UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: Measures of Intestinal Permeability in Preterm infants

Study No.: HP -00049647

Principal Investigator: Sripriya Sundararajan, M.D.

Sponsor: University of Maryland Institute for Clinical and Translational Research

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You are being asked to allow your child to take part in a research study. Your child does not have to take part in this study. You may ask questions at any time. This research is sponsored by the University of Maryland, Baltimore.

PURPOSE OF STUDY

Under normal circumstances, cells from the gut form a tight but selective barrier. Most substances are kept inside the intestine, but food is absorbed. The ability to absorb food while keeping out other substances matures over time. It begins soon after birth but we do not understand much about how it works. Low birth weight, prematurity, and early postnatal age are associated with problems with this process called "leaky gut". The ability to allow substances to cross from the intestine is called intestinal permeability. The gut is leakier at birth in preterm than term infants and allows more substances to cross the barrier. We are trying to identify infants at high risk for problems associated with prematurity by measuring their intestinal permeability. We are trying to find the best way to measure leaky gut in very low birth weight infants.

You are being asked to allow your child to participate because his/her birth weight is very low. Your child is one of approximately 230 infants that will be asked to participate in this study. The study will take place at the University of Maryland Medical Center. Around one hundred and sixty participants will be enrolled at this local site.

PROCEDURES

If you agree to allow your child to be in this study, we will collect urine and stool samples. Everyone will receive the same tests. We will measure the leakiness of your child's gut 1 time. Your child's part in the study will last 16 days. We will do the urine test during your child's hospitalization between 7-10 days of age.

Your child will be given one dose (1/5 tsp) of a sugar solution through a feeding tube. We will collect urine for the next 4 hours after your child is given the solution. The urine will be tested for the amount of sugar that crossed from the gut. We will collect stool specimens daily from the diaper from the day of the study enrollment until 14 days of age and again on day of life 21. The stool will be tested for the different types of bacteria and whether bacteria associated with a healthy gut (probiotic bacteria) are present. Individual results will not be disclosed.

The investigators will review your child's medical records. We will use your child's hospital record to collect information about your child's race and gender. We will also collect information about labor and delivery. We will record your child's birth weight, feeding data (formula or breast milk, age of starting feeding, feeding difficulties, age when receiving the full amount of feeds, etc), growth during the study period, and illnesses related to prematurity. We will collect some laboratory results such as blood counts and facts about any infections your child might develop.

If we do not use all of your child's samples, we plan to store them for future use. They will be identified only by number. Only the investigators will have access to the code that identifies your child.

Please check one of the following choices and sign below:

-----My child's samples (urine and stool) may be used for this project only. Do not use them for any other project and do not contact me again for permission.

-----My child's samples (urine and stool) may be used for this project only and for other projects with my permission. If my samples could be used for another project, contact me to ask my permission.

-----My child's samples (urine and stool) may be used for any scientific purposes involving this or any other project. Do not contact me again for permission.

Parent's/Guardian's signature_____

You will not receive any individual test results. The results of the study will be published in publicly available journals and will be made available in summary form. Individual results will not be disclosed. You may choose to receive a summary of the study's results. Please indicate below if you wish to be notified. If you want be told the results of the study, we will give you the contact information for the principal investigator, Dr. Sripriya Sundararajan.

___ Yes I would like to be contacted by Dr. Sundararajan or one of her associates if potentially important results are found from my child's participation that may be helpful in diagnosing, treating or preventing disease.

___ No I do not wish to be contacted about any results obtained in the future from the study of my child's genetic sample.

Parent/Guardian signature _____

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to:

- Ask questions about anything you do not understand
- For your child to complete all research procedures unless you formally request to withdraw from the study
- Notify study staff of all changes to your contact information including your address, phone numbers, and e-mail address

POTENTIAL RISKS/DISCOMFORTS:

There is a potential for the loss of confidentiality. To prevent this risk, the results of all tests will be kept private. Files will be kept in a locked room. Only research staff can use computers or files with your information. Tubes for urine and stool samples will be labeled with a number, your child's name will not be used.

POTENTIAL BENEFITS

Your child will not benefit from being in this study. Your child's participation may help the doctors better understand leaky gut in very low birth weight babies. You need to decide if your child's participation in this research study is in your child's best interest.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is not to take part. If you choose not to take part, your child's healthcare will not be affected.

COSTS TO PARTICIPANTS

It will not cost you anything for your child to take part in this study.

PAYMENT TO PARTICIPANTS

You will not be paid to be part of in this research study. If your child is hurt by being in the study, he/she will receive emergency medical care if needed. Your child will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. If you have uninsured medical costs, you are responsible for them. The study staff will give you more information about this if you have a study injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

All information collected as part of this study will be kept confidential to the fullest extent permitted by law. The data from the study may be published. However, you will not be listed by name. We will not give out your personal data unless the law requires it. Everyone using study data will work to keep your personal data safe. The university or the hospital where the study takes place may assign people to inspect the research including the parts of your medical record related to research. Study records may be reviewed by the sponsor, or the Institutional Review Board.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Sundararajan at 410-328-6003. If you decide to withdraw your child, you must notify Dr. Sundararajan in writing. If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff if the person in charge decides that the research study is no longer in your child's best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury because of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland
Human Research Protections Office
620 W. Lexington St, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree for your child to participate in this research study. You will receive a copy of this signed consent form.

If you agree for your child to participate in this study, please sign your name below.

_____
Signature of Parent/Guardian

Relationship:_____

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

_____
Witness*

Date:_____

*Witness is optional unless parent is illiterate or unable to sign.