

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

Request for OMB Approval for Data Collection

Statement B

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PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe consists of children and parents/guardians of enrolled children (ages 2-17y) in selected at-risk counties in Alabama and Mississippi. The total combined sample size is estimated to be 1,000 participants per year. The Division of Parasitic Diseases and Malaria (DPDM) is requesting a three-year approval to collect information.

The methods for data collection differ slightly between states; this is because each locality has identified the best and most culturally appropriate methods to engage with their individual communities. Potential participants for this data collection will be selected using the following methods:

- In Alabama, participants will include school-aged children recruited through participating schools, after school programs and through sharing investigation information at community gatherings (e.g. churches, school events, or beauty salons). Stool samples and dried blood spots will also be collected from participating children. Children and/or their parents/legal guardians will complete a self-administered questionnaire.
- In Mississippi participants will be children aged 2-17 years recruited through regional outpatient clinics run by the University of Mississippi Medical College (UMMC) and health fairs. Stool samples and dried blood spots will be collected from participating children, but the respondents to questionnaires will be the enrolled children's parents/guardians.

Power calculations have been conducted to determine appropriate sample sizes based on the specific health indicators of interest and desired precision of the data collection.

DPDM and contracted partners will conduct non-response bias analysis on each quantitative collection and transparently report the limitations of the generalizability of this collection to the users of the information.

IRB approval has been obtained as required by all engaged collaborators.

B.2. Procedures for the Collection of Information

Information will be collected through in-person interactions at the community center, after school program, health fair, clinic, house or other location where the target population can be

sampled. When telephone surveys are necessary, investigators will do so. 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. (See Attachment E for Sample Surveys)

Potential survey participants will be screened for appropriate demographic or other characteristics as indicated by the project purpose. Written, informed permission will be obtained from parents/guardians of participating children and verbal assent will be obtained from children who are at least 7 years of age.

Estimation procedures

There is no reliable or recent STH prevalence data available for either study site.

The Alabama study intends to enroll 600 children per year as participants from multiple sites. This large sample size and breadth of recruitment venues will make the collected data more generalizable to the population in the area. A sample size of 600 subjects produces a two-sided 95% confidence interval with a width equal to 0.075 when the sample proportion is 0.30. If we observe 30% of the 600 subjects to have an STH infection, the resulting 95% confidence interval will be (26.3%, 33.7%).

The Mississippi study location intends to enroll 358 children per year between the ages of 2 and 17 years from multiple health fairs, which may be sponsored by local churches and schools, and UMMC Regional Outpatient Centers. This large sample size and breadth of recruitment venues will make the collected data more generalizable to the population in the area. The primary endpoint for the study is calculation of prevalence of STH infection. As there are no reliable or recent STH prevalence data available for Mississippi, UMMC statisticians used a conservative estimate of 50% with a 95% confidence interval and a difference worth detecting +/- 5% ($d=0.05$), resulting in a sample size of 358 subjects/area tested.

All analyses will be conducted under the advice of a statistician/data analyst as needed, and involve generating descriptive statistics and performing regression analysis. Collected data will be linked to stool specimens using a unique identifier in the event anti-parasitic treatment is required. Linking collected data to existing data sources by non-personal identifiers (e.g., state, county, city name) may be used to increase the overall utility of a proposed data collection. Sub-analyses that include analyzing knowledge, attitude, and belief disparities among different sub-populations will be conducted. Corrections will be made for over/under sampling, non-response, non-standard distributions, or any other unanticipated sampling or measurement error that may skew or bias the information collection and analyses.

Degree of accuracy needed for the purpose described in the justification

The use of simple but scientifically sound sampling methods and power calculations will ensure that DPDM collects data with enough accuracy to inform the Division about parasitic disease

issues in order to effectively design and implement programs and services. Collaboration with local community-based organizations and leaders will help ensure that data collection activities are conducted in a culturally appropriate manner, and will also enhance participation from community members, which will reduce non-response bias. The data collected will provide information to better understand attitudes, beliefs and practices related to parasitic disease issues among affected communities.

B.3. Methods to Maximize Response Rates and Deal with Non-response

The following are the examples of the procedures that have proven effective in previous studies and will be used to obtain an adequate response rate:

- Engaging with the target communities ahead of time to ensure community buy-in and identify the best ways to enhance participation.
- Informing respondents of what the project is asking, why it is being asked, who will see the results, and how the results will be used, as well as discussing how respondents will benefit from the results and how the findings will be put into action.
- Addressing data security and anonymity with respondents.
- Minimizing the time needed for participation in the project.
- Informing respondents how much time the project will take so that they know what to expect.
- Utilizing deadlines, reminders, and follow-ups to remind respondents and encourage participation.
- Potential respondents will be informed about the importance of these projects and encouraged to participate through a variety of methods, including announcements from community organizations and letters of support from key individuals.
- When appropriate, a dedicated toll-free number and e-mail account will be established at the contractor's office to allow potential respondents to confirm a research activity's legitimacy, ask questions, and voice concerns.
- For telephone surveys, outgoing calls that result in no answer, a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts.
- Over-sampling if necessary to address potential for non-response.
- Obtaining support for information collections from trusted leaders from the target populations.
- Providing a small, non-coercive monetary reward for completing all required study activities (e.g. the return of up to three stool specimens).

B.4. Test of Procedures or Methods to be Undertaken

UAB contractors, with input from community partners, plan to develop the most culturally appropriate and least stigmatizing recruitment strategies and recruitment materials that increase

motivation and self-efficacy. In the first year, UAB plans to pilot test these materials and strategies to enroll the first 200 subjects at one after school program (BAMA Kids, Inc). Any problems that are identified with recruitment techniques will be modified as necessary before enrolling the remaining 400 participants from additional study sites. In subsequent years of data collection, pilot testing will not be necessary. Participants will be offered a non-coercive incentive (i.e. a gift card) for the return of stool specimens, with increasing amounts for each subsequent stool specimen returned (up to 3 stool specimens collected per participant).

UMMC contractors will recruit participants through health fairs and UMMC Regional Outpatient Centers, targeting “well-child” visits. As in Alabama, participants will be offered a non-coercive incentive (i.e. a gift card) for the return of stool specimens, with increasing amounts for each subsequent stool specimen returned (up to 3 stool specimens collected per participant). These methods have been used before by UMMC on a different project and have been determined to be successful.

The provision of incentives for the return of stool specimens has been determined to increase rates of participation and study completion (e.g. returning stool specimens).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The project has been reviewed by statisticians at UAB and UMMC to ensure the design of statistical and sampling procedures undertaken as part of these data collection activities is appropriate.