VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Title: Auricular Acupressure as an Adjunct Treatment for Opioid Tapering in a Pediatric Cardiac Intensive Care
Version Date:	3/22/22
PI:	Heather Jackson

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this research study is to evaluate the use of acupressure bandages for the treatment of withdrawal in infants needing opioid medication discontinued. You are being asked to have your infant take part in this research study because your baby may have withdrawal symptoms from exposure to medicines needed for pain management. We want to use an acupressure bandage that contains a small seed that puts pressure on certain acupuncture points on the ear. Participants will be randomly assigned to receive the standard of care or the standard of care with acupressure. If your infant is selected to participate in the acupressure group, will place small acupressure bandages that contain a small seed on three spots on your infant's ear while he or she is in the hospital. After 24 hours, we will check the spots to make sure there is no irritation. The acupressure bandage will be switched to the other ear at 48-72 h hours and will continue alternating ears every 48-72 hours until the symptoms of withdrawal have improved. The acupressure bandages are not approved by the Food and Drug Administration (FDA) for this indication and are considered investigational for this study. There is a very low risk in this study but there is a chance of skin irritation from the bandages. Your baby may or may not benefit from participating in this study. Benefits may include improved symptoms of withdrawal. Your participation may help other babies that have withdrawal in the future as well.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your infant may be at risk for withdrawal following discontinuation of certain medications.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
If your infant is randomly selected to participate in the acupressure group, there is a rare (< 1%) risk of irritation (redness, swelling, soreness, or tenderness) and risk of bruising to the baby's ear, however, there have been many other studies on newborn babies using acupressure bandages without any side effects reported. There is a risk of loss of confidentiality. In order to protect your privacy research records will be kept in locked areas within VUMC. Electronic copies of research records will be stored in secure databases available only to the study team.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: improve first line treatments for withdrawal, prevent the need for medications, reduce the length of hospital stay and guide future research in the use of acupressure to treat withdrawal and other medical conditions in infants and children.

Procedures to be followed:
If you agree to be in this study, the following will happen:
1. A meeting will be scheduled with Heather Jackson, the principal investigator, at a location and time that is best for you. The study will be explained and any questions you have answered.
2. If you would like to participate in this study, randomization will be done electronically, and your infant will be assigned to one of two groups: standard of care or standard of care with acupressure stickers.
3. If your infant receives acupressure stickers, you will be included in a group of 20 parents asked to allow

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acupressure bandages to be placed on their baby's ear.
4. On the day your baby is discharged from the hospital, you will be asked your opinion of the bandages.

Payments for your time spent taking part in this study or expenses: You will not be paid to take part in this study.

Costs to you if you take part in this study: There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Heather Jackson at 615-936-9774.
For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615)322-2918 or toll free at (866) 224-8273.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your baby may be withdrawn from the study if medically necessary such as transfer of care to another facility,
moving of acupressure bandages, if you withdraw consent or the study is stopped. If you and your baby are taken
out of the study, you will be told the reason.

What will happen if you decide to stop being in this study?

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If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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.

Confidentiality:
There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. All study documents, including questionnaires, will be stored in a locked location at Vanderbilt University Medical Center and completed documents will remain in a sealed envelope during transportation. You will be discussing the study in a private location. Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, and the VUMC Institutional Review Board for Human Research, will have access to identifying information. This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Results of this study will not be shared with you. A summary of the study results will be available will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____