CONSENT FORM

Title of Research:	**Cross-sectional Cohort Study to Determine the Prevalence of Soil Transmitted Helminth (STH) Infections in School Age Children in a Rural Community in Southern Alabama**
UAB IRB Protocol #:	**300002219**
Principal Investigator:	**David Kimberlin, MD**
Sponsor:	**Center for Disease Control and Prevention (CDC)**

For Children (persons under 18 years of age) participating in this project, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

This is a research screening project. The purpose of this research screening project is to determine if children between the age of 6 and 18 years old who live in the Wilcox and Lowndes County area are infected with one of several intestinal (gut) worms (parasites) from the soil, pets or animals. We are asking your child to take part in this research screening project because your child may live in the area. Most of the time, these infections have very minor, to no symptoms and your child would not know he/she is infected. The infection can cause your child to become anemic (low blood counts) if untreated which in turn can lead to low energy, impaired memory and affect learning. In the past doctors routinely tested for intestinal worms but the testing has stopped because it was thought that intestinal worm infections no longer occurred in the United States. Since the health care community is concerned that these infections are continuing to occur in certain parts of the United States, the CDC (Center for Disease Control) is supporting this research screening to determine if there is a problem and how large of a problem.

Explanation of Procedures

If you and your child agrees to take part in this research project we will need you to complete the attached questionnaire. On return of the signed consent form and completed questionnaire we will enroll your child in the project. At time of enrollment your child will be assigned a unique identifying number and a small drop of blood will be collected on a card by sticking the tip of a finger.

Your child will then be given a collection container to take home with written instructions on how to collect and return a stool (poop) sample. On return of an adequate stool (poop) sample to the research nurse or the John Paul Jones Hospital within 12 hours of having a bowel movement another collection container will be provided to collect another stool (poop) sample. We will need to collect a total of 3 separate stool (poop) samples at least 24 hours apart.

We will be testing for several different types of intestinal (gut) parasite (worm) infections. The reason for the 3 separate stool (poop) samples is to improve our ability to determine if your child has an infection. You will be notified if your child tests positive for an infection with an intestinal (gut) parasite (worm) by either the stool (poop) tests or from the finger prick. You have the choice to then get your child treated by your own doctor or by one of the project doctors, Dr. Poole. If diagnosed by the stool (poop) tests, your child will be prescribed a medication that they only need to take a single dose by mouth. If they test positive for a parasite (worm) by

the finger stick blood test, they will need to have a repeat blood test to make sure they have the infection, and if they do will be prescribed a medication that they have to take by mouth for 7 days. There will be no charge for any further testing or this medication if done by the project doctor.

Risks and Discomforts

This research project requires the collection of personal information, blood by finger stick and stool (poop) collection. While taking part in this research project your child may be at risk for the following:

- Personal information loss. Your information will be protected by research codes and no identifiers will be recorded on the data collection forms or collection containers.
- Finger stick pain or bruising may occur on your child's finger and mild discomfort from the stick may be noticeable for a short period of time.
- Self-collection stool (poop) samples have no known risks.

Benefits

By participating in this screening project your child will be identified and treated if they are found to be infected with an intestinal parasite (worm) that would otherwise go unrecognized.

Alternatives

You can choose not to allow your child to participate and instead ask your child's own health care provider to test and treat your child for an intestinal worm.

Confidentiality

Information obtained about your child for this project will be kept confidential to the extent allowed by law. However, research information that identifies your child may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research.
They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the project to protect the rights and welfare of research participants.
- The Center for Disease Control and Prevention (CDC)
- The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your child's identity will not be given out. Information obtained during the course of the project which, in the opinion of the investigator(s), suggests that your child may be at significant risk of harm to themselves or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Voluntary Participation and Withdrawal

Taking part in this project is your choice. You are free to withdraw your child from this research project at any time. Your child may be removed from the project without your consent if the sponsor ends the project, if the research doctor decides it is not in the best interest of your child's health, or if your child is not following the project rules.

Cost of Participation

There will be no cost to you or your child for taking part in this research project.

Payment for Participation in Research

Your child will be paid according to this scheduled for samples collected as part of his/her participation.

- $25.00 for the collection of the first adequate stool (poop) sample
- $50.00 for the collection of the second adequate stool (poop) sample
- $75.00 for the collection of the third adequate stool (poop) sample

An adequate stool (poop) sample needs to be about the size of the palm of your hand, not mixed with urine and delivered to the project staff within 12 hours of being passed.

A charge card will be mailed to your child's address by UAB and money will be transferred onto the card as described above.

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this project. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

UAB and CDC has not provided for any payment if your child is harmed as a result of taking part in this research project. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by the UAB doctor or the project staff if new information becomes available that might affect your choice to stay in the project.

Optional Research

Taking part in this optional research is voluntary. You can still be a part of this screening project even if you say no to take part in any of the optional research.

Storage of Specimens for Future Use

As part of this research project, we would like to store left-over stool (poop) and blood specimens collected from your child for future research of intestinal (gut) infections. The left-over stool will be stored in laboratories at the Georgia Institute of Technology and the Center for Disease Control (CDC) in Atlanta, Georgia. The finger stick drop of blood collected on a card, will be stored in the laboratory at the CDC. The future research may be conducted by the research project doctor or by other researchers that obtain IRB approval for their research. The specimens will be labeled with a code that only the research project doctor can link back to your child. Results of any future research will not be given to you or your doctor. The specimens obtained from your child in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you or your child should this occur. You do not have to agree to allow your child's specimens to be stored in order to be part of this project.

You may request at any time that your child's specimens be removed from storage and not be used for future research. If you decide you want your child's specimens removed, you may contact the project doctor. Once the request is received, and if your child's specimens have not already been used for other

research, they will be destroyed. If you do not make such a request, your child's specimens will be stored indefinitely or until used.

Initial your choice below:

___ I agree to allow my child's specimens to be kept and used for future research related to intestinal (gut) parasites.

___ I do not agree to allow my child's specimens to be kept and used for future research related to intestinal parasites.

Questions

If you have questions about the project, results or treatment you can contact Dr. Claudette Poole, a Pediatric Infectious Disease doctor who works at Children's of Alabama who is participating on this project. She can be reached by phone at 205-934-2441 or by mail at 1600 6th Ave South, CHB 308, Birmingham AL 35233. Additionally, research staff will be available at the following locations on the specified dates and times if you wish to speak to the research staff in person and be present for the enrollment of your child:

BAMAKids Community Center:	date:_____ times:_____
John Paul Jones Hospital:	date:_____ times:_____
Camden Health Department:	date:_____ times:_____
Open Door Resource Center:	date:_____ times:_____
Lily Baptist Community Outreach Center and Youth Development Inc:	date:_____ times:_____
Mind Mentoring Program. Pine Hill, AL:	date:_____ times:_____
Community Health Center of West Wilcox County:	date:_____ times:_____

If you have questions about your child's rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

The assent of _____ (name of child/minor) was waived because of:
Age _____ Maturity _____ Psychological state of the child _____

_____

Signature of Participant 7 Years of Age and Older Date

_____

Signature of Parent or Guardian Date

_____

Signature of Person Obtaining Consent Date

Reviewed by:

_____

Signature of Principal Investigator Reviewing Consent Document Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Cross-sectional Cohort Study to Determine the Prevalence of Soil Transmitted Helminth (STH) Infections in School Age Children in a Rural Community in Southern Alabama

UAB IRB Protocol Number: 300002219
Principal Investigator: David Kimberlin, MD
Sponsor: Center for Disease Control and Prevention (CDC)

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____