Informed Consent Form

Title: Trial to Improve Multisensory Neural Processing, Language & Motor Outcomes in Preterm Infants

NCT Number: NCT03232931

Document IRB Approval Date: April, 15, 2022

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study your baby will be one of 130 who are being studied, at Emory, Children's Healthcare of Atlanta, or Grady Health Systems.

Why is this study being done?

This study is being done to answer the question: We want to find out if hearing a female caregiver's voice, sucking on a pacifier and being held with light pressure containment can help with brain development in preterm infants. You are being asked to be in this research study because your baby was born prematurely, and is now between 32 and 36 weeks postmenstrual age.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. If you choose not to, there will be no changes in your baby's care from what is normally offered at Emory Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, The researchers will ask you to do the following: Subjects will receive research therapy sessions where either a therapist visits to hold your baby against a T-shirt that smells like you while your baby sucks on a pacifier and listens to your voice recording, or your voice recording is left at bedside to be played for your baby by staff and/or family.
If you are visiting and holding your baby we will not interrupt your time with him/her.
2 test visits lasting 30 minutes each will be completed, once prior to sessions and once following.
Research therapy sessions will last 20 minutes, 1-2 times per shift, for 2-3 weeks.
Follow-up visits in the neurodevelopmental follow-up clinic will be per standard schedule at 3-4, 9-12 and 23-26 months.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You may not benefit from being in this study. We hope that the information learned will help others.

What are the risks or discomforts I should know about before making a decision?
The study will take time. We believe that there is very little chance that there is any risk as a result of being in this study.

Alternatives to Joining This Study
Your participation is this study is voluntary. It is not necessary to participate in this study. Your child can still receive the standard of care program listening to the recording of your voice if you choose. If you do not participate your baby will receive the care normally offered.

Costs
You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University, Children's Healthcare of Atlanta, and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: **Trial to Improve Multisensory Neural Processing, Language & Motor Outcomes in Preterm Infants**

IRB #: 00003034

Principal Investigator: Nathalie Maitre, MD, PhD

Sponsor: National Institutes of Health (NIH)/Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child.

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available as trial number NCT03232931 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.

What is the purpose of this study?

The purpose of this study is to find out if hearing female caregiver's voice, sucking on a pacifier and being held with light pressure containment can help with brain development in preterm infants. You are being asked to be in this research study because your baby was born prematurely, and is now between 32 and 36 weeks postmenstrual age. If you agree to be in the study your baby will be one of 130 who are being studied, at Emory, Children's Healthcare of Atlanta, or Grady Health Systems

What will I be asked to do?

If you agree to participate in this study with your baby and sign the consent form, the Study Coordinator will schedule a time to record your voice as you read a few books and sing a few simple lullabies. Then she/he will schedule the first visit. We will come to your baby's room for the study visits. This study will last for 2-3 weeks. We will visit your baby 1-2

times per shift for 20 minutes to hold your baby and to play your voice recording to him/her. If you are visiting and holding your baby we will not interrupt your time with him/her.

You will also have an option of giving us a T-shirt that smells like you after you wear it. We will provide you with the T-shirt. We will cut the shirt into squares and store in a zip-lock bag so that your scent can be used while a therapist is holding your baby. T-shirt squares will be handled with gloves and placed safely by your baby's face during the daily research visits. We will make sure your baby only smells your scent against his/her face. Two of the sessions will be randomly chosen to be video recorded to ensure therapist fidelity of intervention.

There will also be 2 test visits: the first on day 1 and the second after 12-20 sessions have been completed. Each test visit will take about 30 minutes at your baby's bedside. The evoked response potential test records your infant's brain waves using soft sensors placed on your child's head with a net, like a shower cap. Your child's head will be measured to find the right size cap. Before putting on the cap, it will be soaked in warm salt water. Once the cap is in place, your baby will hear sounds from a speaker; then your baby will hear sounds and feel a puff of air his/her hand. During this time, the brain's response to these stimulations will be recorded. The entire testing session will last about 30 minutes. Information about your baby's birth and hospital stay will be collected from their medical record.

This study is randomized. Randomized means that each subject will be picked by chance, like tossing a coin or drawing straws to be included into 1 of 2 groups. Half of the infants will hear their caregiver's voice recording 2 times per day and be held by you when you visit. The other group of infants will hear their caregiver's voice recording 1-2 times per shift for 20 minutes combined with being held by a therapist. The voice recordings will be played at sound levels appropriate for your baby.

Each participant has a 50/50 chance of being assigned to one of the two groups. If your baby is in the second group, 2 out of the first 12 research therapy sessions will be video recorded. The recordings will only be viewed by research personnel for the purposes of this study.

We may ask you to complete a parent questionnaire while your baby is still in the NICU or as soon as possible after discharge, either in writing or via phone. We may complete a brief neurological examination prior to your infant's discharge from the NICU. Follow-up visits in the neurodevelopmental follow-up clinic will be per standard schedule at 3-4, 9-12 and 22-26 months and may also include parent questionnaires in writing or via phone. If you are unable to attend follow-up visits in clinic, visits in our lab or in your home will be offered to you.

How long will you be in the study?

Research therapy sessions take place in the NICU and will last about 20 minutes, 1-2 times per shift, for 2-3 weeks. Follow-up visits in the neurodevelopmental follow-up clinic will be per standard schedule at 3-4, 9-12 and 23-26 months.

Who owns my study information?

If you join this study, you will be donating your study information.

What are the possible risks and discomforts?

The risks associated with the brain waves assessment are no greater than those risks involved in being in a hospital setting. There is a chance that there may be a breach in confidentiality, even with protections in place to prevent this.

We will audiotape your voice singing or talking in order to play it for your baby in the NICU. This voice recording is a required part of study participation. We may also videotape portions of the intervention and assessments in the NICU

and at follow up visits for training and supervision of study team members. Any recordings and videos will be stored in secure research institute servers and will not be accessible except to trained and authorized study team members.

What if there is new information about this study?

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Although there may be no benefit to you from being in this study, we hope to learn information that could help better inform doctors, therapists, and parents about an inexpensive NICU intervention that can be easily adapted to settings with limited resources and can help other babies born prematurely.

What are the alternatives to being in this study?

Your participation is this study is voluntary. It is not necessary to participate in this study. Your child can still receive the standard of care program listening to the recording of your voice if you choose. If you do not participate your baby will receive the care normally offered.

What is the cost of being in this study?

All costs related to the research parts of this study will be covered by the research team. However, the parts of the hospitalization that will be done for routine clinical care will be billed to you and to your insurance company or third party payer.

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Will I be compensated for my time and effort?

You will receive a board book for your baby to promote literacy and bonding. We may also take a picture of your baby for a certificate that you may take home with you. A parking voucher can be provided when you come for your 3-4, 9-12, and 23-26 month study follow up visits. For your time and inconvenience, you (study participant’s parent) will receive $45.00 during the 3-4 month clinic assessment visit, $60.00 during the 9-12 month clinic assessment visit, and $75.00 during the 23-26 month clinic assessment visit. If you complete all the questionnaires at the 9-12 month and 23-26 month visits, you will receive an additional $10 each visit.

You will be compensated using “ClinCard”, which works like a debit card and is provided by Greenphire. When visits are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. To issue your card, we need to give Greenphire some of your personal information (or your child’s). If you do not wish to provide this information, you can still take part in the study, but you will not be paid. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory, Children’s, or Grady is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep you social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study.

Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information.

This is a Clinical Trial that involves services related to your usual medical care and services related to research. Services related to the research are done only for the purpose of the study; these include: the research therapy sessions, the parent audio recordings, the brief neurological examination prior to discharge, and the two test visits in the NICU. Any research services are provided at no cost to the participant or insurance company.

What if you are injured while in this study?
If you think you have been harmed from this study, please call the Principal Investigator at: 404-712-8920.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality
There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information
De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory, Children's, or Grady Health System patient before, then you already have an Emory, Children's, or Grady Health System medical record. If you have never been an Emory, Children's, or Grady Health System patient, you do not have one. An Emory, Children's, and/or Grady Health System medical record will be made for you if an Emory, Children's, or Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory, Children's or Grady Health System medical record you have now or any time during the study.

Tests and procedures done at non-Emory, Children's, or Grady Health System places may not become part of your Emory, Children's, or Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Can I leave this study?

You have the right to leave a study at any time without penalty. It is your choice to be in this study. You may decide to stop being in this study at any time. If you do not want to be in the study, contact the study team at (404)778-1465. If at any time the Principal Investigator believes that this study is not good for you, the study staff will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator may decide to stop your participation in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment
This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory, Children's and Grady Health System may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.

- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory, Children's,and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and Children's IRB, the Emory and Children's Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research, and the Grady Research Oversight Committee.
    - Government agencies that regulate the research including: the Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.
- Greenphire, an independent company specializing in payments for research studies and clinical trials.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

[redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.
To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI

that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

If you are a patient receiving care from the Children's Healthcare of Atlanta and have a question about your rights, you may contact the Children's Institutional Review Board (IRB) at (404) 785-7477 or via email at irb@choa.org.

The IRB is a committee of people that approves all research in this hospital and follows all the rules and regulations made by government agencies about how research is done.

Informed Consent and Authorization

Your signature below indicates that:

- You have read this informed consent form and have been given enough time to consider the decision to participate in the study;
- The research study has been satisfactorily explained to you;
- You have been given the chance to ask questions and have had those questions answered to your satisfaction;
- You understand this study is voluntary and you can withdraw at any time;
- You are signing this consent form prior to participation in any research activities; AND
- You agree to participate in this research study and allow the use of associated protected health information (PHI) as described above.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**