TUFTS UNIVERSITY
TUFTS MEDICAL CENTER
Department of Anesthesiology and Perioperative Medicine

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

A Randomized Controlled Trial of Music Use in Parturients Admitted to Labor & Delivery

Principal Investigator: Dan Drzymalski, MD
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Study team telephone number: 617-913-8168

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form. Someone will explain this research study to you. Please also read all of the following information carefully.

Who to Contact?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 617-913-8168.

If you have questions about your rights as a research study subject, call the Tufts Medicine and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress. This research study has been reviewed and approved by the IRB of Tufts Medicine and Tufts University Health Sciences.

Research Participant Advocate

The Tufts Clinical and Translational Science Institute (CTSI) Research Participant Advocate is a trained research specialist who acts as a resource for research participants who participate in research studies. If you have questions, concerns, or feedback about this research study, you can contact the Research Participant Advocate:

- E-mail: rpa@tufts.edu
- Phone: (617) 627-4255

Why am I being invited to take part in a research study?

We are inviting you to take part in a research study because you are currently in the labor and delivery unit.

What should I know about a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.

- You can decide to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide. Do not sign unless you understand the information in this consent form and have had your questions answered to your satisfaction.
- If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers, that you may wish to refer to.

Why is this research being done (Purpose)?
We are doing this study to learn more about the effects of music on anxiety and pain levels during labor.

We expect up to 106 subjects will be enrolled in this study at Tufts University and Tufts Medical Center.

How long will the research last and what will I need to do?
We expect that you will be in this research study for about 1-8 hours, depending on the length of your labor.

You will be asked to tell us about your pain and anxiety at a few different times, and we will collect information from your medical charts. If you are assigned to the intervention group, instead of the control group, you will also be asked to listen to music of your choice for 10 minutes.

You may participate in other studies while participating in this one.

More detailed information about the study procedures can be found in the **"Procedures to be Followed"** section.

Is there any way being in this study could be bad for me?
There is a risk that the volume might be too loud on the music, which could hurt your ears. However, we will be checking volume with you to make sure this doesn't happen.

More detailed information about the risks of this study can be found in the **"Risks"** section.

Will being in this study help me in any way (Benefits)?
We do not know if your participation in this study will benefit you or others. However, possible benefits to others include improving our understanding of ways to ease anxiety and pain for women during labor.

What happens if I do not want to be in this research (Alternatives)?
Participation in research is completely voluntary. You can decide to participate or not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

PROCEDURES TO BE FOLLOWED

We will ask you some questions about your anxiety and pain, as well as collect some vital sign data from your medical records, after you enroll in the study. This information will be collected through some questionnaires and some questions we will ask you or your standard care nurses (such as your blood pressure reading).

You will be asked by the study team what your music choice would be, to listen to for 10 minutes during your labor. You will then be randomly assigned to either listen to the music for this study, or not listen to the music for this study.

If you are selected to listen to music for this study, we will help you get the listening volume to a good level and then ask you to silence all devices (such as tv, phone) in the room and listen to your selected music for 10 minutes. We will wait outside the door and then come back in to ask you the same questions we asked before, and we will collect the same vital signs again and ask one additional question.

If you are selected to not listen to music for this study, we will ask you to not listen to music for 10 minutes. We will wait outside the door and then come back in to ask you the same questions we asked before, and we will collect the same vital signs again and ask one additional question.

If you decide to ask for an epidural, we will ask you questions and collect vital signs 2 more times after you ask for it and after it is placed (if we are in the room while this is happening). Otherwise, we will just collect vital signs from your medical records, if available. The collection of data at these 2 timepoints is optional. This means that you do not have to participate in answering questions and collecting vital signs at these 2 timepoints to participate in the main study. Whether or not you decide to participate in this part will also not affect your future care or treatment at Tufts Medical Center. You can withdraw from this part of the study at any time and still participate in the main study.

Please initial next to your choice for the optional procedure:

_____ YES, ask me questions and collect vitals at 2 more timepoints upon epidural request.

_____ NO, do NOT ask me questions and collect vitals at these 2 timepoints.

Data Collection

This study includes the collection of data about your labor experience.

The use of your data may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

Your information that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

WITHDRAWAL

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if he thinks it is in your best medical interest. In the event of intrauterine fetal demise (the death of the baby in the womb) during this study, you will be withdrawn from the study. This is because the safety and well-being of the baby are a priority, and continuing the study may no longer be appropriate. You can also leave the research at any time and your decision will not be held against you. If you decide to withdraw from the 2 optional timepoints after consent, you can still remain in the rest of the study. If you refuse to participate in the study or stop being in this study, your decision will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

We will tell you about any new information that may affect your health, welfare, or decision to stay in the research.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will not still be used for the study. We will destroy it if you withdraw.

RISKS

There is a risk that the volume of the music could be too high and damage your hearing. We will make sure it is set at the volume determined to be safe by experts and will check with you that you are listening to it at a comfortable level.

Another potential risk of study participation is that your private information could be seen by somebody who should not see it. This is called loss of confidentiality. More detailed information about how we will protect your confidentiality can be found in the **"Privacy and Confidentiality"** section.

RESEARCH-RELATED INJURY

A research-related injury is an injury or illness determined to be directly caused by your participation in the study or any properly performed procedures required for the study. If you think you have experienced a research-related injury, let a member of the study team know in person or call Dan Drzymalski at 617-913-8168.

If you think you have experienced a research-related injury, you may choose to receive medical care at Tufts Medical Center or another healthcare facility of your choice. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the

general public. Tufts Medical Center will not pay for your treatment if you become ill or injured as part of this study.

You or your insurance carrier will be required to pay for any such medical care. You have not given up any of your legal rights by signing this form.

COSTS

There will be no medical charges associated with this study.

Any medical visits and procedures you have that are unrelated to the study will be billed to your insurance through normal hospital billing practices. Your insurance may not cover some or all the services if you are part of a research study. Pre-authorization is not a guarantee of payment. You should talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study.

If you have any questions about what will be provided to you free of charge or what may result in a cost to you, please ask the study doctor or a member of the study staff.

PAYMENT

You will not be paid for participating in this study.

PRIVACY AND CONFIDENTIALITY

Data will be coded, with a separate key that keeps your identifiers separate from your data.

If you decide to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing or if otherwise required by law. It will also only be given for regular hospital treatment, payment, and hospital management activities.

We will make every effort to keep your information private, but such privacy cannot be completely guaranteed. Certain government agencies such as the Institutional Review Board of Tufts Medicine and Tufts University Health Sciences may check records that identify you. This might include your medical or research records and the informed consent form that you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

We may publish the results of this research. However, we will not include any of your personal identifying information in the publication.

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.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

If you sign this document, you allow Tufts Medical Center and the Principal Investigator named above to use or disclose (release) your identifiable health information for this study to those described in the list below. This information includes all information in your medical record related to your labor as well as any information collected or created during the study.

Your information may be disclosed to:

- Individuals or organizations working under the Principal Investigator(s) for the study,
- Outside individuals or entities that have a need to access this information to perform activities relating to the conduct of this research, such as analysis by outside laboratories on behalf of Tufts Medical Center,
- Other researchers and institutions that are conducting or participating in this study,
- The Office for Human Research Protections in the U.S. Department of Health and Human Services, the United States Food and Drug Administration (FDA) and other federal and state agencies that have the right to use the information as required by law, and
- The members and staff of any Institutional Review Board (IRB) that oversees this study.

Tufts Medical Center is required by law to protect your health information. Some people who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by law. You may not be allowed to see or copy the information described in this form as long as the research is in progress, but you can do so after the research is completed in accordance with hospital policies.

Tufts Medical Center may not withhold or refuse to provide you with clinical care based on whether or not you sign this form.

This authorization does not have an expiration date. You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, Tufts Medical Center and Tufts University Health Sciences may still use or disclose health information they already have collected about you for the study. To revoke this authorization, write to: HIPAA Privacy Officer for Research, 800 Washington Street, Box 5100, Boston, MA 02111. If you revoke this authorization, you may no longer be allowed to participate in this study.

Documentation of Consent

I will be given a signed copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study. I understand that by signing this form I do not give up any of my legal rights.

_____	_____	_____
Participant's Signature	Date	Time

I have fully explained to _____ the nature and purpose of the
(Print Name of Participant)

above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____	_____
Date	Signature of Principal Investigator or Person Conducting Informed Consent Discussion
	_____
	Printed Name of Principal Investigator or Person Conducting Informed Consent Discussion

Witness Signature:
My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____
Witness' Signature	Date	Time

_____
Witness' Printed Name