THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

Quantifying the impact of the peanut ball on the duration of the active stage of labor.

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1. KEY INFORMATION:

You 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 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 research study is to provide information about your pregnancy and your delivery to to the study doctor. This study will examine the impact of the peanut labor ball by comparing two groups of patients: laboring patients who use the peanut ball, and laboring patients who are repositioned with wedges and pillows. Currently, peanut balls are not included in the standard of care for laboring women at the Rout Center, and are offered as an optional device to laboring women in addition to/in place of traditional methods using wedges, pillows, or physical assistance.

The peanut ball is an exercise ball that is shaped like a peanut shell, and it is used to support the progression of labor. Peanut balls come in a variety of sizes, based upon your height, and they are used to support various laboring positions while you are resting in bed, sitting, or lying on your side. Please view the attached informational packet and the pictures below for more information about the peanut ball and various positions that it supports.

The peanut ball is an investigational device. An investigational device is one that has not been approved by the US Food and Drug Administration (FDA) as treatment for your condition. The peanut ball is currently available as an optional device for laboring women in the Rout Center, and it has been determined that there is no significant risk associated with using this device.

The effects of the peanut ball are not known on the developing fetus (unborn infant) in humans at this time. The peanut ball that you may use may cause problems in your pregnancy or birth defects in the unborn baby you are carrying.

It is recommended that you receive routine prenatal (obstetric) care. Your regular obstetric care is not part of this research study. Your/your partner's study doctor may need to disclose details of this study to the doctor taking care of you while you are pregnant.

The collection of information regarding your pregnancy and outcomes are for research purposes.

Procedures:

In this study, we will be collecting data from your medical record as you complete visits for your clinical care. If you agree to provide your health information, it will be copied from your medical record throughout your pregnancy until the delivery of your infant(s).

This is a randomized trial, meaning that after you sign this document you will be randomly assigned (like the flip of a coin) to one of two groups: participants who will be supplied with a peanut ball during delivery, and those who will not be supplied with a peanut ball during delivery. If you are selected to receive a peanut ball, the device will be issued to you when you present to Regional One Health for delivery of your infant(s). UT Regional One Physicians and nursing staff will assist you in proper use and placement of the peanut ball during delivery. If you are selected to not receive a peanut ball, the device will not be issued to you when you present to Regional One Health for the delivery of your infant(s). UT Regional One Physicians

and nursing staff will perform traditional positioning with pillows and wedges during your labor. It is not known whether the use of the peanut ball results in shorter laboring times, compared to traditional positioning with pillows and wedges.

Your participation in this study will begin after you sign this document, and your participation will terminate after delivery of your infant(s). Neither you nor your infant(s) will be asked to undergo any additional tests or procedures other than those that your health care provider would normally perform in taking care of your pregnancy, your fetus, and/or your newborn infant(s). Your medical records will remain with the study doctor and co-investigators after your infant(s) is delivered, however there will be no contact or communication unless there is new information about your participation in the study that could affect your/your infant's safety. In that event, we will attempt to find you or make contact with you in any way possible.

The following procedures are being performed for research purposes only:

- Reviewing your medical records to ensure inclusions criteria have been met prior to utilizing the peanut ball
- Copying information such as your medical history, etc. from your medical record
- Positioning on a peanut labor ball (if randomly assigned to receive this treatment)
- Positioning and use of the traditional wedge/pillow (if randomly assigned to receive this treatment)

Participation in this study will involve regular repositioning on the peanut ball every 1–2 hrs. No other restrictions will be placed on the patient as part of the study protocol. Patients who are assigned to receive a peanut ball will be expected to utilize the peanut ball as the main source of position assistance, instead of ambulating (walking).

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Risks:

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.

Some of the most common side effects from positioning with the peanut labor ball are discomfort with positioning and skin irritation.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
There is no direct benefit to you for allowing your health information to be collected.

If you are randomized to receive the standard therapy of traditional repositioning during labor, it is likely to be as safe and effective in decreasing labor time as it is when given outside the research setting. If you are randomized to receive the peanut ball, its safety and effectiveness in shortening labor times and reducing cesarean section rates may be the same as, better than, or worse than standard treatment.

This information will help doctors better understand the effects of the peanut ball on the course of labor progression in pregnant women.

Alternatives:
You may receive the peanut ball without participating in this study. You will receive medical treatment to support the progression of your labor when you present for delivery of your infant(s), regardless of your participation in this study.

You do not have to participate in this research. If you do not participate, you do not have to share any information with the study doctor and/or co-investigators.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Deciding to not take part in this research study will not change your regular medical care in any way.

If you decide to stop having your information collected, you should tell the study doctor. If you decide to stop taking part in this research study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

2. DETAILED PROCEDURES TO BE FOLLOWED:

Approximately 400 subjects will be participating in this study.

The study will take place at the following:

Regional One Health
Outpatient Center- Ob-Gyn Clinic
880 Madison Avenue
Memphis, Tennessee 38103

Regional One Health
Labor and Delivery
853 Jefferson Avenue
Memphis, Tennessee 38103

Hollywood Primary Care
2500 Peres Avenue
Memphis, Tennessee 38108

Kirby Primary Care
2725 Kirby Road Suite 1
Memphis, Tennessee 38119

You are being asked to provide information on your health, pregnancy, and the delivery of your infant(s). We are asking that you allow information concerning the outcome of your pregnancy to be collected and analyzed by the Study Doctor and Co-Investigators to determine if use if the peanut ball has affected your pregnancy or your unborn baby.

If you, your fetus, or newborn infant(s), experience a medical problem during this time, you may be requested to inform the study doctor, either directly or through your health care provider or obstetrician, until the problem is solved or becomes stable.

The tests and procedures that will be performed your labor are the standard of care for laboring patients. Additional procedures that are required for this study include medical record abstraction and placement on a peanut ball (if randomly assigned to receive one). The Study Doctor and Co-Investigators will collect information about the duration of labor, positioning with or without a peanut ball, and additional medical information about previous pregnancies, medical diagnoses, pregnancy complications, and obstetric risks.

You will not be asked to undergo any additional tests other than those that your health care provider would normally perform in taking care of your pregnancy and your fetus or newborn infant(s).

The medical information that will be collected for research purposes about your progress and outcome of your pregnancy and your unborn infant(s) from you and your doctor includes:

- Your medical history including known history of hereditary diseases
- Previous pregnancy(ies) history and outcomes
- Details about your current pregnancy including date of conception and date of delivery

- Medications used during pregnancy
- Results of any tests taken prior to birth
- Details of any events or assessments that you have during or after birth
- Details of any complications during the pregnancy
- The progress and outcome of your pregnancy

Visit 1 (this will take an 10-15. at your routine doctor visit):

- The doctor will explain the study, provide this consent form, and allow you to consider whether or not you would like to participate.
- After you leave your appointment, you will be randomly assigned to receive the peanut ball or traditional positioning when you present for delivery of your infant(s).

Visit 2 (positioning options during labor):

- Your doctor, nurse, or midwife will provide you with a peanut ball or traditional positioning pillows/wedges.
    - The size of the peanut ball that you receive will be based upon your height using the following parameters. Patients <5'3" will receive a 40cm peanut ball, patients between 5'3" and 5'6" will receive a 50cm peanut ball, patients ≥5'7" will receive a 60cm peanut ball. A 70cm peanut ball may be used for sitting or straddling.
- You will be repositioned at a regular time interval (for example, every 20, 30, or 60 minutes).
- After your deliver your infant(s), medical information about your labor and delivery will be shared with the study doctor.

3. RISKS ASSOCIATED WITH PARTICIPATION:

All devices can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your study doctor about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of the study regardless of whether or not you think these are related to the study device. You should discuss these with your study doctor as well as your regular health care provider, if you choose.

As a result of your participation in this study, you are at risk for the following side effects.

Very Common (51-100%)
- Hip pain, if the peanut ball is too large.

Occasional (6-20%)
- Discomfort with positioning
- Skin irritation

If you are not randomized to receive the peanut ball, you will not be exposed to the risks listed above.

If you are randomized to receive standard positioning with pillows and wedges, you may experience a longer labor time, as well as a higher likelihood of requiring a cesarean section. You may experience discomfort associated with the use of traditional wedges and pillows, particularly if you do not receive an epidural. As pillows are not sized based upon your height, as are peanut balls, there is a risk of hip and/or pelvic discomfort based upon the pillows or wedges that are used in traditional positioning.

The research may involve risks to you or to the embryo or fetus, which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

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.

4. CONFIDENTIALITY:

Research records

All your 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 your 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 identifiable research records will be transmitted to the Study Doctor and/or co-investigators using an encrypted method (not regular email), where your information is replaced with a code and password only known to the study investigators.

A master key/list which links your name with the code on your research record will be maintained at Regional One Health by the Study Doctor.

Identifiers might be removed from your private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Medical Records

Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record. As such, it may be available to your insurer. However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

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.

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

Limits to Confidentiality

Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes

Under federal privacy regulations, you have the right to decide who can review and copy your identifiable 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 your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Regional One Health
- The US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) or other government agencies
- Your medical insurance provider
- A Data and Safety Monitoring Board (DSMB)

However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.
You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you 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.

5. COMPENSATION AND TREATMENT FOR INJURY:

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

If you 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 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.

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.

6. QUESTIONS:

Contact Dr. Mary Butts at 901-448-2531 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.
If you feel you have had a research-related injury contact Dr. Mary Butts at 901-448-2531 (office number) during business hours. Call 800-615-6201 after business hours or on weekends and ask for the doctor on call to be paged.
You may contact Cameron Barclay, MSA, UTHSC IRB Director, 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.

7. PAYMENT FOR PARTICIPATION:

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

8. COSTS OF PARTICIPATION:

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

You will be responsible for all costs related to your pregnancy, delivery, and/or care of your infant(s). You will not be responsible for the cost of the peanut ball or traditional wedges/pillows.

You may want to talk with your insurance company about its payment policy for medical care or procedures performed as part of a research study. If your insurance company does not pay, you may be billed for those charges.

9. FUTURE CONTACT:

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order 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, as well as your infant's health information, to ask you about participating in future studies.

_____We MAY NOT keep your contact information and health information, as well as your infant's health information,] to ask you about participating in future studies.

10. 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 at this time. 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 Subject **Date** **Time**

_____
Printed Name of Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject 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**