Study Title: A randomized controlled trial of respiratory function monitoring during stabilization of preterm infants at birth

Short Title: MONITOR Trial

NCT Number: NCT03256578

Document IRB Approval Date: February 14, 2019

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Monitor Trial (Monitoring Neonatal Resuscitation Trial)
Principal Investigator:	Dr. Elizabeth Foglia The Hospital of the University of Pennsylvania Ravdin Building, 8th Floor 3400 Spruce Street Philadelphia, PA 10104 215-662-3228
Emergency Contact:	Neonatology Attending on call for the Hospital of the University of Pennsylvania: 215-300-9475

Thank you for taking the time to read this when so much is happening to you. We know this is a difficult time for you. We would like to discuss a research study we are conducting to determine if a new monitor in the delivery room improves the care providers deliver to premature babies in the first few minutes after delivery.

Why am I being asked to volunteer?

You and your baby are invited to participate in a research study because we are interested in understanding whether a monitor placed in the delivery room improves the care our providers give to premature babies who need help breathing after they are born.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to determine if looking at a Respiratory Function Monitor (RFM) (defined below) helps providers give better support to premature babies who need help breathing after birth.

When babies are first born, their lungs are filled with fluid, and in order to clear the fluid they must quickly fill their lungs with air. While full term babies are often able to do this by crying after birth, most premature babies need help opening their lungs. As part of routine care for preterm babies after birth, the medical team gently places a mask attached to a small breathing device on your baby's mouth and nose. This breathing device delivers air mixed with oxygen and gives breaths to your baby so that the baby can start breathing on his/her own.

In the delivery room, we use standard monitors to look at your baby's heart rate and oxygen levels. Unfortunately, the monitors do not tell us about the breaths given to babies in their first few minutes of life. We do not know if the breaths being given are too small and not fully filling the lungs, or too large and possibly damaging the lungs.

To help us get this information, we will use another monitor to display information about the breaths the medical team provides to babies. This is called a Respiratory Function Monitor (RFM). As part of standard practice at the Hospital of the University of Pennsylvania we use the RFM to collect data in a 'masked mode' on all preterm babies. This means that the screen is black but the monitor records the information on baby's breaths. Using this monitor in 'visible mode' to deliver care is investigational, which means that viewing the monitor while the medical team provides care to help your baby breathe is experimental and not yet approved by the FDA.

A very small sensor is attached between the mask and breathing device and records information from each breath onto this RFM. The sensor attached to your baby's mask is FDA approved and is safe for preterm babies. While data will be recorded for all babies, in this study, some clinicians will be able to see the information on the RFM monitor screen and some will not. We would like to see whether clinicians directly looking at the information on the RFM monitor screen are better able to adjust how they give breaths and stabilize premature babies after birth.

How long will I be in the study?

The RFM monitor is only used for the first few minutes after the baby is born. There are no other research procedures in this study. The study team will continue to collect data about your baby's stay in the Neonatal Intensive Care Unit (NICU) until your baby is discharged. If your baby is transferred to CHOP before 36 weeks post-menstrual age, data from your baby's CHOP medical record will be collected.

How many participants are in the study?

There are 5 other NICUs that are participating in this study. Roughly 300 infants will be enrolled in this study across all NICUs. At the Hospital of the University of Pennsylvania (HUP), we plan to enroll 80 preterm infants.

What am I being asked to do?

If you agree to participate in the study, after your baby is born they will be randomized to one of two groups. Randomized means that their assignment into a group is up to chance; like the flip of a coin. Your baby will be placed in either:

1) **The 'RFM masked' group**, where the providers involved in the care of your baby will not see the information on the RFM screen; This is standard in our NICU, or,
2) **The 'RFM visible' group**, where the providers have access to all the information displayed on the screen.

There are no other changes to your baby's care after delivery.

Regardless of what group your baby is in, a sensor will be attached to the mask placed on your babies face and data on your baby's first breaths will be recorded. You are being asked to allow the research team to keep all the information that was recorded on the monitor, and to collect data from your baby's medical record until she/he is discharged.

We routinely use video to record resuscitation of preterm infants during the first minutes of life after a baby is born. These videos are not part of the medical record; however they are used for the clinicians to improve the quality of care we provide. You are also being asked for your permission to use the video of your baby in this research study to review the first few minutes of resuscitation.

What are the possible risks or discomforts?

During the resuscitation of an infant after birth, the standard of care does not involve looking at the information on the RFM screen. The purpose of this study is to determine whether looking at the information is helpful. Allowing the RFM screen to be visible by caregivers at the delivery is not expected to result in increased risk of harm, but this possibility also exists.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

This study may not directly benefit your baby, although one group of infants may receive improved respiratory support after birth. We do not yet know whether using the monitor will improve the way providers perform resuscitation for premature infants. We hope that knowledge gained from this study may improve the resuscitation process for premature babies in the future.

What other choices do I have if I do not participate?

Your other choice is not to participate in this study. You also can choose to be in this study, but not to give your permission for the use of video.
Your choice not to participate will not change the medical care your baby receives.

If you chose not to participate in this study, the RFM will still collect data on your baby, but the health care providers will not see the screen. Information will still be collected from your infant's medical record for quality improvement purposes.

Will I be paid for being in this study?

No, participants will not be paid for being in the study.

Will I have to pay for anything?

There is no charge to you or your baby for participating in the research. You and your baby's health insurance may be billed for the cost of routine medical care during this study if these expenses would have happened even if your baby were not in the study.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or Children's Hospital of Philadelphia to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

Your baby's participation in this study will end after the monitoring has been performed and we have collected all necessary data from your baby's medical record. This study may also be stopped at any time by your physician without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal from the study will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

HIPAA AUTHORIZATION SECTION

How will my personal information be protected?

This section gives more information about how your and your baby's personal health information may be used and disclosed by the University of Pennsylvania Health Systems (UPHS), the School of Medicine, Children's Hospital of Philadelphia, and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might be disclosed?

The following personal health information will be collected and used for research, and may be disclosed during your involvement with this research study:

• Name, date of birth, and medical record number

• Personal and family medical history

• Current and past medications or therapies

• Information from current or past examinations, tests, or procedures

• Video recording of the resuscitation following delivery. These videos are used to help interpret the data that is recorded on the RFM monitor.

Why is your information being used?

Your baby's personal health information and results of tests and procedures are being collected to conduct the research and ensure the research was done correctly. In some situations your baby's personal health information might be used to help guide his/her medical treatment.

Which of our personnel may use or disclose your and your baby's personal health information?

• The Principal Investigator

• A member of the Institutional Review Board (IRB) or ethics committee that has approved the study

• Researchers working on this study from the Hospital of the University of the Pennsylvania

Who outside of UPHS and the School of Medicine might receive your or your baby's personal health information?

As part of the study the Principal Investigator, the study team and others listed above, may disclose your baby's personal health information. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- The Principal Investigator, Dr. Elizabeth Foglia, and the investigator's study team
- Authorized members of the workforce of the UPHS, the School of Medicine, Children's Hospital of Philadelphia (CHOP), and CHOP and University of Pennsylvania support offices, who may need to access you and your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).
- Leiden University Medical Center, the Data Coordinating Center and a member of the research team at the Department of Medical Statistics; Leiden University will have access to the collected data, including video recordings, but will not have access to your infant's name or medical record number.

Regulatory and safety oversight organizations:

• The Office of Human Research Protections

• Study Data and Safety Monitoring Committee

Once personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are

any additions to the list above during your baby's active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS, CHOP, and the School of Medicine be able to use or disclose your or your baby's personal health information?

Your authorization of use of your baby's personal health information for this specific study does not expire. Your baby's information may be held in a research database indefinitely. However UPHS, CHOP, and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

• You have given written authorization to do so

• The University of Pennsylvania's Institutional Review Board grant permission after ensuring that appropriate privacy safeguards are in place

• As permitted by law

• If you authorize the use of the video recording for this study, the video will be securely transferred to the collaborating study team at Leiden University Medical Center. Once the RFM files are analyzed, the video recording will be destroyed.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) or Children's Hospital of Philadelphia and are participating in a University of Pennsylvania/CHOP research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS or CHOP.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in

the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614. If you are a CHOP patient and have questions about your rights or if you have a complaint, you can call the CHOP Office of Research Compliance and Regulatory Affairs at 215-590-2830.

When you sign this form, you are agreeing to allow yourself and your child to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have agreed to allow you and your baby to be enrolled. Your signature also means that you are permitting the University of Pennsylvania and CHOP to use your child's personal health information and your maternal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania and CHOP to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____ (initials) I agree to the use of video recording for this research study

_____
Name of Subject (Please Print)

_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

_____	_____	
Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person authority to serve as the subject's authorized representative.