Informed Consent

Date 10/19/2011

NCT# 04006509

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?

Prenatal breast pumping education of mothers and their support person.

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

Principal Investigator: Leslie A. Parker; 352 215-9360.

4. Who is paying for this research study?

The sponsor of this study is The University of Florida.

5. Why is this research study being done?

The purpose of this research study is to collect information in regards to providing prenatal education about breast pumping to mothers and their support person when the mother is at risk for delivering a premature infant.

You are being asked to be in this research study because you have decided to provide breast milk to your infant and your infant may deliver prematurely.

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)?

You will pump your breasts as instructed by the nursing staff and bring your breast milk to the NICU.

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

a. If you are enrolled into the study, you will be randomly assigned (like the flip of a coin) to one of the two groups. This means that you have an equal chance of being in either one of the assigned groups. If your support person declines to participate or withdraws from the study before you deliver your baby, you will no longer be able to remain in the study. Neither the researchers nor you will make the choice of which group to which you are assigned. The two groups are Group 1 (mother and support person will receive prenatal breast pumping instructions) Group II (will receive standard instructions regarding breast pumping). The amount of breast milk you pump will be measured (as per normal NICU protocol) and recorded for three weeks following delivery.

b. Group 1 will receive instructions regarding breast pumping prior to delivery in their hospital room at their convenience Instructions will include watching a DVD, a breast pump video, written instructions and a demonstration of the breast pump assembly. These instructions will be done in one session lasting approximately 20-30 minutes. You will be allowed to watch the video tapes at your convenience. Group 2 will receive standard instructions regarding breast pumping including written instructions about when to pump, how long to pump and how to use a mechanical breast pump that are provided to all mothers expressing milk for their infants in the NICU.

c. Before you are discharged from the hospital, you will complete a survey regarding your experience with breast pumping.

d. You will be asked while in the hospital or visiting your infant when you experienced a full feeling in your breasts to indicate you “milk has come in”

e. You will provide a sample of your breast milk to be analyzed for sodium at days 1-7, Day 14 and Day 21.

f. Because your mood can impact the amount of breast milk you produce, you will take a test that assessed your mood. You will take this test once before you go home from the hospital and once at 7 days after your delivery. This test has 132 words that you circle to describe your mood and takes about 3 minutes to take.

g. You will be provided a hospital grade pump to use until your infant has been discharged from the hospital or you stop lactating whichever comes first. You will sign a contract stating that you will return the breast pump. You will be responsible for the cost of the research team retrieving the pump from you

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?

You will continue in this study for 3 weeks or until the baby is discharged from the hospital, whichever comes first.

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

80 mothers are expected to take part in this research study.

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?

Potential risks includes stress regarding receiving information about breast pumping.

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?

You may begin breast pumping sooner and you may experience an increased breast milk supply.

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

It is hoped that the information gained from the study will help mothers of premature infants begin breast pumping earlier and have an increased breast milk supply.

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 will receive the standard educational instructions provided by your nurse.

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?

No.

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

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

- If the researchers believe it is in your best interest or if you fail to follow study procedures.
- If your support person declines participation or withdraws from the study before you baby is born

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

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 Principal Investigator: Leslie A. Parker; 352 215-9360.

All other medical services you receive would have been provided to you even if you were not in the 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, and/or co-payments for these services, and any non-covered or out-of-network services.

Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

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

No. You will receive a video regarding pumping your breast milk and you will be provided a breast pump for use until your infant is discharged home or you stop lactating whichever comes first.

16. What if you are injured because of the study?

Since this is a data collection study, there is a very low risk of study-related injury, however, 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 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:

- Your name and medical record number and your infant's name and medical record number, your phone number
- Complete past medial history to determine eligibility criteria
- Measurement of breast milk amount
- Amount of sodium in your breast milk
- Surveys

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. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To collect information regarding providing prenatal education about breast pumping to mothers and their support person when the mother is at risk for delivering a premature infant.

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 and foreign 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

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 questions at any time.

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 Person Consenting and Authorizing	Date