NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Effect of a vibratory stimulus on the mitigation of nociception-specific behavioral and electroencephalographic responses to skin puncture in neonates: a randomized control trial

PRINCIPAL INVESTIGATOR: Lance M. Relland

CONTACT TELEPHONE NUMBER: 614-355-3142

STUDY SPONSOR: Nationwide Children's Hospital Research Institute

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "your child" are used in this consent form. These words refer to the study volunteer

Key Information About This Study
The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is being done to find out ways of reducing the pain that infants experience from needles that are poked through the skin.

Study participation: The procedures that are part of this study will not replace any standard care, but the research personnel will work alongside the medical care team. Each session should not take more than 10 minutes, including applying or removing any equipment. The time that information is being collected for the study should only take about 5 minutes.

Study visits: The whole session will be videotaped in a way that focuses only on the face and legs of your child without recording any sound or any part of the surrounding area. We will also perform a test called Event-Related Potential (ERP). It is a special kind of a measurement of natural brain electricity. This test records your child's brain waves using soft sensors placed on your child's head with a net, like a shower cap. Once the cap is in place, your child will feel a vibration on the heel that will eventually be poked with a needle. This part of the testing session will last only a few minutes, including a vibration that is repeated to total three times and possibly one more time just before the skin gets poked by the needle.

See a more detailed discussion later in this form.

The main risk(s) of the study: we believe that there is very little chance that bad things will happen as a result of being in this study.

The benefit(s) of the study is that your child might be a lower pain response and less stress from a needle poke. And, we might learn something that could help others.

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

1) INTRODUCTION

We are inviting your child to join in a research study. Your child's involvement is voluntary, meaning you can choose whether you want your child to be a part of it. If you choose not to, there will be no changes in your child's care from what is normally offered at Nationwide Children's Hospital (NCH) clinics.

Before you can decide, you will need to know what is involved with the study. The study team is going to talk to you about the research study, and they will give you this consent form to read. You can also discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study team member about this form. If you agree to have your child participate in this study, we will ask you to sign this form.

Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. Once you understand this study, we will ask you whether or not you would like your child to participate. If you do not want your child to be involved with this study, all regular and standard medical care will still be available to your child. You also have the right to remove your child from this study at any time, even if you agree to join now.

We will give you a signed and dated copy of this consent form if you decide to have your child involved in the study.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This study is being done to find out ways of reducing the pain that infants experience from needles that are poked through the skin. Such needle pokes are required to collect blood as part of care in the Neonatal Intensive Care Unit (NICU), but the pain from this may be less if skin is first treated with a non-painful vibration. The idea behind this approach is that the non-painful vibration will help mask the pain that is normally felt with a needle poke. The vibration is otherwise pain-free and it is the only experimental part of this study. The equipment that will be used to collect information for this study is described in more detail later in this document. We will test how the vibration changes behavior and brain waves that are related to pain as a response to a needle poke.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital and we hope to enroll 134 participants.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

After you agree to have your child participate in this study and sign the consent form, the Study Coordinator will enroll your child into the study. The procedures that are part of this study will not replace any standard care, but the research personnel will work alongside the medical care team.

Each session should not take more than 10 minutes, including applying or removing any equipment. The time that information is being collected for the study should only take about 5 minutes. Details of a given session is provided below.

Assessment Session
The whole session will be videotaped in a way that focuses only on the face and legs of your child without recording any sound or any part of the surrounding area. We will also perform a test called Event-Related Potential (ERP). It is a special kind of a measurement of natural brain electricity. This test records your child'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 correct size cap. Before putting on the cap, it will be soaked in warm salt water. Once the cap is in place, your child will feel a vibration on the heel that will eventually be poked with a needle. During this time, the brain's response to the vibrations will be recorded. This part of the testing session will last only a few minutes, including a vibration that is repeated to total three times and possibly one more time just before the skin gets poked by the needle.

This study is randomized. Randomized means that each subject will be picked by chance, like tossing a coin or drawing straws, to receive this additional vibration that occurs just before the needle poke. Every subject will receive three sets of vibrations, but each subject has a 50/50 chance of being assigned a vibration just before the needle poke, and a 50/50 chance of having the standard needle poke without any vibration.

This study is blinded. Blinded means that the study team members who analyze the data, and the study sponsor, the Research Institute and NCH, will not know who is receiving the vibration needle pok versus the standard needle poke. In case of a medical emergency, there is a way for the study team to quickly find out what each subject is receiving.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study. It is possible that you could feel upset when answering questions about your child's diagnosis or medical treatment, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study team will be available to discuss this with you further. The risks associated with the videotaping, vibrations, assessments and ERP are no greater than those risks involved in a standard of care.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Possible benefits to your child might be a lower pain response and less stress from a needle poke. And, we might learn something that could help others.

7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your child's participation in this study is voluntary. It is not necessary to participate in this study in order for your child to get care for his/her condition. The alternative to not participating in this study is simply to receive the standard of care.

8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

All costs related to the research parts of this study will be covered by the research team. However, the parts of the study that would be done for routine clinical care will be billed to you and to your insurance company or third party payer. You may have to pay any costs that the insurance company or third party payer does not pay. The study team will discuss these costs with you.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study. If you believe something bad has happened to your child because s/he has been part of this study, you can contact the study Principal Investigator (PI), Dr. Lance Relland at 614-355-3142 (Monday-Friday from 8am to 5pm). Dr. Relland or his personnel can go over things with you, let you know of resources that may be available and give you information on what you need to do.

10) WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE TREATMENT?

If new information is found out during this study that might change your mind about your child's participation or might affect your child's health, a study staff member will discuss it with you as soon as possible.

11) WHAT HAPPENS IF MY CHILD DOES NOT FINISH THIS STUDY?

It is your choice to have your child be in this study. You may decide to remove your child from this study at any time. If you decide to stop your child from continuing to be in this study, we ask that you call the study team at 614-355-3142. If your child stops being in the study, there will be no penalty or loss of benefits to which your child is otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for your child, the study team 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 child's participation in the study.

12) OTHER IMPORTANT INFORMATION

Being in more than one research study at the same time may cause injury. Tell us if your child is in any other research studies.

While your child is participating in this study, you may not be able to get access to your child's medical records related to this study because it could interfere with the results of the study. As soon as the study is finished, you will have access to these medical records.

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to have your child participate or withdraw your consent to have your child participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to have your child participate in other research studies in the future. You have the right to decide to have your child participate or decline to have your child participate in any future studies. We will not share your child's contact information with researchers outside Nationwide Children's Hospital.

13) HOW WILL MY CHILD'S STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify your child. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your child's PHI for this research study. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

PHI that may be used or disclosed: Name, Diagnosis, Birth Date, Birth History, Weight, Sex, Admission Date, Medical Record Number, Video of Infant's Face

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: to locate medical charts

You may decide not to authorize the use and disclosure of your child's PHI. However, if it is needed for this study, your child will not be able to be in this study. If you agree to have your child be in this study and later decide to withdraw your child's participation, you may withdraw your authorization to use your child's PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, J2-2394-N3, Columbus, OH 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if your child has a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your child's entire medical records.

The results from this study may be published but your child's identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

14) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, or complaints about anything while your child is on this study or your child has been injured by the research, you have 24 hour access to talk to the Principal Investigator at 614-355-3142.

If you have questions, concerns, or complaints about the research; if you have questions about your child's rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

All efforts, within reason, will be made to keep your child's personal information in your child's research record confidential, but total confidentiality cannot be guaranteed. We will use REDCap (Research Electronic Data Capture) a secure, web-based application designed for research studies. The data entered in this database will not have the name or medical record number of your child. Instead we will assign a study number to your child and the list of numbers with names will be kept in a locked research office and only available for view to Dr. Relland, Dr. Maitre, and their team.

Subject's Name _____ **Date of Birth**_____

SUBJECT or SUBJECT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (SUBJECT TO THE SUBJECT'S GENERAL MEDICAL CARE)

I have read this consent form and I have had an opportunity to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participating in this study or a research-related injury, I may contact the study team. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. If allowed by law, I understand that my right to any information that is created or collected by Nationwide Children's Hospital for this study can be temporarily suspended if necessary for the purposes of this research project. I also understand that my right to access to this information from this study will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study or I give permission for my child to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____ _____

SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

_____ _____

PERSON OBTAINING CONSENT **DATE & TIME AM/PM**

I certify that I have explained the research, its purposes, and the procedures to the subject or the subject's legal representatives before requesting their signatures.

_____ _____

WITNESS (IF PHONE CONSENT) **DATE & TIME AM/PM**