THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

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APPROVAL LETTER

TO: Kimberlin, David Winston

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 12-Mar-2019

RE: IRB-300002219
Cross-Sectional Cohort Study to Determine the Prevalence of Soil Transmitted Helminth (STH) Infections in School Age Children in a Rural Poor Community in Southern Alabama

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The IRB reviewed and approved the Revision/Amendment submitted on 12-Feb-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	2, 3, 7
Determination:	Approved
Approval Date:	11-Mar-2019
Expiration Date:	19-Nov-2019

The following populations are approved for inclusion in this project:

- Children – CRL 1

Documents Included in Review:

- consent.clean.190211
- surveryquest.190228
- praf.190211

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board
Telephone (601) 984-2815
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DHHS FWA #00003630
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

Approval Notice
Amendment

10/29/2018

Charlotte Hobbs,
Pediatrics
University Of Mississippi Medical Center
2500 North State Street
Jackson, MS 392164505

RE: IRB File #2016-0111
Parasitic infections in children living in Mississippi

Your Amendment was reviewed and approved by the Expedited Review process on 10/29/2018. You may implement the amendment.

Please note the following information about your approved research protocol:

Protocol Approval Period:	10/29/2018 - 06/04/2019
Sponsor:	The University of Mississippi Medical Center
Approved Enrollment #:	2000
Participant Population:	Minors < 18 Adults - Patients
Performance Sites:	SON ? Mercy Delta Express School Clinics, Friends of Children of MS, Inc./Ripley-Blackwell Center, University Hospital and University Physicians - Grants Ferry

Amendment Summary: While the overall objectives and study procedures are not being altered. The following changes relate to a general expansion of the project into other areas of Mississippi as well as a refinement of collection:1. We propose to change the study title from "Parasitic infections in children living in the Mississippi Delta (Delta Parasite Project)" to "Parasitic infections in children living in Mississippi (Mississippi Parasite Project)"2. We propose to recruit and enroll patients from UMMC Pediatric outpatient clinics (Children"s of Mississippi) and the School of Nursing/Delta Mercy Project health fairs3. We propose to increase the number of stools

collected from each subject from 1 to 3 after guidance received from the Centers for Disease Control and Prevention4. We propose to offer non-coercive compensation to parents/guardians of those subjects who complete study-related procedures (return their stool samples)5. Working with the UMMC School of Population Health, we have added a more robust community engagement plan to the study.

Documents / Materials:

Type	Description	Version #	Date
Research Protocol	Mississippi Parasite Project v8	8	09/23/2018
Funding proposal/Grant application/Contract	CDC BAA Sept 2018	1	09/21/2018
Parental Permission Document	Permission Document October 2018 CLEAN	2	10/11/2018
Assent Document	Assent CLEAN Sept 2018	2	09/23/2018
Flyer	Gelp get rid of germs CLEAN	2	10/11/2018

Review History:

Date	Type	Decision
10/04/2018	Administrative Review	Revisions Required
10/11/2018	Administrative Review	Revisions Required
10/25/2018	Administrative Review	Revisions Required
10/29/2018	Expedited Review	Approved

Please remember to:

- Use the IRB file number (2016-0111) on all documents or correspondence with the IRB concerning your research protocol.

- Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, if this study involves an intervention (whether or not it involves a drug or device) you (or the "responsible party") must register the study before enrollment begins and report results within 12 months of study closure through Clinicaltrials.gov http://www.clinicaltrials.gov/. Penalties for responsible parties who fail to register applicable clinical studies are significant and include civil monetary penalties and, for federally-funded studies, withholding or recovery

of grant funds. For additional information please go to http://irb.umc.edu/GuidanceInfo/ClinTrialRegistry.htm.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

IRB 2

Enclosure(s): (1) Investigator Responsibilities, Protection of Human Research Participants

UMMC Investigator Responsibilities
Protection of Human Research Participants

The IRB reviews research to ensure that the federal regulations for protecting human research participants outlined in UMMC policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), as well as other requirements, are met. The University of Mississippi Medical Center's Federalwide Assurance (FWA), FWA# 00003630, awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research participants in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the UMMC FWA to understand their responsibilities in conducting research involving human participants**. Both documents are available on the Human Research Office webpage, http://irb.umc.edu/ , and in hard copy by request from the Human Research Office. Some of the responsibilities investigators have when conducting research involving human participants are listed below.

1. Conducting the Research: You are responsible for making sure that the research is conducted according to the IRB approved research protocol. **You are also responsible for the actions of the study's co-investigators and research staff**.

2. Participant Enrollment: You may not recruit or enroll participants prior to the IRB approval date or after the expiration date of IRB approval. All recruitment materials for any form of distribution or media use must be approved by the IRB prior to their use. If you need to recruit more participants than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of participants.

3. Informed Consent: Informed consent is a process that begins with the initial contact and ends at some point after the study is complete. You are responsible for the conduct of the consent process, ensuring that effective informed consent is obtained and documented using **only** the IRB-approved and stamped consent document(s), and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Whoever is presenting the consent document to the potential participant and conducting the consent discussion must have all pertinent information at hand, be knowledgeable about the study and the disease or condition involved, if any, and have the ability and experience to answer questions regarding the study and any treatment involved. Please give all participants a signed copy of each consent or assent document they sign, and keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the consent document in the participant's medical record.

4. Continuing Review: The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Prior to the date on which IRB approval of the research expires, the IRB will send you three reminders to submit a Continuing Review, 90, 60 and 30 days prior to expiration. Although reminders are sent, **it is ultimately your responsibility to submit the renewal in**

a timely fashion to ensure that a lapse in IRB approval does not occur. If IRB approval of your research lapses, you must stop new participant enrollment, and contact the IRB immediately.

5. Amendments and Revisions: If you wish to amend or change any aspect of your research, including research design, interventions or procedures, number of participants, participant population, consent document, instruments, surveys or recruitment and retention material, you must submit the amendment or revisions to the IRB for review with a Request for Change. You **may not initiate** any amendments or changes to your research without first obtaining IRB review and written approval. The **only exception** is when the change is necessary to eliminate apparent immediate hazard to participants. In that case the IRB should be immediately informed of this necessity, but the change may be implemented before obtaining IRB approval.

6. Unanticipated Events: All adverse events that are unanticipated **(unanticipated means that the event is serious,unexpected, related or possibly related to participation in the study and places participants at greater risk of harm than previously recognized)** and serious protocol deviations, must be reported to the IRB **within ten (10) business days** of discovery. The only exception to this policy is death - **the death of a UMMC research participant must be reported within 48 hours of discovery.** Reportable events should be submitted to the IRB with the Adverse Event/Unanticipated Problem Report form.

   Events that do not meet the definition of an unanticipated problem involving risk to participants or others, including research related injury occurring at a UMMC performance site or to a UMMC study participant, participant complaints, problems, minor protocol deviations and non-compliance with the IRB's requirements for protecting human research participants should be reported as follows: Minor deviations and problems should be submitted at the time of continuing review, as instructed on the form. All other events should be reported in writing via letter or email to the IRB with sufficient detail to allow the reviewer to understand the problem and any actions taken to prevent it from happening again.

7. Research Record Keeping: At a minimum, you must keep the following research related records in a secure location for at least six years: the IRB approved research protocol and all amendments; all versions of the investigator's brochure; all informed consent documents; all recruiting materials; all renewal applications; all adverse or unanticipated event reports; all correspondence to and from the IRB; and all raw data.

8. Reports to FDA and Sponsor: When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the IRB. You may submit the report with your IRB continuing review application.

9. Provision of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research and the data cannot be used in support of the research.

10. Final Reports: When you have completed the study, (no further participant enrollment, interactions, interventions or data analysis) or stopped work on it, you must submit a Final Report to the IRB using the Final Report form.

11. On-Site Evaluations, FDA Inspections, or Audits: If you are notified that your research will be reviewed or audited by the FDA, OHRP, the sponsor, any other external agency, or any internal group, you **must** inform the IRB immediately and submit all audit reports received as a result of the audit to the IRB.

If you have questions or need assistance, please contact the Human Research Office at 601 984-2815.