NCT02784821

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Antibiotic Effects on the Developing Microbiome, Metabolome and Morbidities in Preterm Neonates

3. Who do you call if you have questions about this research study?

Principal Investigator: Josef Neu, MD 352 273 8985 or 352 265 0033

Co-investigators: Catalina Bazacliu, MD 352 273 8985 or 352 265 0033

Diomel de la Cruz, MD 352 273 8985 or 325 265 0033

Lauren Ruoss, MD 352 273 8985 or 352 265 0033

Other research staff: Sue Sinnamon, BSN 352-294-8642

4. Who is paying for this research study?

The sponsors of this study are The University of Florida, the Children's Miracle Network, the National Institutes of Health, and the Society for Pediatric Dermatology.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research is to evaluate the risks and benefits of current antibiotic use in babies born less than 33 weeks of gestation. Researchers want to know the best way to prevent infection in preterm babies and also keep their bowels healthy. The majority of preterm very low birth weight (VLBW) infants are exposed to antibiotics, despite data showing that proven blood infections in these infants at birth is only between 1-2 of 100 babies born. Neonatal Intensive Care Units (NICUs) in the US have different reasons to give antibiotics to preterm babies, but (NICUs) around the country have very similar rates of infections and other problems that are common with preterm babies. Mothers who choose to participate in this study will have information collected from the chart and babies will be enrolled until discharge.

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b) What is involved with your participation, and what are the procedures to be followed in the research?

If your baby needs a gastric tube, researchers will collect less than a teaspoon of stomach fluid, if available. If your baby does not need a gastric tube, no stomach fluid will be collected and no gastric tube will be placed. Every week after your baby is born, research staff will attempt to collect stool from your baby's diapers. In addition, staff will attempt to collect a skin swab by rubbing a cotton swab on your baby's forearm or other area of skin that is easily accessible. If you choose to breastfeed your baby, about a teaspoonful of breast milk will be collected after your baby is fed. From the babies chart, we will collect information about the baby's diet, feeds, bathing, episodes of holding, the type/humidification of bed, soaps, lotions, types of IV's/fluids, measurements, lab values and certain problems that preterm babies may develop. Your baby will be included in one of three groups: Babies that definitely need antibiotics, Babies that do not need antibiotics, and Babies that might or might not need antibiotics.

c) What are the likely risks or discomforts to you?

The risk of not giving antibiotics is that the baby may have bacteria that could cause an infection. The risks of receiving antibiotics that are not needed are not known. We do not know whether the risks outweigh the benefits. Researchers will take appropriate steps to protect any information they collect about you and your baby. There is a slight risk that information could be revealed accidentally. Participation in more than one research study may further increase the risks to you.

d) What are the likely benefits to you or to others from the research?

Your baby may have healthier intestines and develop fewer infections as he or she stays in the NICU. Our goal is to find out if giving routine antibiotics to babies who do not have infections causes more health problems like bowel infections and other infections that happen after the first week of life.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

You may choose not to participate in this study.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

Why is this research study being done?

The majority of preterm very low birth weight (VLBW) infants are exposed to antibiotics, despite data showing that proven blood infections in these infants at birth is only between 1-2 of 100 babies born. Neonatal Intensive Care Units (NICUs) in the US have different reasons to give antibiotics to preterm babies, but (NICUs) around the country have very similar rates of infections and other problems that are common with preterm babies.

There are “good” bacteria in the bowels that are needed to help with digestion and fight infections. In preterm babies, these “good” bacteria are also needed to help the baby’s immune system develop. Some studies have suggested that early, unnecessary antibiotic use makes preterm babies less able to fight infections later. Antibiotics kill “good” bacteria. When the bacteria that should normally live in the intestine are reduced or killed, harmful bacteria may take their place inside the bowels. These harmful bacteria can cause a potentially deadly infection in the bowel called necrotizing enterocolitis or NEC. Harmful bacteria can also leave the bowel and enter the baby’s blood. Bacteria in the blood can make the baby very sick and cause long term problems. Many harmful bacteria can also cause inflammation in the brain tissue of preterm babies. Some studies have shown that preterm babies who have a bacterial blood infection while in the NICU have a higher risk of developing cerebral palsy when they are older.

There is some data that babies who received no antibiotics had considerably healthier intestinal environments at 6 weeks after birth compared to those infants who received antibiotics for 1 week or longer.

The purpose of this research is to evaluate the risks and benefits of current antibiotic use in babies born less than 33 weeks of gestation. Researchers want to know the best way to prevent infection in preterm babies and also keep their bowels healthy.

You are being asked to be in this research study because

Your baby is less than 33 weeks gestational age and:

- Needs antibiotics because he or she has a high risk of getting an infection

OR

- Does not need antibiotics because he or she is at low risk of getting an infection

OR

Would normally be treated with antibiotics because he or she is having trouble breathing

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Your baby will receive standard NICU care. Your baby's doctor will monitor him or her for common but serious problems that are associated with babies who are born early. Preterm babies are at risk for these problems, but not all babies all develop them. The earlier a baby is born, the more chance that he or she will have some of these problems.

- Necrotizing Enterocolitis (NEC), which is a serious and sometimes deadly bowel infection. You baby will be monitored very closely to make sure he or she is digesting milk and that his or her bowels are not becoming inflamed.
- Spontaneous ileal perforation (SIP), which is when the baby's bowel develops a small hole near where the small bowel connects to the large bowel. SIP is not necessarily linked to having an inflamed bowel.
- Bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD), which can be caused from the need to have a breathing tube and or breathing machine because they baby's lungs are immature. Babies with BPD sometimes need a ventilator even after they go home. Babies with CLD sometimes need extra oxygen after they go home. Your baby will be given the least amount of breathing help that he or she needs to reduce the amount of time a ventilator or oxygen is needed.
- Retinopathy of prematurity (ROP) which is an eye problem that is specific to preterm babies. ROP causes the blood vessels in the back of the eye to grow in areas where they shouldn't. This can cause vision problems or blindness. Depending on how early your baby is born, he or she will have eye exams done to watch the growth of the blood vessels in the eyes.
- Infections. Because the immune systems of preterm babies do not work well, preterm babies are risk of infection in the blood, in the urine, and in the spinal

fluid. Your baby will be monitored closely for early signs that an infection might be starting.

- Intraventricular hemorrhages (IVH) can happen when the very fragile blood vessels in the preterm baby's brain rupture. Sometimes this bleeding is minor and goes away as the baby grows. Other times the bleeding is severe and can cause long term changes in the brain tissue, called periventricular leukomalacia (PVL).

7. What will be done only because you are in this research study?

- Many preterm babies are too small to eat by mouth and need a gastric tube to be placed into their nose or mouth for feeding. This tube goes to the stomach. This tube can be used to feed your baby or to remove extra stomach fluid that sometimes builds up. If your baby needs a gastric tube, researchers will collect less than a teaspoon of stomach fluid, if available. If your baby does not need a gastric tube, no stomach fluid will be collected and no gastric tube will be placed.
- Researchers will attempt to collect the first stool your baby passes. This is called meconium.
- Every week after your baby is born, research staff will attempt to collect stool from your baby's diapers. In addition, staff will attempt to collect a skin swab by rubbing a cotton swab on your baby's forearm or other area of skin that is easily accessible.
- If you choose to breastfeed your baby, your preterm baby may not be able to feed directly from your breast at first. Mothers of preterm babies who provide breast milk, use a breast pump to help remove milk from the breast. This breast milk is then collected and given to the baby. If you choose to participate in this study, about a teaspoonful of this collected milk will be collected. We will only collect breast milk if you have milk left over after your baby is fed.
- There are bacteria in all mother's breast milk. Researchers would like to see what type of bacteria are in your breast milk. This will be done in order to see whether the potentially good microbes from your milk are getting into the baby's intestine. We will compare this to the bacteria in the stool of the babies fed donor milk. In order to determine if other factors cause a healthy intestinal environment, all babies who enroll in this study will have information collected from the mother including: method of delivery, the time from when the mother's water broke until birth, mother's medication use, mother's infections, an optional diet history, mother's height and weight, and a copy of the placenta pathology report that is normally done after the baby's birth.
- We will collect information about the baby's diet (baby's own mothers' milk, donor breast milk, formula, breast milk fortification) from the baby's chart. Also,

from the baby's chart we will collect the timing of feeding, bathing information, diaper change times, episodes of holding or kangaroo care. We will document what type of specialized beds the baby may use and how long the baby received humidification in the isolette. If there is any documentation in the baby's chart about soaps, lotions, or medical creams used, we will document that also. We will document which arm or area of the body was swabbed for the skin sample.

- Also, while the baby is the NICU, we will collect information from his or her chart about certain problems that preterm babies may develop. These include:
- Necrotizing Enterocolitis (NEC)
- Spontaneous ileal perforation (SIP)
- Bronchopulmonary dysplasia (BPD) and chronic lung disease (CLD)
- Retinopathy of prematurity (ROP)
- Intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL
- Infections before the baby is 3 days old and infections that happen after the baby is 3 days old

These conditions are commonly seen in premature infants and may be decreased or increased depending on whether we treat with antibiotics.

- We will collect information from your baby's chart about what type of IVs are used and how long IV fluids were given, how well your baby grows including weight, length and head growth, and lab values used to decide if a baby has an infection.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Groups:

Your baby will be included in one of 3 groups:

- the Antibiotic-indicated group(babies that definitely need antibiotics)
- the Antibiotic not indicated group(babies that do not need antibiotics)
- and two randomized groups (babies that might or might not need antibiotics).

Babies that definitely need antibiotics: Babies in the "Antibiotic Indicated Group" have a diagnosed infection either from the mother or the baby. These babies will receive routine antibiotics for as long as the doctors caring for your baby decide. The antibiotics that are usually used are ampicillin and gentamicin, however, if the baby has a bacteria that is not killed with ampicillin and gentamicin, the baby's doctor will choose another antibiotic for that bacteria. Some babies show signs of decreased blood flow to their kidneys. Gentamicin can be difficult for the body to use

if the kidneys are not working well. If your baby needs to be started on antibiotics and s/he has signs of decreased blood flow to the kidneys, your doctor will choose another antibiotic to be given along with ampicillin.

Babies that do not need antibiotics: Babies in the "Antibiotics Not Indicated Group" are babies who are at extremely low risk of having an infection. Sometimes babies are delivered early because of health problems with the mother. If your baby's doctor believes that your baby should not receive antibiotics, because s/he is doing very well, your baby will not receive antibiotics right after birth. If your baby is in the "Antibiotics Not Indicated Group" and shows signs and symptoms of infection, your baby's doctor may still choose to start antibiotics. The antibiotics that are usually used are ampicillin and gentamicin. Some babies show signs of decreased blood flow to their kidneys. Gentamicin can be difficult for the body to use if the kidneys are not working well. If your baby needs to be started on antibiotics and s/he has signs of decreased blood flow to the kidneys, your doctor will choose another antibiotic to be given along with ampicillin.

Babies that might or might not need antibiotics: Nationwide, most babies born prematurely receive antibiotics after birth even if there is not a diagnosed infection in the mother or baby. These are babies who the doctors are not sure whether they should be receiving antibiotics or not, but in the past have received antibiotics for at least 2 days. We are finding that these antibiotics may actually cause harm, like NEC and infections that may happen later in the baby's NICU stay.

Babies in the "might need antibiotics group" will either receive routine antibiotics or will not receive routine antibiotics. This decision will be made randomly, like "flipping a coin" where the chance of receiving the antibiotic or not is 50%. If your baby is placed in the group that receives antibiotics, s/he will receive ampicillin and gentamicin. Some babies show signs of decreased blood flow to their kidneys. Gentamicin can be difficult for the body to use if the kidneys are not working well. If your baby is in the group of babies that receives antibiotics and s/he has signs of decreased blood flow to the kidneys, your doctor will choose another antibiotic to be given along with ampicillin.

If your baby is placed in the group that does not receive antibiotics, his/her doctor will still be able to start antibiotics if s/he starts showing signs that an infection may be developing. This will be left to the judgment of your baby's doctor.

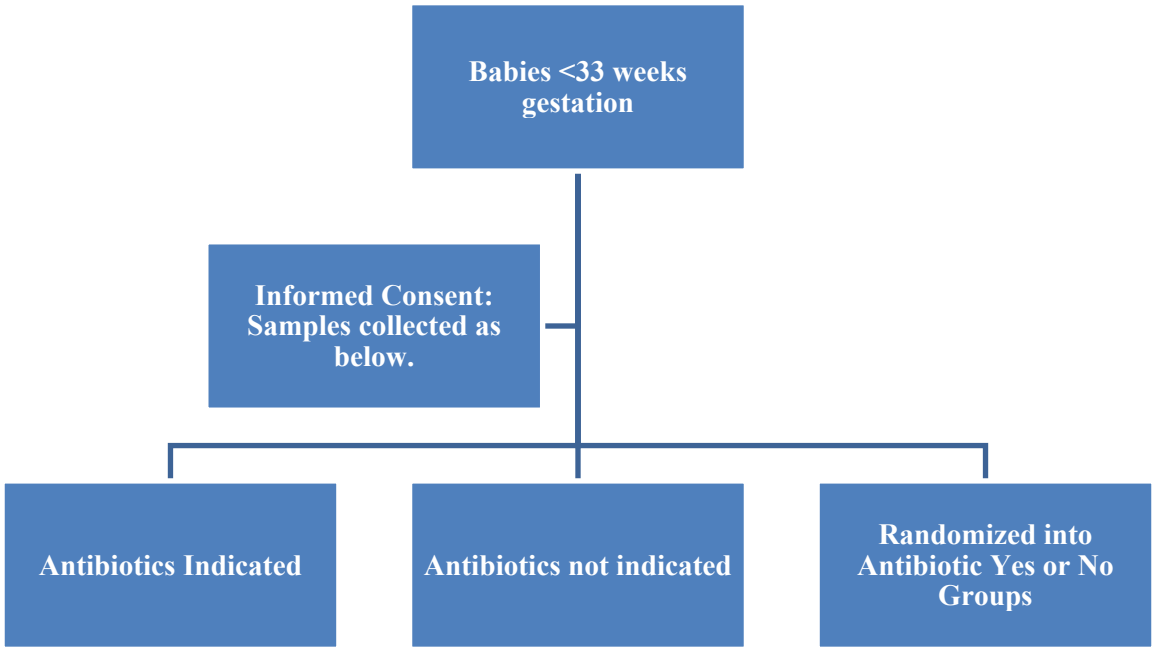
Information collected on all babies in the study: It is strongly suggested to the baby's medical team that all of the enrolled infants have blood cultures, complete blood counts and C-reactive proteins done shortly after birth as per routine care in our NICU Infants whose blood cultures are positive at any time or begin to show signs of infection will have intravenous antibiotics started.

We know that antibiotics kill “good” and “bad” bacteria. In some babies, once the “good” bacteria are killed, they don’t come back even after antibiotic treatment stops. This can allow the “bad” bacteria to grow in large numbers in the baby’s body. Not all of these “bad” bacteria are easy to kill with antibiotics and can become resistant to antibiotics.

By collecting and comparing gastric fluid, skin swabs and stool from babies in this study and collecting and comparing breast milk from these babies’ mothers, researchers are trying to figure out if giving unneeded antibiotics causes long-term changes to preterm babies’ immune systems. Specific things the researchers will look at are:

- Whether or not antibiotics increase the levels of “bad” bacteria in the baby’s body
- Whether or not antibiotics allow “bad” bacteria to cause NEC in the bowels
- Whether or not antibiotics, permanently reduce “good” bacteria and cause infections after the first week of life
- Whether or not antibiotics change how the intestines and immune system digest nutrients
- Whether or not antibiotics change how well the baby grows. Sometimes if preterm babies do not grow well after birth, they have a harder time weaning off the ventilator or oxygen. The longer the baby needs a breathing machine or oxygen, the more risk that s/he will develop BPD, CLD, or ROP.

The following scheme will be used for patient enrollment:



Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

Mothers who choose to participate in this study will have information collected including: method of delivery, the time from when the mother's water broke until birth, mother's medication use, mother's infections, an optional mother's diet history, mother's height and weight, and a copy of the placenta pathology report that is normally done after the baby's birth. Most of this information will be collected shortly after the baby's birth. Sometimes the placental pathology report takes a few days to be completed. After this report is filed and the other information above is collected, researchers will no longer need to get information from the mother.

Babies enrolled in this study will have stool and skin swabs collected at least once a week until they are discharged from the hospital. Researchers will collect information from the baby's chart until hospital discharge.

9. How many people are expected to take part in this research study?

220 babies and 220 mothers.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The risk of not giving antibiotics is that the baby may have bacteria that could cause an infection. By not giving antibiotics, the infection could get worse and make the baby very sick or die. We do not know whether the risks outweigh the benefits and that is the purpose of this study.

The risks of receiving antibiotics that are not needed are not known, however some studies are showing that there may be an increased risk of NEC and infections that occur later in the baby's NICU stay. Understanding what problems unnecessary antibiotics cause is the purpose of this study.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

Your baby may have healthier intestines and develop fewer infections as he or she stays in the NICU. Researchers hope that if your baby can avoid getting infections while in the NICU, that he or she will grow faster and go home sooner.

11b. How could others possibly benefit from this study?

Our goal is to find out if giving routine antibiotics to babies who do not have infections causes more health problems like bowel infections and other infections that happen after the first week of life. We hope that our study will help reduce these problems from happening to other preterm babies.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

You can decide not to participate in this study.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you decide to withdraw from the study, the data collected prior to withdrawal will not be used.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- There is no foreseen medical reason for the principal investigator to withdraw babies from this study. However, if there is any reason to believe that the study is harmful to your baby, or if samples cannot be collected for any reason, the principal investigator may decide to withdraw your baby from the study.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Services

The Sponsor will pay for all services required as part of your participation in this study as described above in the question *"What Will Be Done Only Because You Are In This Research Study*". If you receive a bill for these services, please contact Josef Neu, MD at 352-273-8985 or Kelly Curry, MSN at 352-273-8979

Items/Services Not Paid for by the Sponsor

The cost of antibiotics and the gastric tube placement (if applicable) will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for these items/services and for any non-covered or out-of-network items/services.

Any other medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services.

15. Will you be paid for taking part in this study?

No.

16. What if your baby is injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Method of delivery (vaginal or Caesarean Section)
- Maternal infections during pregnancy
- Maternal health history including a diet history
- Maternal medication use during pregnancy and time of delivery.
- Your baby's lab values including blood cultures, complete blood counts, and C-reactive protein levels.
- Your baby's diet (breast milk or formula)
- Information collected from stomach fluid, breast milk, skin swabs, and stool samples, and the placental pathology report that will be done after birth
- Your baby's growth will be monitored which will include weight, length and head circumference.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study.

- Information collected from the mother's chart that is important for study purpose includes use of antibiotics or other medications, weight changes during pregnancy, and factors related to delivery that may have an effect on baby's chances to develop infections after birth.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____
Signature of Person Obtaining Consent and Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Adult Consenting & Authorizing for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____
Consent & Authorization Signature Date
of Parent/Legal Representative

_____ _____
Print: Name of Legal Representative Print: Relationship to Participant:

_____
Print: Name of Subject: