Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Pediatric Acute Respiratory Distress Syndrome (ARDS) Management (PARMA) Trial

Version Date: August 26, 2024

Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Pediatric Acute Respiratory Distress Syndrome (ARDS) Management (PARMA) Trial

Version Date: August 26, 2024

Principal Investigator: Nadir Yehya Telephone: (215) 590-5907

Emergency Contact: Nadir Yehya Telephone: (925) 413-6501

Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You are being asked to take part in this research study because you have a breathing tube (or tracheostomy) and a condition of severe respiratory failure called acute respiratory distress syndrome (ARDS). ARDS is commonly treated in our PICU, but some aspects of how we manage the ventilator are not well understood.

The purpose of this study is to find out if higher or lower ventilator pressures are better and safer at getting oxygen into your child's body. We think that higher pressures may be better; however, higher pressures can also potentially be riskier. Lower pressures may be less good at getting oxygen into your child, but may be safer. Both pressure protocols being tested are commonly used in children with ARDS at CHOP and across the country, but the only way to tell if one strategy is better is to compare them directly.

If you agree to take part, your participation will last until your child leaves this hospital, but no longer than 90 days. Your team will adjust ventilator settings according to their assigned protocol while the breathing tube is in place, and we will collect data for up to 90 days. There are differences between this study and your usual care. As a participant in the research, you will:

- Receive a study ventilator protocol, with specific instructions for ventilator settings, that will be managed by the clinical team and the research team together
- Receive daily monitoring of clinical data by the research team

The main risks of this study are from the study ventilator protocols, either high or low pressure. These include: pneumothorax (air in chest) requiring chest tube; other air leak (air under skin or in chest) not requiring chest tubes; new pneumonia (new lung infection); new or worsening organ failures (problems with liver, kidney, or heart). It is important to note that children with ARDS sometimes get these problems even when they are not on a study like this one.

You may benefit directly from this study if one of the two ventilator protocols speed up how well oxygen is delivered to your child, as this will shorten their time on the ventilator. Additionally, you may benefit from being in the study because the study provides a specific protocol for how to manage the ventilator, so that everyone involved in your care knows exactly how to adjust the ventilator.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study. Please see below for additional details about the study.

How many people will take part?

We anticipate that 180 children will be enrolled, and about 160 children will take part in this study, all from CHOP.

What is the current standard of treatment for this disease?

For most children with ARDS, the treating team will provide mechanical ventilation loosely based on adult guidelines for suggested pressures. At CHOP, we have found that clinicians prescribe pressures and other ventilator settings across a broad range. However, we do not know whether some pressures (such as on the higher end) are better at getting children off the ventilator.

What is involved in the study?

A computer will assign your child to a specific ventilator protocol (with higher or lower pressures). We will not know before-hand which protocol will be assigned. After being assigned the protocol, the research team works with the clinical team to ensure that the protocol is carried out safely. Clinical and laboratory data that are collected in the electronic medical record will be recorded by the research team.

What are the study procedures?

Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal. The study involves the following tests and procedures.

Experimental Procedures:

Randomization: A computer will assign you to a specific ventilator protocol (with either higher or lower pressures) randomly, based on chance like the flip of a coin. You have an equal chance of being in either group. We will not know before-hand which protocol will be assigned.

Study Intervention: After being assigned to a specific ventilator protocol, ventilator changes will be made according to the protocol. The research team and clinical team will work together to manage the ventilator and collect data.

Electrical Impedance Tomography (EIT): You will have a band placed across your chest to non-invasively measure how the lung is opening and closing. This measurement will be made when we start the ventilator protocol and again 1 to 3

days later. There are minimal risks associated with placing the belt, and the device does not use radiation.

Routine Clinical Trial Procedures:

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with randomization:

We are testing if one set of ventilator pressures is better at getting oxygen into your body. Both pressure protocols use pressures commonly used in managing children on ventilators. However, usually the clinical team is able to adjust the pressures according to what your body needs. When we assign one type of ventilator protocol, we may lose some of the advantages of the team adjusting the ventilator specifically for you, such as adjusting the pressures specifically to what the team thinks your lung needs at that moment. However, the type of ventilator protocol assigned will provide a consistent approach to ventilation. A consistent approach to ventilation may be an advantage, since it means that everyone caring for you manages the ventilator with the same approach. The ventilator protocol still allows adjustments to be made within the range of usual ventilator settings used by our PICU, and so the team can still somewhat adjust your ventilator according to what you may need.

Risks associated with study intervention:

The main risks of this study are from the study ventilator protocols, either high or low pressure. For the higher pressure protocol, these risks include:

- pneumothorax (air in chest) requiring chest tube;
- other air leak (air under skin or in chest) not requiring chest tubes; or
- new or worsening organ failures (problems with liver, kidney, or heart).

For the lower pressure protocol, risks include:

- more acid building up in the body,
- more need for blood pressure medications.

These types of risks are expected to occur at a frequency of less than 1 in every 20 subjects. It is important to note that children with ARDS can get these problems even when they are not on a study like this one. The study team has made sure that the ventilator settings used are within the ranges used by CHOP and other hospitals that manage ARDS in an effort to minimize the risks associated with the study.

Risks associated with EIT:

There are minimal risks associated with placing the EIT band across the chest for measurements. These risks are primarily related to discomfort, and the bands can be adjusted so they are more comfortable. In some children, the bands cannot be placed in the correct position to get good EIT images, which is also a potential risk.

Risks associated with breach of confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on electronic data collection forms and in the database instead of names and other private information. A separate list will be maintained that links each participant's name to the study identification number for future reference and communication.

Are there any benefits to taking part in this study?

You might benefit by being in this study if one of the two ventilator protocols speed up how well oxygen is delivered to your lungs, as this might shorten your time on the ventilator. In addition, you might benefit from having a specific ventilation protocol. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors determine how to best set the ventilator for all children with ARDS.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your health care provider at CHOP will continue to provide you with health care services even if you refuse to sign this form.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason. There is no new or additional risk to you for stopping early.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- Your condition worsens and you need to change ventilator types.

- The study is stopped.
- New information suggests taking part in the study may not be in your best interests.
- The investigator can withdraw your child without your approval. If at any time the investigator believes participating in this study is not the best choice of care, the study may be stopped and other care prescribed. If unexpected medical problems come up, the investigator may decide to stop your participation in the study.

What choices do you have other than this study?

There are options for you if you choose not to participate in this study. You will continue to receive the standard of care for ARDS, including all options for mechanical ventilation deemed appropriate by your clinical team. Participation in the study is entirely voluntary, and you do not need to take part in order to receive care. You may be a candidate for other studies taking place at CHOP and in the PICU.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and tests. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data. These groups include:

- Members of the research team and other authorized staff at CHOP
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health who is sponsoring this research;
- An independent Data Safety and Monitoring Board appointed by the National Institutes of Health that is monitoring the safety of this study

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your

information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for:

- other scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Nadir Yehya
The Children's Hospital of Philadelphia, 9NW39
Department of Anesthesiology and Critical Care
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

The NIH is providing financial support and material for all experimental procedures, as listed above, for this study.

Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. Yehya if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctor, Dr. Yehya at 215-590-5907. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://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 website at any time.

What happens if you are injured during the study?

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. Yehya at (215)-590-5907. They can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

What will be done with my data when this study is over?

We will use and may share data for future research. Information that can identify you may be kept permanently in a computer database at CHOP. Your data may be shared with researchers/institutions at, or outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing your data for future research. We will remove identifiers from them before sharing them with others. This means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data. Some of this may not be possible if your data have already been shared.

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The NIH repository stores data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual. Importantly, there is no genetic information collected as part of this study.

The NIH intends to share the collected de-identified information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Controlled Access

The data about you will be made available by the NIH through controlled access. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project.

Optional Consent for Use of Identifiable Data for Future Research

As part of the study, we will collect clinical and ventilator data . We may wish to use and share this information in a future study about ventilator management in ARDS.

The information will be given a unique code and may include information that can identify you. Information that can identify you may be kept permanently in a computer database at CHOP.

Future research could occur at CHOP, or at outside institutions, which could include for profit companies.

- Your identifiable data may be shared with other researchers at CHOP. They will use it for future research. When shared outside of CHOP, no identifiers will be included.

We may not ask for your consent before using or sharing your identifiable data. You will not receive any results or financial benefit from the future research done on your data.

If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data. This may not be possible if your data have already been shared.

Please indicate whether you will allow the identifiable data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable data may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable data may be used for other future research studies.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Study Summary Signature Pages

For Subjects with Non-English Preferred Language

Consent to Take Part in this Research Study and Authorization to Disclose Health Information

Name of Subject

Name of Authorized Representative (if different than subject)

Relation to subject:
☐ Parent ☐ Legal Guardian

The research study and consent form have been explained to the subject or parent/legal guardian/legally authorized representative.

By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child's participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date:

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date: