Title:
Refinement of the LaborView Electronic Fetal Monitor

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Refinement of the LaborView Electronic Fetal Monitor

PROTOCOL NO.: None
WIRB® Protocol #20162194
PRO00009835

SPONSOR: OBMedical

INVESTIGATOR: Tammy Y. Euliano, MD (352) 265-0077
University of Florida
PO Box 100254
Gainesville, FL 32610
United States

STUDY-RELATED PHONE NUMBER(S): Tammy Y. Euliano, MD
(352) 265-0077
(352) 265-0111 (24 hours)

OB Medical
(352) 225-3682
24 hour phone #: (844) 220-8097

Name of person seeking your consent:_____

Place of employment & position: UF, Department of Anesthesiology

Name of Participant ("Study Subject")

_____

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 Western Institutional Review Board at (800) 562-4789.

GENERAL INFORMATION ABOUT THIS STUDY

2. What is the Title of this research study?

Refinement of the LaborView Electronic Fetal Monitor

3. Who would you call if you have any questions?
If you have any questions, concerns or complaints about the study or if you have a research-related problem, contact:

Principal Investigator: Tammy Y. Euliano, MD (352) 265-0077

Other research staff: Judith Wishin, RN (352) 494-3165

If you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

or

The University of Florida liaison in Gainesville at (352) 273-9600.

4. Who is paying for this research study?

The sponsor of this study is OB Medical.

5. Why is this research study being done?

The purpose of this study is to compare monitoring of your labor, both the baby's heart rate and your contractions, obtained by LaborView® and traditional monitoring. LaborView® is an FDA-approved device that is just being introduced to the market. The developers wish to collect comparison data to further improve the device.

You are being asked to be in this research study because the pattern of the fetal heart rate is the best monitor we have to tell us how the baby is doing during labor and in preparation for cesarean delivery. We usually monitor this with a strap across your abdomen and an ultrasound sensor that "listens for" the fetal heart. At times this monitor has difficulty reading the heart rate, and can be confused by the mother's heart. When the ultrasound monitor is unreliable, the fetal heart rate may be monitored by placing a wire (fetal scalp electrode) into the baby's scalp (through the opening in your cervix).

LaborView can monitor the baby's heart rate through a set of ECG stickers, positioned on your abdomen.

The activity of your uterus is monitored also with a strap across your abdomen or a tube placed inside your uterus. We can detect this using the same stickers, reducing the number of monitors you must wear.

Finally, the stickers will also pick up your own ECG and therefore heart rate.

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)?

Normal clinical care is not changed in any way. You would still be monitored by the normal maternal fetal monitoring systems described above (the straps across your abdomen that monitor the baby's heart rate and the activity of your uterus in addition to, if placed by your doctor, the wire placed in your baby's scalp and the tube placed inside your uterus).

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

After gently scrubbing the skin, an array of electrodes will be applied across your abdomen, and connected wirelessly to a computer for collection of electrical activity. We will collect information including your heart rate, your baby's heart rate and your uterine activity from the electrodes and from the normal mother-baby monitors mentioned above. This data will be analyzed later. The information will not be used to change anything about your medical care. We would like to collect data for several hours during labor, or for the entire time until delivery, but can stop at any time.

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?

We would like to monitor the baby through delivery, but the monitor can be removed at any time.

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

150

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

10. What are the possible discomforts and risks?

There is a small chance that your skin may become irritated from the electrodes. There are no known risks to your baby.
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?

There are no direct benefits to participation in this study.

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

Any improvements we can make to the monitoring system could benefit women and babies in the future.

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

The sponsor is paying the University of Florida for conducting this research study. In general, presenting research results helps the career of a scientist. Therefore, the study doctor may benefit if the results of this study are presented at scientific meetings or in scientific journals.

If this study results in the development and sale of a monitor of labor, The University of Florida and the Principal Investigator, Dr. Euliano, may benefit financially as she is an inventor and is married to the chief technology officer of OB Medical, which intends to sell the monitor.

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

The care that you will receive is not altered by whether or not you participate in this study. You can receive standard maternal/fetal monitoring outside of this study.

13a. Do you have to be in this study?

Your participation in this 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.
If you leave this study for any reason, please contact Tammy Y. Euliano, MD at (352) 265-0077 or Judith Wishin, RN at (352) 494-3165. 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?

We will use only that electronic data already collected, but will discontinue collection immediately.

13c. Can you be withdrawn from this research study?

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

Rapid progression of labor to delivery; need for emergency cesarean section; change in your condition and it is felt that our equipment is in the way.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

Study Services
The Sponsor will pay for all activities 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 Tammy Y. Euliano, MD (352) 265-0077.

Items/Services Not Paid for by the Sponsor
All 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, or co-payments for these services, and for any non-covered or out-of-network services.

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

Yes. You will receive $50 in gift cards.

16. What if you are injured because of the research 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.

An 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.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

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

If you agree to participate in this study, the study doctor 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 study doctor 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:

- Past obstetric history
- Details of the current pregnancy, including delivery and health of the baby
- Data obtained from our device
- Data obtained from the standard labor monitoring system
- Medical record number
- Name

This information will be stored in locked filing cabinets or in computers with security passwords.

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 include only information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, or numbers, codes, or so forth 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, throughout 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 determine whether or not the devices in this study provide reliable information concerning the monitoring of the fetal heart rate and the muscle activity of the womb.

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 doctor 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

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

Your PHI may be shared with:

- the study sponsor OBMedical.
- 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.
- Western Institutional Review Board
- Your insurance company for purposes of obtaining payment

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 study doctor.

A description of this clinical trial will be 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.

CONSENT TO PARTICIPATE IN THIS RESEARCH STUDY

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 Conducting Informed Consent Discussion	Date

I have been informed about this study's purpose, procedures, possible benefits and risks. I have also been told alternatives to being in the study and how my protected health information will be collected, used, and shared with others. I have been given the opportunity to ask questions. My questions have all been answered satisfactorily. I agree to be in this research study. I have received a copy of this form.

Signature of Person Consenting and Authorizing	Date