# Informed Consent Form

**Official Title:** Relationship Between Electrical Impedance Tomography (EIT) Measurements and Parameters of Respiratory Status in Very Preterm Infants: An Observational Cohort Study

**ClinicalTrials.gov Identifier:** NCT06609135

**Sponsor:** Lawrence Rhein

**Responsible Party:** Lawrence Rhein, University of Massachusetts, Worcester

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**UMASS CHAN MEDICAL SCHOOL**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Title:** Relationship between Electrical Impedance Tomography (EIT) Measurements and Parameters of Respiratory Status in Very Preterm Infants: An Observational Cohort Study (STUDY000001180)

**Sponsor:** UMass Memorial Medical Center and UMass Chan Medical School, Department of Pediatrics

**Investigators:** Lawrence Rhein, MD, MPH and Mohammad Jaber, MD

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**Daytime Phone Number:** (508) 334-6581

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

## KEY INFORMATION

The following is a summary of this study to help you decide whether to be a part of it. More detailed information is listed later in this form.

A person who takes part in a research study is called a research subject. This consent form is used to document the permission of a parent(s) or guardian(s) to allow a minor to take part in a research study. In this consent form "you" refers to the parent and "your baby" or "your infant" refers to the newborn infant.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

**You are being invited to participate in a research study** because you have a baby born less than 30 weeks' gestation admitted to the University of Massachusetts Memorial Medical Center Neonatal Intensive Care Unit (NICU).

**The main question this study is trying to answer** is how Electrical Impedance Tomography (EIT) measurements are related to respiratory status in preterm infants.

**If you join this research,** EIT measurements, which are obtained using a non-invasive medical imaging device that can help us understand how well your infant's lungs are functioning, will be obtained for up to 3 hours per day starting at 28 weeks corrected gestational age or 7 days after birth, whichever comes later, until they are discharged from the NICU. These measurements are taken by wrapping a cloth belt around your baby's chest that makes contact with his/her skin.

We will also place another non-invasive monitor that measures your baby's carbon dioxide levels, called Transcutaneous Monitoring (TCM), at the same time as the EIT monitor. This will be collected via a probe that is placed on your baby's skin.

As part of the study, data from your and your baby's electronic medical record will also be obtained including information about your baby's delivery, their respiratory support, and their feedings.

**You may not want to be in this study if you are uncomfortable with:**

- Placing extra monitors on your baby for short periods of time
- Sharing your private information with researchers

**Risks:** We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. There is also risk of redness to skin or imprint of the EIT belt, but this is temporary. Lastly, there is a potential risk of burns from using these monitors.

**Benefits:** Your participation will help us to gain knowledge that may help preterm infants in the future. However, there is no direct benefit to you.

**Alternatives:** Your alternative is to not take part in the research.

**If you would like to participate in this research, please continue reading to learn more about this study's details.**

## STUDY DETAILS

**Why is this research being done?**

The purpose of this research is to investigate the relationship between EIT measurements and respiratory status parameters in very preterm infants. EIT is a non-invasive medical imaging technique that can help us understand lung function. We hope to gain a better understanding of the relationship between EIT measurements and other parameters of respiratory status, such as $CO_2$ levels measured from the skin and events with decreased oxygen levels.

**How many people will take part in this research?**

About 60 infants will take part here at UMass Chan Medical School.

**How long will my baby be in this research?**

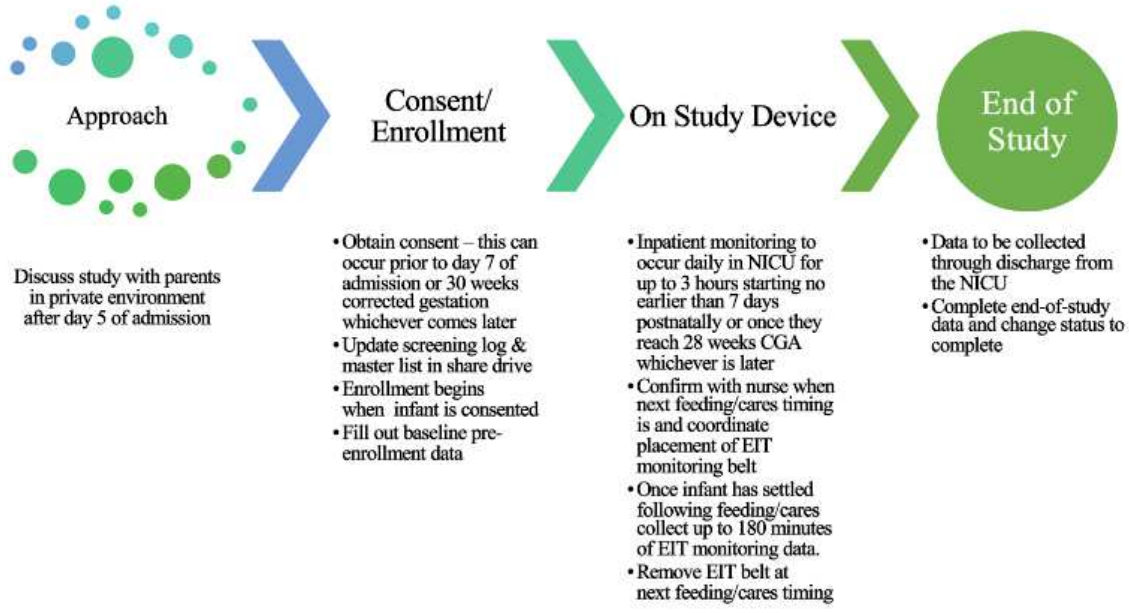
We expect that your infant will be enrolled from the time of consent through NICU discharge.

**What happens if I say yes, I want to be in this research?**

If you consent to this research, we will collect demographic and medical information from your baby's electronic medical record which includes demographic, respiratory, and feeding data. This information is stored securely in a computer database.

Up to once a day during your baby's NICU hospitalization, we will obtain daily EIT measurements while your baby is resting between feedings which should take two to three hours. This will be collected via a belt placed around your baby's chest that is connected to a monitor. We will also obtain TCM measurements, which are obtained by placing a small sticker on your baby's skin. These recordings will be done only for research purposes and the measurements will not impact your baby's care in the NICU.

A chart outlining the study organization is below:



**Could being in this research hurt me or my baby?**

*One of the risks of being in this study is a loss of your or your baby's personal information. This is very unlikely to happen, and we will take steps to protect your information.*

It is possible, but unlikely, that using the EIT belt could irritate your baby's skin or leave an imprint. This occurs in approximately 10% of babies. Additionally, the TCM sticker may irritate your baby's skin.

**Will it cost me any money to take part in this research?**

There will be no cost for the monitors used in this study. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for your baby's NICU hospitalization. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

**Will I be given any money or other compensation for being in this study?**

You will not be paid for taking part in this research.

**What happens if my baby is injured because I took part in this research?**

If your baby is injured while in this study, please notify his or her nurse or physician and he or she will be cared for by the NICU team as continuing care for their NICU admission. The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If your baby is injured due to participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

**What are my responsibilities if I and my baby take part in this research?**

There are no added responsibilities if you participate in this study.

**What happens if I say yes, but I change my mind later?**

*You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data we have used will stay in the study database and cannot be removed to maintain the integrity of the research.*

**Can my baby be removed from the research without my approval?**

The person in charge of this research study can remove you even if you want to continue. This may happen if it is in your baby's best interest or if the entire study is stopped.

We will tell you about any information that may affect your health, welfare, or choice to stay in this research.

**How will my baby's information be stored and when will it be destroyed?**

We will remove your baby's name and any other information that could directly identify your baby from his or her data. We will replace this information with a code number. We will create a key linking your baby's code number to your baby's name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data, including data files from the monitor and video recordings, on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the key to identifiers three years after the study closure.

We might use the research data in future research. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your or your baby's name or other information that identifies you or your baby directly, and we will not come back to you to ask you for your consent.

**Who has access to my and my baby's information?**

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your baby's name and date of birth
- Medical information like your baby's medications or medical conditions
- All procedures that will be done in the study

Your baby's health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- Federal and state government agencies, such as state auditors
- The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research

We will protect your and your baby's identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Your baby's medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your baby's original medical records for verification of clinical trial procedures and data. These individuals have been trained to protect confidentiality.

Any disclosure carries the potential for re-disclosure. Once your baby's protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you or your baby. However, information we have collected will stay in the study database and cannot be removed to maintain the integrity of the research. Your baby's information may still be used and disclosed if he or she has an adverse event.

You do not have to sign this authorization. If you choose not to sign, it will not affect your or your baby's treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. Your baby will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your baby's name and other identifying information confidential.

**Will you share any results with me?**

It may be several years before the results of the research are available. If you want us to try to reach you then, please tell us. We will ask for your contact information.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent reviews of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

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.

**Signature Block for Children**

Your signature documents your permission for the individual named below to take part in this research.

| | |
|---|---|
| Printed name of research participant | |
| Signature of child participant's parent, or individual authorized to consent to the child's general medical care | Date |
| Printed name of child participant's parent or individual authorized to consent to the child's general medical care | |
| Explain signer's relationship to, and authority to act on behalf of, the child | |

**Note on permission by guardians:** An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child's general medical care. Attach the documentation to the signed document.

| | |
|---|---|
| Signature of person obtaining consent | Date |