

Main Consent Form

TITLE: Gastrointestinal microbiota influence on the pathogenesis of bronchopulmonary dysplasia in very low birthweight neonates

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1. INTRODUCTION:

A person who takes part in a research study is called a research or study subject. In this consent form “you” or “your baby” always refer to the research subjects.

You and your baby are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want you and your baby to be in the research study. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. Please tell the study doctor or study staff if you are taking part in another research study.

The purpose of this study is to understand whether the bacteria that normally live in a baby’s gut contribute to a very premature baby developing a type of lung disease called bronchopulmonary dysplasia or not.

This is a pilot study. A Pilot study is the first exploration study that is done when very little information is known for sure about a research question.

Approximately 200 infants and their mothers (400 subjects) will be participating in this study.

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The study will take place at the Neonatal Intensive Care Units (NICU) at Regional One Health and Le Bonheur Children's Hospital. It will also take place at the Well Baby Unit at Regional One Health.

From you, the mother, we ask only for permission to access data from your medical chart that provides basic information about you and describes your pregnancy. Therefore, your participation will last only as long as it takes the researcher to access your chart and record this data and code it on a data collection sheet.

Your baby's participation in this study will last from birth until 4 weeks after birth during if your baby is a premature baby admitted to the NICU. Participation will last only while your baby is admitted to the NICU and will stop if your baby is discharged home before becoming 4 weeks old.

If your baby is admitted to the Well Baby Unit, your baby's participation will last only during the part of the first week of life while they are admitted to the hospital and will stop when they are discharged home.

2. PROCEDURES TO BE FOLLOWED:

1. Once a week for up to four weeks while your baby is admitted to the NICU or Well Baby Nursery a stool ("poop") sample will be collected from your baby's diaper after they have been changed by the baby's nurse as part of your baby's normal care. Approximately one teaspoon of stool will be collected at a time. Nothing different will happen to your baby as part of this research study other than the stool from the diaper being saved instead of being thrown away. The stool sample will then be frozen and stored by the research staff so that it can be saved for studying later in the study.
2. When your baby enters the study and while they are participating the research staff will look at your baby's the medical record to learn basic facts about your baby such as age, weight, disease risk factors they were exposed to, and any diseases/medical conditions that your baby developed while they were in the NICU.
3. At 4 weeks of age, the stool samples will be examined to measure the amount and types of bacteria living in the baby's stool, if your baby meets either of the following criteria:
 - a. Your baby developed the lung disease bronchopulmonary dysplasia (BPD); OR
 - b. Your baby did not develop BPD, but his/her characteristics (male/female, weight, gestational age) are similar to a baby that did develop BPD.
4. We will also access your chart at the time of admission to the NICU to learn basic facts about your pregnancy. In particular, we want to be able to study if you were given antibiotics, and if so, for how long. Your participation in the study will last only as long as it takes to record this information on a coded data sheet.

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3. RISKS ASSOCIATED WITH PARTICIPATION:

This study presents only minimal risk. This study will not influence the care your baby receives. No harm or risk is expected from sampling stool from your baby's diaper.

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to your baby which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study.

4. BENEFITS ASSOCIATED WITH PARTICIPATION:

You and your baby will not receive any direct benefits from being in this study. The results of this study may help people with bronchopulmonary dysplasia (BPD) in the future by limiting the development of the disease.

5. ALTERNATIVES TO PARTICIPATION:

You and your baby do not have to participate in this study. Not entering this study will not change the care you or your baby will receive.

Your baby will not have to undergo the following procedures if you do not take part in this study:

- Have a stool sample collected from your baby's diaper once a week.

- Have information such as your baby's age, weight, and medical history copied from your medical record.

- Have your information copied from your medical record.

6. CONFIDENTIALITY:

Research records/specimens

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All paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your baby's stool sample will be labeled with a code (this code will not contain any identifiable information about you or your baby). This coded sample will be sent to the University of Alabama, Birmingham to have genetic code of the bacterial living in the stool sequenced. Due to the how the sequencing will be performed, your baby's genetics will not and cannot be sequenced at the same time. No individual at the University of Alabama, Birmingham will be able to use the coded sample to identify any specific information about your baby as they will only access information about the genetics of the bacteria living in the stool. Information learned about the sample will be sent back to the study researchers using an encrypted method (not regular email).

A master key/list which links your name with the code on your baby's stool sample will be maintained at The University of Tennessee Health Science Center by the research staff and no one at The University of Alabama, Birmingham will have access to this information.

Medical Records

Information about your participation in this study will be placed in your medical record.

Presentations/Publications

While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Authorization to Use and Disclose Information for Research Purposes

Under federal privacy regulations, you have the right to decide who can review and copy you and your baby's personal health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about study visits
- Records about phone calls made as part of this research
- Research records

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By signing this consent form, you are giving your permission for the study doctor and the study staff at the University of Tennessee to get your PHI from your doctor and/or facilities where you/your baby have received health care. They may also share you and your baby's PHI with:
The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
Le Bonheur Children's
Hospital Regional One Health

Your PHI and the PHI of your baby will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your and your baby's PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you/your baby may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

7. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, LeBonheur Children Hospital, Regional One Health, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee, LeBonheur Children Hospital and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee, LeBonheur Children Hospital and Regional One Health do not provide for treatment or reimbursement for such injuries.

If you or your baby are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

If you or your baby are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

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No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

8. QUESTIONS:

Contact Kent Willis, MD at (901) 287-5265 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you or your baby feel your baby have had a research-related injury contact Kent Willis, MD at (901) 287-5265 (Office number).

You may contact Terrence F. Ackerman, Ph.D., UTHSC IRB Chairman, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

9. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

10. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study.

11. VOLUNTARY PARTICIPATION AND WITHDRAWAL:

You and your baby's participation in this research study is voluntary. You may decide not to participate or to not to allow your baby to participate. You or your baby may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to stop being part of the study, you should tell the study doctor, and any information that have already provided will be kept in a confidential manner. You may ask that your baby's identifiable samples be destroyed.

You and your baby's participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

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If your baby has an immune deficiency.

12. FUTURE CONTACT:

Sometimes we wish to keep your contact information, medical diagnosis, and other health information to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

_____ We CAN keep your contact information and health information to ask you about participating in future studies.

_____ We MAY NOT keep your contact information and health information to ask you about participating in future studies.

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13. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have now. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

Signature of Adult Subject

Date

Time

Printed Name of Adult Subject

I give my permission for my baby to be entered into this study.

_____ Initials – Yes

_____ Initials – No

Printed Name of Infant Subject

Signature of Person Obtaining Consent

Date

Time

Printed Name of Person Obtaining Consent

In my judgment, the Legally Authorized Representative has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Signature of Investigator

Date

Time

April 25, 2017

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Gastrointestinal microbiota influence on the pathogenesis of
bronchopulmonary dysplasia in very low birthweight neonates

Patient Information Sheet

STUDY TITLE: Gastrointestinal Microbiota Influence on the Pathogenesis of Bronchopulmonary Dysplasia in Very Low Birthweight Neonates

You and your newborn are being asked to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information and ask for anything that is unclear to be explained.

What is the purpose of the study?

The purpose of this study is to help us understand if the bacteria that normally live in a baby's gut affect if a very premature baby develops a type of lung disease called bronchopulmonary dysplasia (BPD).

Why have my baby and I been chosen?

Your baby has been chosen to participate because they are a very small premature baby. Very small premature babies have a higher risk to get the lung disease bronchopulmonary dysplasia (BPD) than larger or older babies.

If your baby is a full-term newborn and not a premature baby, you were chosen because your baby can help us understand the bacteria that normally live in healthy babies and how these bacteria are different from the bacteria that live in the gut of sick premature babies.

Do I have to allow myself and my baby to participate?

You do not have to take part. Participation is entirely voluntary. We will describe the study in this information sheet, which you can then keep for reference. If you decide to participate, you will be asked to sign a consent form to show you have understood and agree to allow you and

your baby to take part in this study. You are still free to withdraw at any time without giving a reason. Choosing not to take part will not change the care your baby receives.

What is the gut microbiota?

We humans have many microorganisms living in our body, over 100 trillion of them. Microorganisms outnumber our human cells ten to one. The majority live in our gut, particularly in the large intestine. The collection of all the microorganisms living in our body is called the microbiota. These microorganisms do many useful things for us like help us digest our food and make some of the vitamins we need to be healthy. We also know that these microorganisms play a role in the development of our immune system and in the development of the lungs. We want to explore if the microbiota in the gut affect the development of the lung disease bronchopulmonary dysplasia (BPD).

The microorganisms from the gut are collected from a stool (feces or “poop”) sample.

What is bronchopulmonary dysplasia (BPD)?

Bronchopulmonary dysplasia, or BPD, is a serious lung condition that affects infants. BPD mostly affects premature infants who need oxygen therapy.

Most infants who develop BPD are born more than 10 weeks before their due dates, weigh less than 2 pounds at birth, and have breathing problems. Infections that occur before or shortly after birth also can contribute to BPD. Some infants who have BPD may need long-term breathing support. Most babies who have BPD get better in time, but they may need treatment for months or even years. They may continue to have lung problems throughout childhood and even into adulthood. There's some concern that people who had BPD as babies may never have normal lung function.

What will happen if I take part?

1. Once a week for up to four weeks while your baby is admitted to the NICU, or once on admission to the Well Baby Nursery, a stool (feces or “poop”) sample will be collected from your baby’s diaper by the baby’s nurse as part of your baby’s normal care. About one teaspoon of stool will be collected at a time. Nothing different will happen to your baby as part of this research study other than the stool from the diaper being saved instead of being thrown away. The stool sample will then be frozen and stored by the research staff so that it can be saved for studying the microorganisms at the end of the study.
2. When your baby enters the study and while they are participating the research staff will look at your baby’s medical record to learn basic facts about your baby such as age, weight, disease risk factors, and any diseases/medical conditions that your baby developed while they were in the NICU.
3. At the same time researchers will also look at your medical record to learn basic facts about you such as your age, disease risk factors, and information that describes your pregnancy.

4. Only the stool samples of some of the babies in the study will be used. There is a chance that your baby's samples will be disposed of at the end of the study without being examined.

A code will be assigned to you and your baby for research purposes. This will be labelled on the samples provided so that research staff cannot personally identify you or your baby. We will require your contact details and name, but these will be kept separate from the study material and stored in an encrypted database at the University of Tennessee Health Science Center.

What do I need to do?

If you would like yourself and your baby to participate in this study, you can let your nurse, doctor or one of the research staff know. You will then be asked by a member of the research staff to review and sign a consent form that says that you agree to allow your baby to participate.

Will participating in the study directly help me or my baby?

The results of the study will not directly help you or your baby, but the information may help to improve the future treatment of people with bronchopulmonary dysplasia (BPD).

What are the risks of participating in the study?

This study presents only minimal risk. There is no known risk of obtaining stool from your baby's diaper. With any research study, there is a risk that your private identifiable information might be exposed to unauthorized persons (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets and computer encryption) to minimize the chance that any unauthorized persons might see your private information.

Will the research influence the treatment my baby or I receive?

The research does not change your treatment or the treatment your baby receives.

What happens if I do not want my baby or myself to continue in the study?

You and your baby's participation in this research study is voluntary. You may decide to stop participating or to not to allow your baby to participate. You or your baby may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to stop being part of the study, you should tell the study doctor. Any information that have already provided will be kept in a confidential manner. You may ask that your baby's identifiable samples be destroyed.

If you do withdraw your baby from the study, we may, with your permission, like to use any samples already donated and we will need to use the data collected up until the time of your baby's withdrawal.

Will my baby and I's participation in the study be kept confidential?

Yes, all information collected remains strictly confidential. All clinical data will be stored securely.

Your baby's stool sample will be labeled with a unique code. This coded sample will be sent to the University of Alabama, Birmingham to have the genetics of the bacteria in the sample examined. No persons at the University of Alabama, Birmingham will be able to use the coded sample to learn any identifying information about you or your baby. Results from the stool sample will be sent back to the study researchers using an encrypted method and stored in a secure database at the University of Tennessee Health Science Center.

What happens to the stool samples after the study?

Your baby's stool samples will be disposed of at completion of the study.

What will happen to the results of the research study?

Results of these studies will be published in scientific journals and presented at national and international scientific meetings. All information will be presented in a way that cannot identify you or your baby.

The nature of this research is to examine patterns of gut microorganisms and lung disease in large numbers of individuals. Because of this, it will not be possible to give you information about your baby's own results.

Who is organizing and coordinating the study?

The study is being organized jointly by the University of Tennessee, Regional One Health and Le Bonheur Children's Hospital. The lead researcher, Kent Willis, MD, can be contacted at (901) 287-5265.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the lead researcher, Kent Willis, MD, who will do his best to answer your questions at (901) 287-5265. You may also contact Terrence F. Ackerman, Ph.D., UTHSC IRB Chairman, at (901) 448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research. You may also consult your consent document.

Who has reviewed this study?

Before any research study is allowed it must be approved by a research ethics committee to make sure the research is fair and not likely to be harmful. This study was reviewed and approved by the Institutional Review Board of the University of Tennessee Health Science Center.

Code: _____

Demographics and Antibiotics

EGA (weeks)	
Birth weight (grams)	
Sex	
Race	
APGAR 1 min	
APGAR 5 min	
Antenatal Steroids	
Prenatal Antibiotic Given (within 72 h)	
Postnatal antibiotics given	
Postnatal antibiotics given	
Duration of antibiotic exposure (h)	
Other	

Infant History

Bronchopulmonary dysplasia	Y	N
Died	Y	N
Surfactant	Y	N
NEC \geq Stage 2	Y	N
Pneumonia	Y	N
Intubation	Y	N
RDS	Y	N
High frequency ventilation	Y	N
Pulmonary hemorrhage	Y	N
Treated PDA	Y	N
Sepsis	Y	N
IVH \geq Stage 3	Y	N
ROP \geq Stage 3	Y	N
Ventilator Days		
CPAP Days		
Oxygen Days		
Other:		

Code: _____

Demographics and Antibiotics

EGA (weeks)	
Sex	
Race	
Antenatal Steroids	
Prenatal Antibiotic Given (within 72 h)	
Other	

Maternal History

Chorioamnionitis	Y	N
I	Y	N
GBS Positive	Y	N
UI	Y	N
P	Y	N
Cesarean Section	Y	N
ROM (number \geq hr)		
Other:		