Please see attached document for the approved consent form.

Official Title: Utilization of Near-Infrared Spectroscopy Technology to Determine Normative Cerebral Regional Oxygen Saturation in a Preterm Population Born at Altitude

Identifier: NCT04639583

Date of Document: 07/28/2020

**The University of New Mexico Health Sciences Center**

**Consent and Authorization to Participate in a Research Study**

**Key Information for** Utilization of Near-Infrared Spectroscopy Technology to Determine Normative Cerebral Regional Oxygen Saturation in a Preterm Population Born at Altitude

You are being invited to take part in a research study about the use of a special sensor to measure the oxygen level of the blood flow around the brain of your infant. We will include 100 infants in this study.

## WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn how the blood flow around the brain in babies born early normally changes, and what the normal values are for babies that are born at high altitude. Your infant's participation in this research will last about 96 hours. If you agree to have your infant participate in the study after birth, we will place a sensor on your baby's forehead in the first 24 hours of life. That sensor will stay in place until your baby is 96 hours old. We will get information about your baby's hospitalization after birth and again at discharge by reviewing the medical records.

## WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose for your infant to participate in this study so that you can help us learn more about what is normal for babies that are born early and at high altitude. We do not expect any direct benefits for your baby, but the results could help babies that are born in the future. For a complete description of benefits, refer to the Detailed Consent.

## WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may choose to not have your baby participate in the study because you are not comfortable with the sensor being on your baby's forehead for the first 96 hours of life. For a complete description of the risks, refer to the Detailed Consent/Appendix.

## DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to have your infant take part in the study, it should be because you really want to volunteer. Your infant will not lose any services, benefits or rights they would normally have if you choose not to volunteer.

## WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is [redacted]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is [redacted]

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at [redacted]

**DETAILED CONSENT**

**Version** 5/20/20

## ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

Babies that are born at the University of New Mexico Hospital (UNMH) or transferred to UNMH in the first few hours of life and are less than 32 weeks' gestational age at time of birth are eligible for this study. If there is a heart condition in the baby, that would exclude the baby from the study. Additionally, if you, the mother or guardian, are not able to consent, then the baby cannot participate in the study. The mother or guardian must be at least 18 years of age to provide consent for their baby. If the baby has reached 24 hours of age, they will not be included in the study.

## WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of New Mexico Hospital in the Newborn Intensive Care Unit (NICU). The total amount of time your baby will be asked to participate in this study is the first 96 hours of life.

## WHAT WILL YOU BE ASKED TO DO?

If you agree to have your baby participate in this study, a sensor will be placed on the baby's forehead. This sensor will be placed with a protective barrier between the sensor and your baby's skin. That sensor will remain in place until the baby is 96 hours old. At that time, we will remove the sensor using adhesive remover or a warm moist cloth to minimize any discomfort. We will closely monitor the skin around the sensor to make sure your baby is not having any irritation from the sensor being in place. If this is noticed, the sensor will be removed immediately. Placing the sensor is currently not part of routine care in the NICU and having the sensor in place in experimental. Any baby in this study will have the sensor placed. We will collect information about your pregnancy and your baby's hospitalization once they are involved in the study and again at the time of discharge from the hospital by reviewing your baby's and your medical records. This information will be used to help us understand if the sensor can help us know if a baby is at higher risk to have a preterm infant complication.

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The possible risks for your baby include skin irritation at the skin of the sensor. We will use a special skin protectant, Mepitel, to help minimize this risk. It is rare to happen, but if your baby has any skin irritation (redness), we will remove the sensor right away. The other discomfort that your baby may experience is during the removal of the sensor. However, we will use adhesive removal or a warm moist cloth to remove the sensor to minimize the discomfort during this step.

There is the risk for loss of privacy and/or confidentiality. We will minimize these risks by separating any information that identifies your infant after inclusion in the study. If there is any concern for loss of privacy and/or confidentiality, the study team will contact you immediately.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect or unforeseen risk.

## WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if your baby will get any benefit from participating in this study. However, if your baby takes part in this study, information learned may help others with your baby's condition.

**WHAT WILL IT COST YOU TO PARTICIPATE?**

There are no costs associated with taking part in the study.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that your baby would normally receive for any conditions they may have. These are costs that are considered medically necessary and will be part of the care your baby receives even if they do not take part in this study.

The University of New Mexico may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the study.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

When we write about or share the results from the study, we will write about the combined information. We will keep your baby's name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is.

You should know there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

We will collect the information about your pregnancy and your baby and store it in REDCap. Any information that is written down, such as the consent form, will be stored in [redacted] locked office inside a locked cabinet. REDCap is a secure, web-based program to capture and store data at the University of New Mexico.

**CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

You can choose to have your baby leave the study at any time. Your baby will not be treated differently if you decide to stop taking part in the study.

If you choose to have your baby leave the study early, data collected until that point will remain in the study database. Data collected until that point will be used in the study unless specifically asked to be removed by contacting the PI, [redacted]

The investigators conducting the study may need to remove your baby from the study. Your baby may be removed from the study if:

- They find that your baby's participation in the study is more risk than benefit to them.
- The agency paying for the study chooses to stop the study early for a number of scientific reasons.

The study devise is currently not available for clinical use outside of this study at UNMH.

**ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?**

Your baby can take part in this study if they are currently involved in another research study. It is important to let the investigator and the baby's doctor know if your baby is in another research study. You should discuss this with the investigator and your baby's doctor before you agree to allow your baby to participate in another research study while they are in this study.

**WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

If you believe your baby is hurt or gets sick because of something that is due to the study, you should call [redacted] immediately. [redacted] will determine what type of treatment, if any, is best for your baby at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because your baby gets hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if your baby is harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

You will not receive any rewards or payment for taking part in the study.

**WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?**

You will be informed if the investigators learn new information that could change your mind having your baby stay in the study. You may be asked to sign a new informed consent form if the information is provided to you after your baby has joined the study.

**WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?**

Generally, tests done for research purposes are not meant to provide clinical information and cannot be used to make decisions about standard medical care. Because the investigators will not have access to information that identifies you or your baby, the research findings will generally not be provided to you.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you or your baby. At most, the website will include a summary of the results. You can search this website at any time.

**WHAT ELSE DO YOU NEED TO KNOW?**

If you volunteer to have your baby take part in this study, your baby will be one of about 100 babies to do so.

**FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION.**

Your pregnancy and your baby's information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your baby's name, medical record number, or date of birth.

**HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).**

As part of this study, we will be collecting health information about your pregnancy and your baby and sharing it with others. This information is "protected" because it is identifiable or "linked" to you and your baby.

**Protected Health Information (PHI)**

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your and your baby's protected health information for the purposes of this study. This information includes the baby's gestational age at birth, birth weight, mode of delivery, sex of your baby, maternal complications during pregnancy, maternal medications used during the pregnancy, any resuscitation the baby required at time of birth, the length and type of breathing support your baby required, any surgeries your baby had during the hospitalization, the hospital length of stay, any common complications babies have from being born early including intraventricular hemorrhage (bleeding in the brain), necrotizing enterocolitis (complication in the bowel), patent ductus arteriosus and treatments used (a part of the heart vessels that should close after birth but doesn't always in babies born early), chronic lung disease, retinopathy of prematurity (an issue with eye development), and death.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that you or your baby's health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

**Right to Withdraw Your Authorization**

Your authorization for the use and disclosure of your pregnancy and your baby's health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. You and your baby's health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

[redacted]

Please be aware that the research team will not be required to destroy or retrieve any of you or your baby's health information that has already been used or shared before the date that your withdrawal is received.

Your baby may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your baby's:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico

**After signing the form, you can change your mind and NOT let the researcher(s) collect or release you or your baby's health information (revoke the Authorization). If you revoke the authorization:**

- You will send a written letter to [redacted] to inform the study team of your decision.
- Researchers may use and release you and your baby's health information already collected for his research study.
- You and your baby's protected health information may still be used and released should your baby have a bad reaction (adverse event).

The use and sharing of you and your baby's information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at [redacted]

## INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

**Signature of infant's parent / guardian** **Date**

_____

**Printed name of infant's parent / guardian**

_____

**Printed legal name of infant participant**

*If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject: the representative is the mother or guardian for the infant that will be participating in this study.

---

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization

Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

---
---