ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study **Noninvasive Monitoring of Uterine Electrical Activity and Fetal Heart Rate: A New External Monitoring Device**

Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Peter S. Bernstein, MD, MPH . You can reach Dr. Bernstein at:

Office Address:
1825 Eastchester Road

Bronx, NY 10461 USA

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by:

OB Tools, Israel

Why is this study being done?

The purpose of the study is to check the accuracy and clinical usefulness of the EUM300 device (electrical uterine myography) for monitoring uterine contractions and fetal heart rate, by comparing it with simultaneous use (happening at the same time) of current methods that are used in clinical care to monitor uterine contractions and fetal heart rate. EUM300 is an external, non-invasive (not requiring to be placed within the body) device that uses electrodes placed on the abdomen (the belly). The electrodes measure electrical traces (pulses) which are recorded on a computer screen in real time (as they are occurring).The data is stored and retrieved late for analysis.

The EUM300 device is an FDA approved monitor intended for the evaluation of electrical signals originating in the uterus, thus providing a tool for measuring uterine activity as well as fetal heart rate.

Why am I being asked to participate?

You are being asked to participate in this study because you are a pregnant woman, at least 18 years of age, who is being admitted to the hospital for labor.

How many people will take part in the research study?

You will be one of about **330** people who will be participating in this study. This study will be conducted at Montefiore Medical Center (Weiler Division and Wakefield Division).

How long will I take part in this research?

You will participate in the study by having the monitor on for 30 min. to several hours depending upon how long you are evaluated or how long your labor lasts. There will be no additional study visits.

What will happen if I participate in the study?

If you consent to be a part of this study, your uterine contractions and fetal heart rate will be monitored simultaneously with the EUM device (for research purposes only) and also with the currently used methods for standard medical care (either external or internal devices). Wire electrodes from the EUM device will be placed on your abdomen with an adhesive similar to that used in medical tape (just like an EKG electrode is applied). Your doctor will continue standard medical care, as per current guidelines, using the information obtained from the current monitoring methods, not from the EUM device.

Data obtained from the EUM devices will be captured on a study laptop computer, along with your data that will be captured by the currently used (standard care) fetal/uterine monitor(s) to allow researchers to compare data from the monitors later as a part of this research. Once the data is collected all personal information linking you to the data will be destroyed.

Information Banking (Future Use and Storage)

We will destroy the information about you when the study is complete.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment, as determined by the participating hospital or sponsoring company, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.

In addition, the sponsor will provide reimbursement for the reasonable costs of medical treatment.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Peter Bernstein, 718-904-2767.

Are there any risks to me?

The risks associated with this study are the same as for standard of care. No severe or serious events are anticipated with the use of the EUM300 system. There is a potential for an allergic reaction (ie. redness, itching, skin irritation, etc.) to the EUM adhesive. The adhesive is used to temporarily stick the electrodes to your belly.

Confidentiality

We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- clinicians and staff at Montefiore who review your records for your care
- groups that review research (the Einstein IRB, and the Office for Human Research Protections) to be sure that the research is being conducted safely and ethically.

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

New Findings

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You will not experience any direct benefit personally from participating in this study. The study results will support the development of the EUM300pro system, and will generate important information about more continuous and accurate monitoring of fetal heart rate and uterine contractions in a less invasive way; hopefully, increasing the chances of attaining a successful treatment and/or delivery for patients in the future.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Your other choices are:
- To receive only standard medical care for monitoring uterine contractions and fetal heart rate without participating in this study.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?

Your participation will end if the investigator or study sponsor stops the study earlier.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date