

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Connecticut Children's Medical Center

Study Title: Studying the influence of exposure to maternal voice on oral feeding volumes in preterm infants

Study #:20-026

Department: Neonatal Intensive Care Unit

Phone: 860-545-8950

We (the study doctors and researchers at Connecticut Children's Medical Center and affiliated Research Institutions) study diseases and other health problems children may have. Our goal is to try to find better ways to help treat these health problems. To do this, we sometimes ask people to take part in research studies. This study is voluntary, and you will decide if you would like your infant to participate.

This form explains:

- The purpose of this research study.
- What will happen during this study and how it impacts your baby.
- The potential benefits of being in this study.
- The risks associated with your baby being enrolled in this study.

You can ask questions:

You may have questions this form does not answer. Feel free to ask any questions or discuss this with your baby's doctor.

After you read this form, you can:

Take your time to think about the information that has been provided to you. You can have a friend or family member read the form. Talk it over with your baby's doctor. If you choose for your baby to take part in the study, then you can sign the form. If you do not want your baby to take part in this study, you do not sign the form. The alternative to taking part in this study is not participating in this study.

Why is this study being done?

This study is being done to help researchers understand if listening to mom's voice will help premature babies take their oral feeds better. It is important to understand if this occurs so that we can get them home to their parents quicker, at the same time enhance healthy outcomes long term.

The Purpose of the exposure to maternal sounds protocol

Premature babies have been shown to have a preference for mom's voice, but being in the NICU they don't always have the same amount of exposure to mom's voice that they otherwise would have had if they were born full term. This exposure to mother's voice has been shown to be beneficial for the growth of the part of the brain associated with listening. In addition, it has been shown that being in a stimulating environment such as having parents read to babies has been shown to be beneficial to babies in the long term. The purpose of the study is to determine if exposure to maternal sounds will be beneficial to the babies in taking better oral feeds.

Why are you being asked to take part in this study?

You and your baby are being asked to take part in this study because your baby was born prematurely.

What is involved in being a part of this study?

After explaining the study and answering your questions, the study personnel will take a 30 minute recording of mom's voice while reading one of the following books:

Where the Wild Things Are

Book of Lullabies

Goodnight Moon

Blueberries for Sal

Little Bear

True Story of 3 Little Pigs.

If you do read to your baby outside of the recordings, we ask you to keep a record of your readings in a bedside diary and not read before the 2 feeds where we will play your voice recording. The study personnel will begin playing the recordings for the babies once they have been eating by mouth for 2 days. During this time, the study personnel will collect information about feeding before and after mom's voice exposure, and also other factors such as how fast the food is eaten, whether the recordings are started on time, and information on the medical course of the baby in the NICU.

What will the data collected be used for?

The recordings will only be used in the study for your infant to listen to. The data collected will be kept confidential and once all personal identifiers have been removed from the information, we will publish the results in scientific conferences and peer-reviewed journals. This information might be helpful for other preterm babies oral feeding and possibly helping them get home to their parents faster, and also provide positive stimulation while they're in the NICU.

How long will your child be asked to stay in the study?

We will continue the recordings until your baby has learned to eat fully by mouth or 40 weeks gestational age, whichever is earlier. We will continue to collect clinical information until your baby is discharged from the NICU. If your baby is transferred between Connecticut Children's Medical Center NICU's at Hartford or Farmington, we will continue the study the same way at both sites.

In the future, if new studies are developed, a study team member may contact you to see if you may be interested in participating in the new study. You may opt out of this contact.

How many other people will take part in this study?

We anticipate that up to 25-30 babies admitted to the NICU will take part in this study.

How do you get started?

If you decide to let your baby take part in this study, you will need to sign this informed consent and research authorization form.

Will you be paid for taking part in this study?

If you consent to allow your baby to participate in the inpatient portion of this study, you will be paid a \$20 gift card for Barnes and Nobles for your infant's contribution.

What will it cost you to take part in this study?

It will not cost you anything to take part in this study.

What are the potential benefits to me or others if I participate in this study?

You and your child might benefit if mom's voice does help with oral feeding in preterm infants.

What are the risks if your child takes part in this study?

Your infant's participation in this study will be limited to listening to the mom's voice twice a day prior to feeding. These recordings will not affect medical care in any way. As a result, the overall risk to your baby is very low.

Your baby's personal health information will be used but all personal identifiers will be removed prior to publication. The data that is collected will be stored in password protected study computer and can only be accessed by authorized people. Even though multiple steps are in place to protect your baby's personal health information, there is a low risk that the personal information might be seen by someone who is not permitted to see it.

Will your infant's information be kept confidential?

Federal privacy regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you or your infant will not be identified by name, or any other facts that may point to you/him or her in study records shared outside of Connecticut Children's Medical Center. For records disclosed outside of Connecticut Children's Medical Center, your infant will be assigned a unique code number. The log or list which includes the code number and your or your infant's name and/or other personal identifier is confidential and will be kept secure by the research team.

Every effort will be made to maintain your privacy and the confidentiality of your infant's medical records, however, this cannot be guaranteed. There is the potential risk of loss of confidentiality. Certain offices and people other than the researchers may look at your infant's medical charts and study records. These include people from:

- The Connecticut Children's Medical Center Institutional Review Board
- Research monitor for Connecticut Children's Medical Center

Will your baby's medical treatment be affected by taking part in this study?

This is not a treatment study. The medical treatment your baby receives will not be affected if he/she takes part in this study. You and your baby's doctor will always decide on the best treatment for your baby.

What if your child gets sick or hurt while in the study?

If you have an injury or health problem that is directly related to taking part in this study, please contact the Principal Investigator immediately at 860-837-6277.

Treatment for injuries or health problems related to this study is available at Connecticut Children's Medical Center. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance, unless specified otherwise below. This does not prevent you from seeking payment for injury related to malpractice or negligence. You do not give up any of your legal rights by signing this consent form.

What will happen if I choose not to participate in the study?

If you decide that your baby will not to take part in the research study, your baby will not lose any rights he/she normally has, he/she will still have the same health care benefits, and he/she can still get his/her regular treatments from his/her doctor.

What if your baby joins the study and you decide you want him/her to stop later on?

You can decide after signing this consent document that you no longer want your baby to take part in this study. If you decide to stop, your baby will not lose any rights he/she normally has, he/she will still have the same health care benefits and can continue getting care from his/her doctor. If you decide to withdraw your permission to use your infant's samples in this research project, please contact the study doctor, Dr. Chhikara at Connecticut Children's Medical Center, 282 Washington St., Hartford, CT, 06106 in writing and let him know you are withdrawing your permission for your infant's data to be used for this research.

You can get the answers to your questions:

Principal Investigator Dr. Aditya Chhikara is willing to answer any questions you may have about this study, or address any concerns or complaints, and may be reached 860-837-6277. Future concerns or questions about this study may also be directed to Dr. Aditya Chhikara. If you have questions about you or your infant's rights as a research subject, or if you would like to

discuss problems, concerns, or questions, obtain information, or offer input about a particular research study, you may call the Institutional Review Board office at CT Children's Medical Center at (860) 545-9980. Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

Signatures for Consent to Take Part in this Research Study

The choice to let us use your baby's specimens and information for research is up to you. No matter what you decide to do, it will not affect your care. You can still be a part of the main study even if you say 'No' to take part in any of the optional research portions.

If you decide now that your baby's specimens and information can be used for research and banking, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then, any specimens that we have will be destroyed.

Please read the information below and think about your choices. After making your decisions, check "Yes" or "No", then add your initials and the date after your answer. If you have any questions, please talk to your doctor or nurse, or call our research review board at the IRB's phone number included in this consent.

Part A: Consent for playing mom's voice recording:

If you sign Part A of this document, you are agreeing to allow the study team to play mom's voice recording twice a day once your baby has started eating by mouth, as well as collect clinical data until your infant leaves the NICU. It is up to you to decide whether you want your baby to take part in this study.

Based on the information provided, you agree to allow your child to participate in this study.

Upon signing, you will receive a copy of this form. All the questions you have at this time have been answered.

Name of Patient

Signature of Parent or Legal Guardian

Date

Printed Name of Parent or Legal Guardian

Part B: Permission to be contacted for future studies (optional):

When new studies are developed, a representative from Connecticut Children's Medical Center may contact you to see if you are interested. The new study would be explained to you at a later time. Connecticut Children's Medical Center and others working with Connecticut Children's Medical Center request your permission to re-contact you in the future if we find clinical trials that might be suited to your baby and to discuss other matters associated with this study. You may opt out of this request in this consent form.

If in the future there are studies that you may be eligible for we would like to know if you would be willing to be contacted. Please indicate below:

Yes_____ No_____ / _____
Initials Date

Statement of Person Obtaining Informed Consent

I have carefully explained the research study to the study participant's parent/guardian and discussed with him or her, the information set forth in this form. I hereby certify that when the study participant's parent/guardian signed this form, and to the best of my knowledge, he or she: (i) understood this information; (ii) was given the opportunity to ask questions and all questions asked were answered; and (iii) voluntarily decided to allow his/her child participate in the study.

A copy of this signed and dated form has been given to the study participant.

Signature of Person Obtaining Written Informed Consent

Date

Printed Name of Person Obtaining Written Informed Consent