INFORMED CONSENT FORM

University Of Minnesota

Title of Project: Effects of Music Based Intervention (MBI) on Pain Response and Neurodevelopment in Preterm Infants

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Other Investigators:

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Supported By: This research is supported by the National Institute of Health's National Center for Complementary and Integrative Health

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. Your child, as an individual, may or may not be helped by volunteering for a research study.

- The goal of clinical care is to help your child get better or to improve their quality of life. Doctors can make changes to their clinical care plan as needed

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

We invite you to take part in a research study Effects of Music Based Intervention (MBI) on Pain Response and Neurodevelopment in Preterm Infants at the University of Minnesota which seeks to identify a more effective means of decreasing pain and preventing neurodevelopmental impairments in pre-term infants.

In this research study your child will be assigned to have a series of lullabies or no music played during their stay in the NICU. We will then collect information on how your baby is responding

to this by looking at brain activity and their responses to pain during their standard of care procedures in the NICU. We will also see how your baby is doing after they have left the NICU during a follow-up visit at about 43-48 weeks your child's corrected gestational age. More detailed information about the study procedures can be found under "***Section 2. Procedures***."

We cannot guarantee any benefit to your child by being in this study. Your child may experience discomfort from the cap placed on their head to measure the brain activity. The music is played at a safe level but your child will be monitored during the sessions for any signs of discomfort. More detailed information about risk can be found under section "***Section 4.0 Discomforts and Risks***."

Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Detailed Information About This Research Study

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

Section 1. PURPOSE OF THE RESEARCH

Your infant is being offered the opportunity to take part in this research study because she/he is a medically stable preterm infant born at approximately 30 weeks. The purpose of this research is to look at the effect of music on pain responses and preterm brain maturation/neurodevelopment.

Section 2. PROCEDURES

A video electroencephalography (EEG) will be performed on your infant. An EEG takes a look at electrical brain activity using small patches, called electrodes, that are placed on your infant's head. During the EEG, a camera will record a video of your infant in order to help see what may be happening physically during the EEG, such as if they are being held or moving around. This EEG will recur every 2 weeks for a total of 4 sessions during your infant's stay in the NICU. Participation in this study will not affect the discharge plan for your infant. If your infant is discharged sooner, we hope to perform at least 3 sessions. The EEG sessions will be done at the same times as when the clinical staff will perform a heel stick on your infant for their clinical labs. This heel stick is not part of the research study and will be performed whether you decide to have your child participate in the study or not.

Additionally, a pain assessment will be done at the same time as the standard heel stick during these first three EEG sessions. This assessment looks at your child's behavior responses and vital signs during the time of the heel stick and EEG.

Throughout your child's stay in the NICU, either pre-selected lullaby music will be played for your child via headphones that will be placed next to his/her head (i.e. they will not be placed directly on the ears) or, the headphones will be placed next to your infant's head but no music will be played. Whether your child receives the lullaby music or no music played is based chance, like a flip of a coin. The research team and you will not be able to choose or know what your child has been assigned to. If your child is given the music, it will be played for a total of 1.5 hours of music daily (30 minutes on and then 30 minutes off) for an average of four to five times a week for the duration of the study. The music will be played at no more than 70 decibels (dB) in sound level, which is a safe level that is comparable to the sound of two people having a normal conversation.

You and your child will then have a one-hour follow up appointment with researchers when your child is at about 1 month (43-48 weeks) corrected age which is about 1 month old after the original due date. This is expected to be after discharge from the NICU. At this visit, your child will sit on your lap and the researcher will place an electrode net over his/her head, which will capture Event Related Potentials (ERPs,) i.e. brain activity. Then, the researcher will play some sound clips for your child, and record your infant's response via the electrodes.

We will also collect information from your child's medical record that may include information such as physical exams, vital signs, lab values and medicines your child may be on.

We will also ask you, as the mother of the baby, to fill out a survey on anxiety and depression that you may have experienced or are experiencing. This will be filled out only once, at the beginning of the study. If the results of the survey reveal anything concerning, the study investigator will discuss with you and report the results to an appropriate clinical team member who will be able to discuss any assistance or referrals you may need. The results of this survey will not be recorded in your or your child's medical record. Completing this survey is optional. You do not have to complete the survey in order for your child to be in this study.

Section 3. TIME DURATON OF THE PROCEDURES AND STUDY

Most of this research will take place during your child's stay in the NICU; the remainder of the study will be the one-hour follow up visit (expected to be after NICU discharge).

Section 4. DISCOMFORTS AND RISKS

EEG/ ERP: Your child may experience some mild skin irritation from the electrodes and sensors that are placed on your child's head for the EEG and follow-up visit. Study staff will take care to avoid this with gentle cleaning.

There is a risk to the loss of confidentiality, as the study's video EEG will record video of your child and may include you or those caring for the child while it is recording. This video also

includes sound but will not be listened to by the research team. The video taken during the EEG will be protected as outlined in section 6.1 of this form, Privacy and Confidentiality Measures."

Music Based Intervention (MBI): The MBI in this trial (lullabies) will be played for the infants using headphones placed 1 cm away from the ears to avoid discomfort. During music or control (no music) intervention, a study coordinator will actively monitor the procedure to ensure that cords from the headphones do not interfere with standard of care. The MP3 player has bluetooth capability and should not interfere with routine care. Noise levels are calibrated before every session. Music amplitude will be at no more than 70 dB, which has been shown to be a safe noise level. NICU and research staff will observe for signs of distress during the music therapy, such as crying, grimacing, finger splay, or vital sign changes. If these signs continue for more than five minutes, the music therapy will be stopped for that session.

Section 5. POTENTIAL BENEFITS

There are no guaranteed direct benefits to participants of this study. The main benefit to the study will be knowledge gained to improve the NICU environment. If music-based intervention can be shown to have a positive impact on pain responses and neurodevelopment, this intervention could be implemented in the NICU for benefit to new preterm infants.

Section 6. STATEMENT OF CONFIDENTIALITY

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 the Web site at any time.

You will be notified of your child's intervention type (music or no music) at the end of the study. If any preliminary (initial) results are available these will also be shared at that time.

6.1 Privacy and Confidentiality Measures

Every effort will be made during this study to ensure confidentiality. Only authorized study personnel and others authorized for regulatory purposes will have access to this information. Study data will be de-identified and entered by the study coordinators into a password protected, encrypted electronic database for storage, retrieval, and analysis. EEG files will be de-identified and recorded onto a password protected, encrypted computer workstation. Each EEG file will be downloaded onto encrypted hard drives with extra backup copies.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

6.2 The Use of Private Health Information

We are committed to respect your privacy and to keep your and your child's personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child's personal health information that includes health information in their medical records and information that can identify your child. For example, personal health information may include your and your child's name, address, phone number or social security number. Those persons who receive your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share this information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

People usually have a right to access their child's medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your child's identifiable health information will continue for the period of time necessary for the preparation of a related follow-up research study. At that time the research information not already in your child's medical record will be destroyed. Any research information in your child's medical record will be kept indefinitely.

6.3 Certificate of Confidentiality

To help protect your and your child's privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you and/or your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you and your child, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Section 7. COSTS FOR PARTICIPATION

There are no costs to you for participating in this research.

Section 8. COMPENSATION FOR PARTICIPATION

If the one follow-up visit occurs after NICU discharge, you will be given $30 for the visit to compensate you for time and expenses for participating in this study. This visit is planned to occur at about 1 month after the original due date (43-48 weeks corrected gestational age).

Section 9. RESEARCH FUNDING

The institution and investigators are receiving a grant from the National Center for Complementary and Integrative Heath (NCCIH*)* to support this research.

Section 10. VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your investigator may take you out of the research study without your permission. Some possible reasons for this are concerns for your infant's safety or inability to undergo study procedures. Also, NCCIH may end the research study early. If your participation in the research ends early, you may be asked to visit the investigator for a final visit.

Section 11. CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns or believe you may have developed an injury related to this research, contact Sonya Wang, MD at 612-899-9356. You may also contact coordinators Jensina Ericksen, RN (612-624-0581, erick377@umn.edu) or Cydney Coleman (612-624-0519, colem520@umn.edu).

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research

experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Section 12. Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your **initials** next to each activity.

Yes, I agree	No, I disagree	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Wang.

Phone Number:_____ Email: _____

Yes, I agree	No, I disagree	The study team may have me fill out a survey on anxiety and depression that I may have experienced or am experiencing.

SIGNATURE AND CONSENT/PERMISSION TO BE IN THE RESEARCH

Before making the decision regarding enrollment in this research, you should have:

- Discussed this study with a research staff member
- Reviewed the information in this form
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research, and have received answers to those questions. You will receive a copy of the signed and dated form to keep for future reference.

Parent Permission: Your signature documents that you indicate that you are voluntarily choosing for your child to take part in this research.

_____
Printed Name of Child

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

Consent for Parent Participant (if applicable): Your signature documents that you, as the mother of the baby, are consenting to complete the study's anxiety and depression survey.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

Person Explaining the Research: Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research.

_____ _____
Signature of Person Explaining the Research Date

_____
Printed Name of Person Explaining the Research

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is non-English speaking

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other (please specify):

_____

For the Consent of Non-English Speaking Participants when an Interpreter is Used:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual