

Data collection will be limited to information needed to understand risk factors for, knowledge of, and practices to prevent STH infections among high-risk populations in the United States. This may include country of origin, travel history, prior treatment of parasitic disease, risk factor assessments (e.g. sewer situation/condition at residence, contact with soil), basic health history (e.g. asthma, anemia – conditions which are known to be associated with STH infection), anthropometrics (to identify malnutrition or growth retardation), and blood lead levels and hemoglobin levels (potential confounders).

Items of information proposed to be collected can be found in the draft survey in Appendices C-E.

A.2. Purpose and Use of Information Collection

The purpose of this information clearance is to identify risk factors for STH infections and to better understand knowledge and prevention practices of parents in relation to STH infections. Identifying risk factors in addition to studying prevalence of infection will allow DPDM, in collaboration with local partner organizations, to better address STH infections in the United States. Insights gained from this information collection will assist in the planning, implementation and improvement of disease prevention and control activities in order to reduce risks and burden of STH infections in the United States.

Information collected under this ICR will be collected from participants in conjunction with biological specimens (stool specimens and dried blood spots), necessary to diagnose infection. Personally identifiable information must also be obtained so that any positive results from laboratory testing can be referred back to the correct parent/guardian and that child can then be referred for treatment.

DPDM and contractors will follow procedures for assuring and maintaining privacy during all stages of data collection. In Alabama, respondents will be recruited through schools, after school programs, and community gatherings as described previously. In Mississippi, respondents will be recruited through health fairs and mobile medical clinics. Questionnaires will be administered using tablets (Mississippi) or self-completed paper forms (Alabama) or in-person interviews or by phone and recorded on paper forms (Alabama and Mississippi participants who cannot read). These forms will be stored in a locked file cabinet with controlled access. Responses will be deidentified and entered into a REDCap computer database maintained behind CDC's firewall; contracted staff from UAB and UMMC will be required to obtain appropriate security clearances to be able to enter data into the CDC database.

Prior to participating in the information collection, prospective respondents will receive information such as the purpose and sponsorship of the project, their rights as participants, risks and benefits in participating, and contacts for more information about the project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project. Consent will be obtained from all parents/guardians of children ages 2 to 17 and assent will be obtained from children who are at least 7 years of age.

All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner. DPDM staff and contractors will collect and analyze the information.

A.3. Use of Improved Information Technology and Burden Reduction

The targeted population for this information collection consists of residents of impoverished communities; it is likely that many of these residents do not have a home computer or access to one, such that electronic web-based surveys could be reasonably utilized. In Mississippi, tablets may be utilized to allow respondents to enter their responses directly into the questionnaire.

Where possible, particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The number of questions posed will be held to the minimum required in order to elicit the necessary data.

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

CDC has conferred with internal and external staff to avoid duplication of data collection efforts. STH infections are largely neglected diseases in the United States and little to no information is routinely collected on their occurrence. Therefore, it is not expected that any of the information collected under this proposed clearance is duplicative or is already in the possession of the federal government. As indicated above, there is limited information about parasitic diseases in reference to U.S. populations and these infections are missed by routine national health information systems because of a lack of reporting and lack of knowledge, among other factors [8, 10]. Relevant information is especially lacking at the local level. The last large-scale prevalence study done in the United States for STH infections was published in 1982.

The proposed information collection does not overlap with other data collection on nationally notifiable diseases, such as those authorized under OMB control numbers 0920-0728 and 0920-072.

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

No small businesses will be involved in this information collection.

A.6. Consequences of Collecting the Information Less Frequently

There is limited information on parasitic diseases at the local level and for high-risk populations in the United States. Neglected parasitic diseases such as STH infections are missed by routine information collections [8]. In order to design and implement effective public health interventions it is necessary to understand the risk factors for infection, and to assess knowledge, attitudes, and practices of at-risk communities regarding STH infections.

The information collection proposed under this new clearance is needed for DPDM to better identify and respond to STH infection risks at the local level and in a timely manner, in order to reduce risks of disease transmission and address health disparities contributing to parasitic infections in the Southeastern United States. Less frequent data collection limits DPDM's ability to protect local communities against parasitic disease risks.

There are no legal obstacles to reducing the burden.

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

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d) (2). No special circumstances apply.

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

A.8a. A 60-day Federal Register notice was published in the Federal Register on April 2nd, 2019, Vol.84, No. 63, pages 12612-12613 (Attachment B). CDC received no substantive/non-substantive comment.

A.8.b Consultation

The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this information collection.

In Alabama:

- In consultation with the University of Alabama at Birmingham, the need for information on the prevalence and risk of STH infections among children in Alabama was identified.

Dr. Claudette Poole, Associate Professor of Pediatric Infectious Diseases

Phone: 205-996-7108

Email: cpoole@peds.uab.edu

Dr. David Kimberlin, Professor of Pediatric Infectious Diseases

Phone:

Email: DKimberlin@peds.uab.edu

- In consultation with BAMA (Better Activities Make All-Around) Kids, Inc., the need for information on the prevalence and risk of STH infections among children in Wilcox County was identified.

Sheryl Threadgill-Matthews, Director BAMA Kids Inc.

Phone: 334-682-5925

Email: bamakids5@hotmail.com

In Mississippi:

- In consultation with the Mississippi State Department of Health, the need for information to determine the prevalence and risk of STH infections in Mississippi was identified.

Paul Byers, MD, State Epidemiologist

Phone: 601-576-8090

Email: Paul.Byers@msdh.ms.gov

- In consultation with the University of Mississippi Medical Center, Department of Pediatrics, the need for information to determine the prevalence and risk of STH infections in Mississippi was identified.

Mary Taylor, MD, MSCI, Professor and Suzan B. Thames Chair

Phone: 601-984-5214

Email: mbtaylor@umc.edu

Charlotte Hobbs, MD, Associate Professor, Pediatric Infectious Disease

Phone: 601-984-5206

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- In consultation with Mississippi College, School of Nursing, the need for information to determine the prevalence and risk of STH infections in Mississippi was identified.

Deborah Bolian, MN, BSN, RN, Assistant Professor

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

In his memorandum for the President's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..."

For economically disadvantaged populations, such as those who will be included in this study, compensation for time and gas is a necessary measure to facilitate participation and return visits. As stated above, the use of incentives is also necessary to recruit historically underrepresented groups into research studies and for studies that impose exceptional burden, such as those requiring the collection of stool specimens. Collecting stool specimens, especially in marginalized communities, has long been a problem in conducting STH prevalence studies. Failure of respondents to participate fully in this study will jeopardize the quality of the survey data and compromise scientific relevance and generalizability, such that conclusions on the persistence of STH infections in these areas of the southeastern U.S. would be unable to be drawn.

The current study proposal requires each participant to fill out a questionnaire, submit their child to a fingerprick blood collection and then to coordinate the collection and return of three stool

samples, to be collected on separate days and to be returned to research staff within a limited time frame.

Several barriers exist to the successful completion of this study. First, collection of stool samples is unpleasant, inconvenient, and embarrassing. Other researcher studies requiring collection and return of stool samples have found that a monetary incentive is required and is the main motivation for participation (14, 15). Second, children being tested are expected to have minimal symptoms of intestinal parasites, thereby reducing motivation to undergo the hassle of testing for an STH infection (i.e. submitting stool specimens). This project aims to enroll children from poverty-stricken areas of the American south, obtain sensitive information and biological samples, both of which justify the use of incentives. Pediatric populations are considered more vulnerable by definition, and poverty-stricken populations would indeed also be considered as such. In addition, topics for study participants such type of toilet in the home, prior treatment of parasitic disease, presence of health concerns including developmental delay, are generally sensitive by nature.

CDC/DPDM has allowed each investigator (UAB and UMMC) to tailor the amount of incentive to be offered based on their assessment of the target communities. Thus, the amounts differ between Alabama and Mississippi, with higher amounts of total compensation offered to Alabama participants. Mississippi participants are going to be recruited from health fairs and during well-child visits at UMMC Regional Outpatient Centers (ROCs). Mississippi participants are receiving something of benefit (e.g. the provision of healthcare) whether or not they choose to participate in the study. Alabama participants are going to be recruited from the community and as a result are not receiving any additional healthcare services in conjunction with study activities. Regardless of the amount or the site, any gift card incentive will be limited to study participants and distributed when a particular study activity is completed (e.g. questionnaire completion or return of stool specimen).

Alabama:

Rural Alabama communities have a long-standing mistrust of healthcare providers, public health officials and research in general due to the missteps and injustices of the past (16, 17, 18). In the design phase of this study, UAB investigators met with community leaders from at-risk communities in rural Alabama, who both work with children and families within the community and have participated in prior community based research projects. They believe that the provision of incentives is necessary to optimize successful completion of the study.

From their prior research experience, participants have been offered anywhere between \$25 to \$180 dollars for participation in various research projects. They were of the opinion that an amount of \$50 would be needed to incentivize participants to both collect and return a stool sample. In a recent effort by the Alabama Department of Public Health to contain an outbreak of TB in a neighboring county, Perry County, a total of \$160 was being offered to residents to

present themselves to the county health department for TB screening and treatment, which proved to be successful (18).

A staggered compensation approach of escalating payments is proposed to encourage the return of all three samples to counteract declining motivation. The total monetary incentive in the form of a gift card would be \$150 for return of all three stool samples. Based on feedback from community representatives in the areas in which the study is planned, such compensation will help overcome the challenges faced by subjects from these rural, economically disadvantaged areas. Provision of this compensation has been reviewed and approved by the University of Alabama Birmingham IRB.

Mississippi:

Respondents who complete all study measures will receive non-coercive compensation (gift card) to encourage their participation by compensating for time and transportation. Numerous studies have shown that such tokens of appreciation can significantly increase response rates and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses (19, 20, 21, 22). This compensation will be provided in the form of store (Wal-Mart) gift cards, and this provision has been reviewed and approved by the University of Mississippi Medical Center IRB.

The compensation for enrollees who complete all study measures will be offered as follows, based on guidance from the National Institutes of Health Office of Human Research Protection Programs (23):

\$40 for initial visit based on 4.5 X \$7.25/hr for 4.5 hours (hours includes longer consent and initial visit time based on minimum wage in MS (<http://www.minimum-wage.us/states/mississippi>)) with additional approximately \$5.50 for gas).

For the return study visits, \$20 would be offered per each of 3 visits to return sample based on 2X \$7.25/hr for 1-2 hours (minimum wage in MS (<http://www.minimum-wage.us/states/mississippi>)) with additional approximately \$5.50 for gas).

The total monetary incentive to be offered for completion of all study activities would total \$100. Investigators in Mississippi, based on their previous studies done in collaboration with the School of Population Health and local community workers, have developed the aforementioned plan to optimize study success. Additionally, feedback gained from community representatives based in the areas in which the study is planned indicates that such compensation will help overcome the challenges faced by subjects from economically disadvantaged areas of Mississippi.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

DPDM and funded partners at UAB and UMMC will follow procedures for securing and maintaining the security of respondents' information during all stages of data collection. Respondents will be recruited through schools, after school programs, and community gatherings in Alabama and through health fairs and mobile medical clinics in Mississippi.

Funded partners at UAB and UMMC will collect the research data. Analysis of that collected data will be conducted by funded partners and DPDM. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner.

Privacy Impact Assessment Information

1. Respondents will be advised of the nature of the information collection activity, the length of time it will require, and that participation is purely voluntary. Respondents will be assured that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human participants.
2. Both UAB and UMMC will obtain IRB approval to conduct these studies from their respective institutions (Attachment F). The CGH Human Subjects Advisor has determined that CDC is not engaged in human subjects research (Attachment G). Prior to participating in the information collection, prospective respondents will receive information such as the purpose and sponsorship of the project, their rights as participants, risks and benefits in participating, and contacts for more information about the project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project.
3. Paper forms will be stored in a locked file cabinet and accessible only to staff directly involved in the project. Responses from paper forms will be entered into a secured electronic database maintained behind CDC firewalls and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guard the security of data. Data files will be retained for a period of no more than three years and then destroyed. Electronic databases will conform totally to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987] and will be required to have comprehensive, written plans to maintain security. This plan will include having all personnel who will have access to individual identifiers sign data security agreements. They will also be trained in the meaning of data security, particularly as it relates to handling requests for information from respondents, and in providing assurance to respondents about the protection of their responses.
4. . Personally identifying information must also be obtained so that any positive results from laboratory testing can be referred back to the correct parent/guardian and that child can then be referred for treatment. Identification of individuals who are positive for STH infections allows comparison of data on risk factors, such that preventive measures may be identified and implemented. No system of records is being created under the Privacy

Act. This information collection request has been reviewed by the Center for Global Health (CGH), and determined that the Privacy Act does not apply.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, some respondents may find thinking about and discussing a parasite or disease unpleasant, or a portion of respondents could consider questions about race, ethnicity, demographic characteristics, or behaviors to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some respondents may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, and/or adopted preventative behaviors (or lack thereof) associated with STH infections. Such questions are necessary to understand risk factors for STH infections, and thus to the information collection. To minimize psychological distress, the survey administrator or data collection instrument instructions will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

Both UAB and UMMC have received IRB approval through their respective institutions.

A.12. Estimates of Annualized Burden Hours and Costs

A. The information collection instruments for the proposed activity are attached (Appendix C-E). The average burden for each respondent will range from 10-20 minutes.

The estimated burden to respondents is summarized in Table A.12-A below.

Table A.12-A: Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Child or parent/guardian in Alabama	Questionnaire - Alabama	600	1	10/60	100
Parent/guardian in Mississippi	Questionnaire - Mississippi	358	1	10/60	60
Child or parent/guardian in Mississippi	Anthropometric measurements	358	1	10/60	60

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Specimen collection (fingerprick)	N/A	958	1	5/60	80
Specimen collection (stool)	N/A	958	3	5/60	240
TOTAL					540

B. We used the federal minimum wage for the United States. Neither Alabama nor Mississippi has a state minimum wage, so the federal minimum wage applies. This wage (i.e. \$7.25) was obtained from the Bureau of Labor Statistics (<https://www.dol.gov/whd/minwage/america.htm>).

Table A.12-B: Estimated Annual Cost Burden to Respondents.

Respondent Category	Average Hourly Wage	Burden (in hours)	Cost Burden
All occupations in the United States	\$7.25	540	\$3,915.00
Total		540	\$3,915.00

Information will be collected over a three year time period. There are no costs to respondents except their time to participate in the research activities. The total annualized burden to respondents is 540 hours.

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

A.14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is \$1,509,329.04. This figure encompasses contractual costs for information collection by UAB and UMMC, 25% FTE of one GS-11/12 employee, and one 12 month ORISE fellow for laboratory and database management work.. The average hourly rate was obtained from the Office of Personnel Management’s website (http://www.opm.gov/oca/09tables/html/atl_h.asp). The contractual cost for an information collection (e.g. the development of a survey instrument, participant recruitment, data collection, and publishing final reports) is estimated at \$891,921 (UAB) and \$529,129 (Mississippi) (Please see Table A.14-A for details).

Table A.14-A: Estimated Annualized Cost to the Government per Activity and Total

Estimated Annualized Cost to the Government	
Cost Category	Estimated Annualized Cost
Contractual costs for information collection by site: a) Alabama b) Mississippi	a) \$891,921.00 b) \$529,129.00
OC11/12 25% salary/benefits	\$29,831.00
ORISE fellow (laboratory and database management)	\$58,448.04
Total cost of information collections/year	\$1,509,329.04

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request.

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

Activity	Estimated time schedule following OMB clearance
Pilot test	Months 1-3
Recruit and screen participants	Months 3-36
Conduct interviews	Months 3-36
Ongoing data analysis	Months 3-36

It is intended that the results of this information collection will be presented at professional conferences and in peer-reviewed journals and will also be used to inform activities at state health departments, DPDM and academic partners.

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

None.

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

Not applicable. No certification exemption is being sought.

ATTACHMENTS

- A. Legislative Authority: Section 301 of the Public Health Service Act (42 U.S.C. 241)
- B. 60-Day Federal Register Notice
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