Cover Page

NCT04269161

NICU Oxygen Control Study

Consent 1

Nov 08, 2023

PARENTAL CONSENT FORM AND HIPAA AUTHORIZATION FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY

INVESTIGATOR'S NAME: JOHN PARDALOS MD
PROJECT IRB #: 2003117

STUDY TITLE: NICU OXYGEN CONTROL STUDY

We ask your permission to allow your baby to take part in this research study. This consent form tells you why we are doing the study, what will happen if your baby joins the study, and other important information about the study.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or baby's doctor. If there is anything you do not understand, please ask us to explain. Then you can decide if you want your baby to take part in the study or not.

The Principal Investigator (also called the study doctor) is John Pardalos. The people working with him on this study are called the study team.

The National Institute of Child Health and Human Development (called the sponsor in this form) is paying for this study.

This research study involves intellectual property owned by the University of Missouri. Members of the study team have obtained rights to this intellectual property with the goal of marketing a medical device in the future. Members of the study team are the inventors of the patented technology used in this study.

WHAT SHOULD I KNOW BEFORE ALLOWING MY BABY TO TAKE PART IN THIS STUDY?

- Research studies help us to learn new things and test new ideas about treating certain conditions/diseases.

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- Taking part in a research study is voluntary. You decide if you want your baby to take part, and you can stop taking part at any time. Your baby's regular medical care at the University of Missouri Hospitals and Clinics will not be affected now or in the future if you decide that you do not want your baby to be in this study.

- This research is being conducted to see if we can better control oxygen saturation levels in premature babies using an automated system. Babies born less than or equal to 30 weeks gestational age or less than or equal to 1500 grams are at risk for developing long-term complications if they receive too much oxygen or not enough oxygen. Therefor all babies in the NICU that require oxygen are placed on a pulse oximeter that continuously measures the baby's oxygen saturation level. Our goal is to keep the oxygen saturation level in these babies in the 80's to low 90's range until the risk of retinopathy of prematurity diminishes and then it is increased to the term infant parameters. Preterm babies with respiratory distress may require respiratory support from a variety of FDA approved devices ranging from a variety of ventilators to a variety of non-invasive (nasal) devices. One of these non-invasive devices is called a high flow nasal cannula. This device provides flow of air to the baby through a cannula attached to the baby's nose. Another non-invasive device is called bubble CPAP. In this case a flexi-trunk interface is attached to the patient using nasal prongs alternated with a face mask every 3-4 hours to prevent skin breakdown. With this device, the flow of air is passed through a column of water which provides a pressure of air in the baby's lungs. The bubbling of the air through the water also provides a gentle vibration to the air entering the baby's lungs which may help the baby breathe easier. With either device the air is warmed and humidified to be gentler to the baby's lungs. Both of these devices also have an oxygen/air mixing valve attached to them so that the percent oxygen in the air can be adjusted from 21% (or room air) to 100% oxygen depending on the needs of the baby to keep his/her oxygen saturation level in the desired range. Currently adjustments made to the percent oxygen require a healthcare provider to manually turn the knob on the oxygen/air mixing valve in order to increase or decrease the percent oxygen being delivered to the baby to keep the baby's oxygen saturation level in the desired range. We took these same devices and attached a computer that can receive information about the baby's oxygen saturation level from the pulse oximeter and can automatically turn the knob on the oxygen/air mixing valve in order to adjust the oxygen level being delivered

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to the baby to keep the oxygen saturation level in the desired range. The computer will only increase or decrease the oxygen concentration by up to 2% every 10 seconds as long as the oxygen saturation reading is considered reliable (the heart from the cardiac monitor and the pulse oximeter have to agree within 5 beats per min).

- With this study, we will compare how well the computer adjusts the oxygen concentration to keep the baby in the desired range compared to the healthcare providers that must manually adjust the knob whenever the baby's oxygen saturation level falls out of range. We will determine if the automated system kept the baby in the desired range more often than the manual mode that depends on the healthcare providers to make the adjustments. Our goal in the future is to use this automated system to keep our babies in the desired range for longer periods of time to prevent long-term complications from occurring in our patients. This device is currently considered investigational and has not been reviewed by the FDA for approval.

- Your baby has been invited to be in this study because your baby has been admitted to the Neonatal Intensive Care Unit (NICU) and currently has respiratory distress. Your baby's healthcare provider has chosen to place your baby on a high flow nasal cannula device or bubble CPAP as the form of respiratory support to help your baby breathe easier. If you choose to allow your baby to be enrolled in this study, we will place your baby on our investigational oxygen/air mixing valve which is identical to the regular set up except for the computer attachment that allows the computer to automatically adjust the oxygen concentration in the air by turning the knob on the oxygen/air mixing valve. Your baby will not need to have the interface changed on his/her face since the device is exactly the same as the one, he/she is currently using except for the oxygen/air mixing valve. We will place the baby on the device for up to 6 days. Every 6 hours (+/- 1 hour) we will switch your baby between the manual and the automatic modes on the device except at 48 and at 96 hours where it will be kept on the same mode for at 12- hour period in order to switch the time of day the infant is on automatic mode so it not always the same time of day for the full 6 days. When the device is in the manual mode, the healthcare providers will have to adjust the oxygen concentration manually by turning the knob on the oxygen/air mixing valve like they currently do with the regular device we use every day in the NICU. When the device is placed in the automatic mode, the computer will make the adjustments to keep the baby's oxygen saturation level in the

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desired range. The computer will only increase or decrease the oxygen concentration by up to 2% every 10 seconds as long as the oxygen saturation reading is considered reliable (the heart from the cardiac monitor and the pulse oximeter have to agree within 5 beats per min). If the oxygen concentration is increased or decreased by 10% from the baseline oxygen need, an alarm will sound so the nurse will be notified so she can evaluate the infant to determine if adjustments need to be made to the mask/prongs or to the support provided by the device.

- A member of the research team will be at your baby's bedside to make sure it is operating properly for the first 12 hours and then daily for 1 hour to make sure everything is functioning appropriately. They will also be available by phone for the entire time your infant is on the device. The research team members will not be allowed to adjust the oxygen concentration. Once the study is complete, we will determine if the computer was able to keep your baby in the desired saturation range more often than the healthcare providers during the manual mode. We will also download the vital signs and pulse oximeter data from the monitor system for up to 24 hours prior to the study to see how well the healthcare providers kept the baby in the desired range during that time period as well. We will also keep track of the frequency of any acute events (apnea, bradycardia and/or desaturation events) that occur during this study to see if the frequency of these acute events decrease if we keep the infant's oxygen saturation level in the prescribed range longer. Members of the study team will collect the medical history of the baby which includes the mother's pregnancy history by looking at the baby's medical records.

- Our goal is to enroll 60 babies nationally who were less than or equal to 30 weeks gestational age or less than or equal to 1500 grams at birth who were admitted to a Neonatal Intensive Care Unit (NICU) who are currently requiring a high flow nasal cannula or bubble CPAP to treat their respiratory distress. About 30 babies will take part in this study at the University of Missouri.

- We think your baby will be in the study for 6 days. The investigator and/or your baby's doctor may decide to take your baby off this study if your baby needs more respiratory support than can be provided by the high flow nasal cannula or the bubble CPAP device

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or if the patient is deemed well enough that he/she no longer requires the respiratory support.

- Taking part in this study may or may not make your baby's health better. Our pilot study of 6 patients demonstrated that when the device was in the automatic mode, the patient spent more time within the prescribed oxygen saturation goals and that it took less time for them to return to the prescribed oxygen saturation range whenever they were outside of the range. Even though this wasn't considered statistically significant, we felt that this was due to the fact the infants were only on the device for 12 hours (two 3-hour periods of automatic control and two 3-hour periods of manual control). This pilot study did show a significant decrease in the number of bradycardia events while the infants where in the automatic mode. With our current study, the patients will be on the device for 6 days so a total of 72 hours of automatic control and 72 hours of manual control, so we are hoping to find statistical significance in all our study metrics.

  There is no guarantee that taking part in this research will result in any improvement in your baby's condition. Your baby will be treated per our current standard of care. We hope that the information we learn from this study will help in the treatment of future preterm babies by increasing the amount of time their saturation level remains in the desired range whereby decreasing the risk they may develop long-term complications from having too much or not enough oxygen in their blood.

- As with any research study, there are risks that we know about and there may be some we don't know about. The study high flow nasal cannula and bubble CPAP devices are the same exact set ups we currently use in the NICU except that there is a computer attached to the oxygen/air mixing valve that can automatically adjust the percentage of oxygen in the air being delivered to the patient. Since this device may malfunction by making an inappropriate adjustment to the percentage of oxygen, a member of the study team will be present for the first 12 hours that one of these devices is attached to your baby to make sure it is functioning properly and then for 1 hour daily to recheck the device. The devices have a switch that the nurse can use to immediately switch the device back to manual mode at anytime and take over control of the percent of oxygen being delivered to your baby should the need arise.

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- For the safety of every patient in the NICU, we have several systems to monitor our patients. First every patient in the NICU is continuously monitored for their heart rate and respiratory rate. In addition, those babies requiring respiratory support of any type are kept on a pulse oximeter that continuously monitors the patient's saturation levels. If these vital signs fall out of the prescribed range, the monitor starts to alarm. At the beginning of each shift the nurses make sure the alarms of each of their patients ring on all their babies' monitors through a system known as alarm watch. Additionally, throughout the NICU, monitors are present so healthcare providers can monitor these vital signs in key locations throughout the unit. Furthermore the heart rate and respiratory alarms ring directly to the nurse's special secure cellular phone used in the hospital that also functions as an alarm monitor so no matter where the nurse may be located in the NICU she/he can hear these alarms.

- Data gathered will be stored in a secure way to prevent breaches in confidentiality and privacy. Electronic data will be stored in a password protected encrypted storage medium with access limited to specified users that are a part of the study. The data will be overseen by the study investigators. Data in non-electronic hard copy form will be stored in the locked offices of the investigators.

- We will only include your baby in this study if you give us your permission first by signing this consent form.

WHY ARE THE RESEARCHERS DOING THIS STUDY?

The study devices are experimental (being tested) and have not yet been approved by the U.S. Food and Drug Administration (FDA).

We are testing the study devices to see if it can maintain your baby's oxygen saturation level in the desired range more often than the bedside healthcare providers. This should improve the outcomes of preterm infants by decreasing the amount of time the baby has too much or not enough oxygen in his/her system. We don't know if this study will help your baby. Your baby's condition may get better, but it could stay the same or even get worse. We hope the information

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we learn from this study will help us to develop a device that can better keep a baby's oxygen saturation level within the desired range in the future.

WHAT WILL HAPPEN IF MY BABY TAKES PART IN THIS STUDY?

Your baby's healthcare provider has chosen to place your baby on a high flow nasal cannula or bubble CPAP device as the form of respiratory support to help your baby breathe easier. If you choose to allow your baby to be enrolled in this study, we will place your baby on our investigational high flow nasal cannula or bubble CPAP device which is identical to the regular set up except for the computer attachment that allows the computer to automatically adjust the oxygen concentration in the air by turning the knob on the oxygen/air mixing valve. Your baby will not need to have the nasal cannula changed on his/her face since the devices are exactly the same as the ones they are currently on. We will place the baby on the device for up to 6 days. Every 6 hours (+/- 1 hour) we will switch your baby between the manual and the automatic modes on the device except at 48 and at 96 hours where it will be kept on the same mode for at 12- hour period in order to switch the time of day the infant is on automatic mode so it not always the same time of day for the full 6 days. When the device is in the manual mode, the healthcare providers will have to adjust the oxygen concentration manually by turning the knob on the oxygen/air mixing valve like they currently do with the regular device we use every day in the NICU. When the device is placed in the automatic mode, the computer will make the adjustments to keep the baby's oxygen saturation level in the desired range.

Medical Chart Review: The study doctors will review your baby's medical chart which includes mom's pregnancy history.

A laptop will be used to download all the data from the cardiac-apnea monitor and the pulse oximeter so we can analyze the data.

We will keep the data we collect from your baby during this study to use in future research without asking for your or your baby's consent again. Information that could identify your baby will be removed from their research data so no one will know that it belongs to them.

HOW LONG WILL MY BABY BE IN THE STUDY?

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Your baby will be in this study for about 6 days. The investigator and/or your baby's doctor may decide to take your baby off this study device if your baby needs more respiratory support than can be provided by the high flow nasal cannula or bubble CPAP devices or if the patient is deemed well enough that he/she no longer requires the respiratory support.

CAN MY BABY STOP BEING IN THE STUDY?

Your baby can stop being in the study at any time without giving a reason. If your baby stops being in the study, their regular medical care will not change. Leaving the study will not affect your or your baby's future medical care at the University of Missouri.

There is no penalty to you or your baby if they do not join the study or if they leave it early. You and your baby will not lose any benefits that you and they are entitled to if they leave the study.

If you decide to stop your baby's participation in the study, you should discuss your decision with the study doctor.

The study doctor and/or the baby's healthcare team may decide to take your baby off this study device at any time, even if you want to stay in the study. The study doctor and/or the baby's healthcare team will tell you the reason why your baby needs to stop being in the study. These reasons may be:

- Your baby requires more respiratory support than can be provided by the high flow nasal cannula or bubble CPAP devices.
- Your baby has improved and no longer requires respiratory support using the high flow nasal cannula or bubble CPAP devices.
- The whole study is stopped.
- New information becomes available about the study devices.

WHAT HEALTH RISKS OR PROBLEMS CAN MY BABY EXPECT FROM THE STUDY?

- There are risks to taking part in any research study. The study high flow nasal cannula and bubble CPAP devices are the same exact set ups we currently use in the NICU except that there is a computer attached to the devices that can automatically adjust the percentage of oxygen in the air being delivered to the patient. Since these devices may

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malfunction by making an inappropriate adjustment to the percentage of oxygen, a member of the study team will be present for the first 12 hours that this device is attached to your baby to make sure it is functioning properly and then for 1 hour daily to recheck the device. Each of the devices have a switch that the nurse can use to immediately switch the device back to manual mode at anytime and take over control of the percent of oxygen being delivered to your baby should the need arise.

For the safety of every patient in the NICU, we have several systems to monitor our patients. First every patient in the NICU is continuously monitored for their heart rate and respiratory rate. In addition, those babies requiring respiratory support of any type are kept on a pulse oximeter that continuously monitors the patient's saturation levels. If these vital signs fall out of the prescribed range, the monitor starts to alarm. At the beginning of each shift the nurses make sure the alarms of each of their patients ring on all their babies' monitors through a system known as alarm watch. Additionally, throughout the NICU, monitors are present so healthcare providers can monitor these vital signs in key locations throughout the unit. Furthermore, the heart rate and respiratory alarms ring directly to the nurse's special secure cellular phone used in the hospital that also functions as an alarm monitor so no matter where the nurse may be located in the NICU she can hear these alarms.

Data gathered will be stored in a secure way to prevent breaches in confidentiality and privacy. Electronic data will be stored in a password protected encrypted storage medium with access limited to specified users that are a part of the study. The data will be overseen by the study investigators. Data in non-electronic hard copy form will be stored in the locked offices of the investigators.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Our pilot study of 6 patients demonstrated that when the device was in the automatic mode, the patient spent more time within the prescribed oxygen saturation goals and that it took less time for them to return to the prescribed oxygen saturation range whenever they were outside of the range. Even though this wasn't considered statistically significant, we felt that this was due to the fact the infants were only on the device for 12 hours (two 3-hour periods of automatic control and two 3-hour periods of manual control). This pilot study did show a significant decrease in

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the number of bradycardia events while the infants where in the automatic mode. With our current study, the patients will be on the device for 6 days so a total of 72 hours of automatic control and 72 hours of manual control, so we are hoping to find statistical significance in all our study metrics.

Your baby will be treated per our current procedure. By allowing your baby to participate in this study, it may help future preterm babies by increasing the amount of time their saturation level remains in the desired range whereby decreasing the risk they may develop long-term complications from having too much or not enough oxygen in their blood

WHAT OTHER CHOICES DOES MY BABY HAVE?

Your baby does not have to take part in this study. You are free to say yes or no. If you do not want your baby to join this study, your doctor will discuss other choices with you.

Your child's other choices include:

- Not joining this study and continuing your baby's regular medical care

WHAT ABOUT PRIVACY AND CONFIDENTIALITY?

The study team needs to collect some of your baby's health/personal information. This information comes from your baby's medical record which includes mom's pregnancy history. One risk of taking part in a research study is that more people will handle your baby's personal health information. We are committed to respecting your baby's privacy and to keeping their personal information confidential. The study team will make every effort to protect your baby's information and keep it confidential to the extent allowed by law. However, it is possible that an unauthorized person will see it.

State and federal privacy laws (HIPAA) protect the use and release of private health information. If your baby takes part in this study, you also give us your permission to use their private health information, including the health information in their medical records and information that can identify them.

You have the right to refuse to give us your permission for us to use your baby's health information. However, doing so would mean that your baby could not take part in this study.

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The following identifiers will be obtained from your baby's health records:

- ☒ Name
- ☒ Dates related to your child
- ☐ Fax Number
- ☐ Social Security Number
- ☐ Health Plan Beneficiary Number
- ☐ Certificate or License Numbers
- ☐ Web Address (URL)
- ☐ Biometric Identifiers (finger/voice print)
- ☐ Any other characteristic that could identify you
- ☐ Address
- ☐ Telephone number(s)
- ☐ Email Address
- ☒ Medical Record Number
- ☐ Account Numbers
- ☐ Any vehicle or device serial number
- ☐ Internet Protocol (IP) Address(es)
- ☐ Photographic images

The following is the type of protected health information that will be used in the study:

- ☐ Radiology Images
- ☒ Radiology Reports
- ☐ EKG Recordings/Reports
- ☒ Progress Notes
- ☒ History and Physical Exams
- ☒ Operative Reports
- ☐ Pathology Reports
- ☒ Laboratory Reports
- ☐ Photographs/Video Recordings
- ☒ Discharge Summaries
- ☐ Health Care Billing or Financial Records
- ☒ Consultations
- ☐ Medications
- ☐ Emergency Medicine Reports
- ☐ Dental Records
- ☒ Demographics (age, race, etc.)
- ☐ Questionnaires, Surveys, Diaries
- ☐ Audio Recordings
- ☐ Social Security Number (This is only collected for billing/payment purposes and will not be shared with the study sponsor)
- ☐ Other:

Certain sensitive information about your baby can only be released if you give your specific permission. This includes information such alcohol or drug abuse, HIV/AIDS testing, and mental health records. We will ask you to indicate your permission to release this information at the end of this consent form. This is your specific permission for release of this information. Federal rules do not allow any use of the information to criminally investigate or prosecute any alcohol or drug abuse.

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- National Institute of Child Health and Human Development who is sponsoring the study, and their contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your child's name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

The people who get your child's health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your child's information with others without your separate permission.

Your permission for us to use and/or release your child's information will not expire unless you cancel your permission.

You can cancel your permission at any time by writing to:
Investigator's Name: John Pardalos MD
Institution: Women's and Children's Hospital
Department: Child Health
Address: 404 Keene St.
Columbia, MO 65201
The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You have the right to access your baby's protected health information that is obtained or created during this research project until the end of the study.

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If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about privacy rights, you may contact the Privacy Officer at 573-882-9054.

Information that does not become part of your baby's medical record will be stored in the investigator's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

Your baby's records will be given a code number and will not contain their name or other information that could identify them. The code number that connects your baby's name to their information will be kept in a separate, secure location. Information that may identify your baby may not be given to anyone who is not working on this study without your written consent, or if required by law.

The people who may use and/or release your child's research information include:

- Those working on the study team at the University of Missouri or at the Studer Family Children's Hospital at Sacred Heart in Pensacola, Florida.
- The study sponsor, National Institute of Child Health and Human Development.
- The members of the University of Missouri Institutional Review Board (IRB)
- Those who check on research activities to make sure it is being done correctly and safely
- The FDA
- Other government or inspection agencies

If the study investigator is not your baby's regular doctor, he/she must ask your permission before contacting their regular doctor for their health history.

We may present the results of this study in public talks or written articles, but we will not use information that can identify your baby.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you or your baby in any federal, state, or local civil, criminal,

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administrative, legislative, or other action, suit, or proceeding, or be used as evidence (for example, if there is a court subpoena) unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your child's medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the University of Missouri or the National Institute of Child Health and Human Development which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you and your child from voluntarily releasing information about your child or their involvement in this research. If you want your child's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

ARE THERE CONFLICTS OF INTERESTS?

Investigators in this study, Dr. Ramak Amjad and Dr. Roger Fales each have a financial interest in a company called Intelligent Respiratory Devices, LLC (IRD). Intelligent Respiratory Devices, LLC has licensed this intellectual property (IP) from MU. The IP relates to the device being used in this study. Dr. John Pardalos has no conflict of interest for this study.

ARE THERE ANY COSTS TO BEING IN THE STUDY?

There is no cost to you if your baby takes part in this study. All tests and procedures done during this study are routine care for your baby. Your baby would receive these tests and procedures even if they weren't in this study. You and/or your baby's health plan/insurance will be billed for all the tests and procedures in this study.

WILL I OR MY BABY BE PAID FOR TAKING PART IN THIS STUDY?

There is no payment to you or your baby for taking part in this study.

WHAT HAPPENS IF MY BABY IS INJURED DURING THE STUDY?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff.
The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event your baby has suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information.
This statement is not to be construed as an admission of liability.

WHAT ARE MY BABY'S RIGHTS AS A STUDY PARTICIPANT?

Taking part in this study is voluntary. Your baby does not have to take part. Your and your baby's present or future medical care will not be affected if your baby does not take part.

If your baby does take part, you and they can change your mind and drop out of the study at any time. This will not affect your or your baby's current or future care at the University of Missouri Hospitals and Clinics. There is no penalty for leaving the study and you and your baby will not lose any benefits that you or they are entitled to receive.

If the study investigator decides to take your baby off the study, he/she will explain the reasons and help arrange for your baby's continued care by their own doctor, if needed.

We will tell you about any new information discovered during this study that might affect your baby's health, welfare, or change your/your baby's mind about taking part.

WHERE CAN I GET MORE INFORMATION ABOUT THIS STUDY?

[Type here]

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

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have more questions about this study at any time, you can call Dr. Pardalos at 573-499-6180.

You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your baby's rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to have your baby take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573- 882-3181 and their email address is muresearchirb@missouri.edu.

If you want to talk privately about your baby's rights or any issues related to their participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you to remember what we discussed today.

SIGNATURE OF PARENT/LEGAL GUARDIAN

My initials below indicate my permission to release the sensitive information about my baby listed below:

____I agree to the release of information about drug and alcohol abuse, diagnosis or treatment.

____I agree to the release of HIV/AIDS testing information.

____I agree to the release of sexually transmitted disease testing and treatment.

____I agree to the release of mental health diagnosis or treatment.

____I agree to the release of genetic testing information.

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Consent to Participate in Research

By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to allow my baby to take part in this research study. I have been told that my baby can stop taking part at any time.

Parent/Guardian's Signature	**Relationship to Child**	**Date**

Parent/Guardian's Signature	**Relationship to Child**	**Date**

Signature of Witness (if applicable)*	**Date**

**A witness is required when a participant is competent to provide consent but is blind, or cannot read or write.*

SIGNATURE OF PERSON AUTHORIZED TO OBTAIN CONSENT*

I have explained the purpose of the research, the study procedures (identifying those that are investigational), the possible risks and discomforts and potential benefits of the study, and have answered questions regarding the study to the best of my ability.

Signature of Person Authorized to Obtain Consent	**Date**

IRB Approval Date: Nov 08, 2023; Parental Consent with HIPAA Authorization ID #668062; Annual Update ID #398183