DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Calming Alternatives Learned During MRI-Guided Breast Biopsy

CONCISE SUMMARY

The purpose of this study is to test two different ways to support women undergoing MRI-guided breast biopsy. We hope to help women better manage any pain or anxiety they might experience during and after breast biopsy. Women who participate in this study will be assigned to one of two types of supportive care. If you decide to participate in this study, you would receive music or music with a breathing intervention during the biopsy. The music condition includes standard of care procedural information from the radiologist and music. The breathing intervention includes standard of care procedural information from the radiologist, music, and audio-recorded breathing cues. Women who participate in this study will complete surveys and measures of physiological reactivity (i.e., blood pressure and heart rate). Survey questions will be administered before (in-person), during (in-person), immediately after (in-person), and 24 hours after (via phone) the breast biopsy procedure. It should take you approximately 10 minutes to complete each of the surveys (40 minutes total). Blood pressure and heart rate measures will be administered during the breast biopsy procedure. Total study duration is about 24 hours.

The greatest risks of this study include the possibility of a loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are having a MRI-guided breast biopsy. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her 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. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Rebecca Shelby will conduct the study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study. A member of the study team will be in contact with your doctor throughout the time you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

In an effort to improve women's experiences during MRI-guided breast biopsy, we are conducting a study to test two different ways to support women during this process. We hope to help women better manage any pain or anxiety they might experience during and after breast biopsy.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 people will take part in this research study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. Your medical record will be reviewed to obtain information about eligibility criteria. Your radiologist will be asked to provide medical clearance for your participation in the program.

In this study, you will be randomly assigned (like the flip of a coin) to one of two types of supportive care. If you decide to participate in this study, you would receive music or music with a breathing intervention during the biopsy. You have a 1 in 2 chance of receiving the breathing intervention. The music condition includes standard of care procedural information from the radiologist and music. The breathing intervention includes standard of care procedural information from the radiologist, music, audio-recorded breathing cues, and instructions for using the audio recording. Participants will be provided with headphones to listen to either the music or music with a breathing intervention during the biopsy. Music options will include instrumental jazz, classical piano, harp and flute, nature sounds, and world music. After your biopsy, you would be given music or music with breathing a breathing intervention to use at home.

As part of the study, you would also be asked to answer some questions about your experiences before and after biopsy. Women who participate in this study will complete surveys and measures of physiological reactivity (i.e., blood pressure and heart rate). Survey questions will be administered before (in-person), during (in-person), immediately after (in-person), and 24 hours after (via phone) the breast biopsy procedure. It should take you approximately 10 minutes to complete each of the surveys (40 minutes total). Blood pressure and heart rate measures will be administered during the breast biopsy procedure.

Total study duration is about 24 hours.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for approximately 24 hours.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. The 24-hour follow-up assessment will be completed via telephone.

WHAT ARE THE RISKS OF THE STUDY?

There are minimal risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Discussing

your health or stressors associated with your health may be upsetting. You may choose to not discuss concerns you find upsetting. Also, you may stop your participation in this study at any time. There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. Implementing a controlled breathing intervention during MRI-guided breast biopsy has the potential to provide effective pain and anxiety management in this outpatient setting. We hope that in the future the information learned from this study will benefit other people having MRI-guided breast biopsy. In addition, effective pain and anxiety management in the MRI-guided breast biopsy setting could 1) improve the diagnostic yield of procedures, by reducing pain- and anxiety-related patient movement and 2) improve adherence to follow-up breast screening recommendations by reducing pain and anxiety that can lead women to avoid other painful procedures.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, or as outlined in this consent, you will not be identified by name, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned unique code numbers. The key to the code will be kept in a locked file in the research office.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System Institutional Review Board, Duke Cancer Institute, Duke Office of Audit, Risk and Compliance, and Clinical Trials Quality Assurance. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

As part of this study, Dr. Shelby and her study team will ask you to complete surveys and measures of physiological reactivity (i.e., blood pressure and heart rate). Results of the surveys and measures of physiological reactivity done solely for this research study and not as part of your regular care will not

be included in your medical record.

The study results in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study.
Taking part in this study will not cost you or your insurance company more than the cost of getting regular medical treatment.

WHAT ABOUT COMPENSATION?

You will be reimbursed with a parking pass for Duke Medicine Circle Parking Garage or Duke Hospital Parking Garage to cover the costs of parking during your biopsy appointment. In addition, you will receive a copy of the CD used during the intervention. You will receive the parking pass and CD in person for your participation, following completion of the study.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Rebecca Shelby at (919) 416-3410 during regular business hours and at (919) 970-2033 after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your study doctor determines that it is no longer in your best interest to continue. The regulatory agencies may stop this study at any time without your consent.

If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Shelby at (919) 416-3410 during regular business hours and at (919) 970-2033 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

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