

INFORMED CONSENT DOCUMENT

Project Title: Intraoperative Fetal Heart Rate (FHR) monitoring: a Feasibility Study

Principal Investigator: Heather McKenzie, MD

Research Team Contact: Heather McKenzie, MD 314-286-2628

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a healthy pregnant woman having either elective induced labor or a scheduled cesarean delivery.

The purpose of this research study is to determine if it is possible to monitor the heart rate of babies that are born through cesarean surgery in the same way that the heart rate of babies born vaginally is monitored. Currently, baby heart rates are not monitored once the cesarean procedure is started in order to keep the mother's abdomen sterile. We have designed a way to keep the monitoring devices sterile and out of the way of the surgical incision.

Currently, there is no real-time information on the well-being of the babies that are delivered by cesarean delivery. This kind of information is important since anesthetic drugs are given to the mother in order to perform the surgical incision and these drugs are carried to the baby by the blood vessels in the umbilical cord. We think this is an important step toward keeping track of the well-being of babies that are delivered by cesarean surgery.

WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to participate in the study, once you arrive on the Labor and Delivery ward you will be checked in by a Labor and Delivery nurse and then evaluated by the Obstetric doctors as part of your routine care. The labor and delivery nurse will place the standard monitors on your arm and stomach (such as a blood pressure cuff, a finger clip that measures the amount of oxygen in your blood, and an acoustic device that detects your baby's heart beat) and perform any additional tests that the Obstetric doctors order for you. If you are having a scheduled cesarean delivery, you will also have ECG [electrocardiography] leads placed on your chest. All this is the standard care you would receive

whether or not you are in the research study.

After this, the additional ECG monitor to be used in this study will be placed. This ECG sticker is in the shape of a band rather than a circle like the traditional ECG. We will test the additional ECG monitor band in two different places: on your upper abdomen and on your back. We will determine which site provides the best signal of your baby's heartbeat. Once we identify the baby's heart beat with the ECG band, we will monitor this for at least 10 minutes. If we are not collecting good information from the research ECG, we will make adjustments until we are able to record good data for 10 minutes. If you are having your labor induced, we will perform the ECG monitoring before your labor is started. If you are having a scheduled Cesarean section, the process will be similar: we will monitor the baby's heart beat for at least 10 minutes during the surgery or until the baby is born (whichever is the longer). We may also have to troubleshoot in order to get good ECG data, which could extend the time you will have the ECG monitor and the acoustic device applied to your upper stomach area. After this time your involvement in the study will end, though the research team will continue to gather some information from your medical record, such as your vital signs throughout your delivery.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making a 3D image of the ECG band when it is placed on your abdomen and on your back. The 3D image will be evaluated to see if the ECG recording is better in one position or the other. Your face will not be imaged and you will be covered by your clothing and bulky towels will be placed in such a way that no one could tell the 3D images were of a pregnant woman. We will use these images in addition to the ECG information from the monitor to tell us which position is the best for recording the baby's heartbeat. These images will not have your name or any other identifying information on them. They will be labeled with a study ID and the date only.

Having these 3D images made is optional. You may choose not to have these images made and still be in this study. Please indicate below your decision.

I give you permission to make 3D images of me with the ECG electrode band during this study.

<u> </u> Yes	<u> </u> No
Initials	Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 55 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 1½ hours.

WHAT ARE THE RISKS OF THIS STUDY?

Risk of ECG [electrocardiography] - there is a small risk that you may have a reaction to the adhesive that holds the leads in place.

Acoustic monitoring - a gel is applied to the skin where the acoustic probe is placed. The gel is sterile,

but there is a small possibility that you might have a reaction to gel medium

Confidentiality breach - One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because results from this study will demonstrate that we are capable of establishing the well-being of babies whose mothers receive anesthesia drugs during cesarean deliveries.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at Heather McKenzie, MD 314-286-2628 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will store your study information using a study-specific ID. We will keep a key linking your ID to your medical record number until we have finished collecting data from your medical record, then we will destroy the key. At that point, we will not be able to identify you. We will not record any identifiers from your medical record when we gather data. All electronic research records will be stored on encrypted devices that will be password protected. The encrypted devices will be backed up to secure servers maintained by Washington University. Only members of the research team will have password access to the research records. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This consent document will be kept as a paper document in a locked office in a locked cabinet of the study principal investigator. The study ID key will also be kept under the same conditions, but separate from the consent document. Only the principal investigator and the research nurse will have access to both the consents and the ID key.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.

- any benefits to which you are entitled.
- However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
 - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <http://hrpo.wustl.edu/participants//withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
 - **If you revoke your authorization:**
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
 - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at <http://hrpo.wustl.edu/participants/> under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because we decide it is not safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Heather McKenzie, MD 314-286-2628. If you experience a research-related injury, please contact: Heather McKenzie, MD 314-286-2628

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Do not sign this form if today's date is after EXPIRATION DATE: 06/18/18.

(Signature of Participant)

(Date)

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent - printed)