

PERMISSION TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Title: Parasite infections in children living in Mississippi

Principal Investigator: Charlotte V. Hobbs, MD

Introduction

Your child is being invited to be in a research study, because your child lives in Mississippi and we think parasite infections (“germs”) might be common there. Please ask us about anything in this document or that we tell you that you do not understand.

Purpose

We are doing this study to see if these types of infections are a problem in children living in Mississippi. If they are a problem we want to know how many children are affected and if parasite infections are associated with other infections, anemia (low blood counts), poor growth, or asthma symptoms.

Procedures

If you and your child agree for your child to participate in this study:

We will collect your child’s measurements for height, weight, hemoglobin (blood count) and lead from your child’s health records. A drop of your child’s blood will be obtained by study doctors or nurses by finger prick and applied to a special filter paper and used for immune system (infection fighting) tests later.

We will ask you/your child or your doctor or nurse a few questions about your child’s health, including whether or not he/she has or has had asthma symptoms, and about possible exposures your child may have had to put him/her at increased risk for parasite infections (like if you have a dog or cat at home).

We will ask you to collect your child’s stool in a special container THREE TIMES and return it to the clinic or another UMMC site..

If we find out your child is infected with worms, your child will be referred to a local primary care physician or a UMMC clinic for proper treatment.- whichever you choose.

Risks

Pain from getting his/her finger pricked (pain, bruising, or bleeding at the place where the needle goes into the skin). There is also a small risk of inflammation or infection, but this risk is minimized by our use of alcohol to clean the area before the finger prick and a sterile gauze to apply pressure afterwards.

Embarrassment about returning stool sample to clinic (which we will minimize by a private drop-off spot) or infection risk from carrying stool. To minimize this, study personnel will explain how to do this and recommend hand washing.

Benefits

Your child will not receive a direct benefit from being in this research study. If your child is infected, he/she will be referred for treatment.

We also hope to learn information that may help others in the future.

Alternatives

The alternative is not to participate in this study.

Costs

There will not be additional costs to you if your child participates in this study.

Research-related injury

In the case of injury or illness resulting from your child's participation in this study, medical treatment is available to your child at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment your child receives.

Compensation

For your time and inconvenience, you will receive a gift card for \$40.00 at time of enrollment then a \$20.00 gift card for each stool sample (\$100.00 total if you return all 3 stool samples to us).

Voluntary Participation

Your child's participation is voluntary. If you decide not to allow your child to participate in this study your child will not suffer a penalty or loss of benefits to which your child is otherwise entitled.

Withdrawal

You may choose to stop your child's participation in this study at any time. If you decide to withdraw your child the information already collected about your child may still be used in this study but additional information will not be collected. Your decision to stop your child's participation will have no effect on the quality of medical care your child receives at the University of Mississippi Medical Center.

Confidentiality

Every effort will be made to keep the information we learn about your child private. Study personnel, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance and Grants and Contracts may review the study records. If study results are published your child's name will not be used.

Protected Health Information

Protected health information is any personal health information through which your child can be identified. The information collected in this study includes: Your child's name, date of birth and parent's phone number. By signing this permission document, you authorize Dr. Hobbs and her study staff to collect this information and use your child's records as necessary for this study. Dr. Hobbs will use your child's information (elements of medical history, height, weight, hemoglobin count, lead level) for this study.

The information collected for this study will be kept for 6 years after the study is complete and may be combined with information collected through other research studies or used in other studies but no information will identify your child.

Your child's medical information and records, once disclosed, may be re-disclosed and may no longer be protected by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA), which is a federal regulation designed to protect medical information, including medical information and records created through research.

You have the right to cancel this authorization at any time by providing Dr. Hobbs with a written request to cancel the authorization. If you cancel this authorization medical information and records about your child that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

This authorization has no expiration date. If you do not sign this permission document, your child will not be allowed to participate in this study.

Number of Participants

We expect up to 2000 participants to enroll in this study.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please call Charlotte Hobbs, MD at 601-984-5361. After hours and on weekends please call 601-984-1001 and ask for the doctor on call for Pediatric Infectious Diseases.

You may discuss your child's rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi 39216; telephone, 601 984-2815; facsimile, 601 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your child's rights.

You will be given a copy of this permission document after it has been signed.

Statement of Participation

I have been told about this study and the possible risks and benefits. My child's participation is voluntary and I may withdraw my child at any time without any penalty or loss of benefits to which my child is entitled, including medical care at the University of Mississippi Medical Center.

By signing this form I am not giving up any legal rights my child may have.

Participant's Printed Name

Printed Name of Parent or Legally Authorized Representative and relationship to participant

Signature of Parent or Legally Authorized Representative

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained permission.

Signature of Investigator

Date