Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: **Linking Endotypes and Outcomes in Pediatric Acute Respiratory Distress Syndrome (LEOPARDS)**

Version Date: January 28, 2020

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

You, or 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.

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.

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 are admitted to the Pediatric Intensive Care Unit (PICU) and have been diagnosed as having Acute Respiratory Distress Syndrome (ARDS) and have a breathing tube to help you breath.

The purpose of the research is to determine if certain markers in your blood can tell how severe your ARDS is. We want to measure these markers to see if it is possible to predict how severe ARDS is in future patients. We think these blood markers will give more information about ARDS than laboratory tests and x-rays currently do. About 500 children will take part in this study over multiple PICUs, including 150 from CHOP.

If you agree to take part in the study, participation will only last as long as you are in the PICU. The only difference from usual care is

- a single blood sample taken from a blood drawing line already in place

The main risks of this study are a minor risk of infection with the blood draw and the potential for loss of confidentiality. All efforts will be made to minimize these risks.

You will not directly benefit from this study.

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.

What are the study procedures?

Some of the procedures in this study will be repeated several times. 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.

Medical Record Review: Information from your medical record will be recorded and used for this study. This information will include medical history, information about your condition, lab results, medications, treatments, vital signs, and responses to treatments. We may review your medical record up to 90 days.

Blood Test: We will take a sample of a little more than one teaspoon from a blood drawing line that is already in place. We will need to take the sample within 24 hours of becoming eligible for this study. Blood draws will only occur if a blood-drawing line is available and will be coordinated with routine other blood draws when possible.

Visit Schedule

There are no extra visits required. We will only collect data while you are in the PICU.

What will be done with my data and specimens during this study?

During the study, we will collect blood samples from you. By agreeing to participate in the study, you agree to give these samples to CHOP for research purposes.

The study involves looking at gene expression. This is the process the cell uses to read the genetic code. We will not perform genome-wide sequencing.

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. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

Risks associated with blood draws:

There is a small risk of infection when drawing blood from an existing blood drawing line. We will coordinate the blood test for this research project with a blood draw that is done as part of your standard care in order to minimize this risk.

Risk of loss of privacy and 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 data collection forms, blood samples, and in the database instead of names and other private information. A separate list will be maintained that will 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?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help doctors determine if biomarkers are helpful in treating children with ARDS.

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

If you decide to participate in this study, you must tell us that you agree. A copy will be given to you to keep as a record. 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. You do not have to take part in order to receive care at CHOP.

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.

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 the blood test and your medical records. 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. Research laboratory tests will not appear in the medical record. 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 or samples. 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;
- 'If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to

try to re-identify you. You can tell us at the end of this form whether you will allow us to share your data in this way;'

- Lab personnel at CHOP who will be testing your blood sample.

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 us 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

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information and biological samples.

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 or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples 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
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.

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 National Institutes of Health (NIH) are providing financial support and material 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 samples/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.

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 genetic information and phenotypic 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.

The NIH intends to share the collected 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.

The goal of genetic studies is to look for genetic connections that may explain how to identify, prevent, and treat health problems. For example, genetic data may be used to find out:

- Who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;
- What genes affect the progress of a certain disease or condition; and
- What genes may affect treatments which now may or may not work in certain people.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. 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. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).

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

We will use and may share data and/or specimens for future research only if you give your permission. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. The information and samples will be given a unique code and may include information that can identify you. You will not receive any results or financial benefit from future research done on your specimens or data.

You do not have to give permission for future use of your data or blood specimen to participate in this study right now.

Optional Consent for Use of Identifiable Data or Specimens for Future Research

As part of the study, we will collect data and blood. We may wish to use this information or samples in a future study about children with ARDS. Research could occur at CHOP, or at outside institutions, which could include for profit companies. The information and samples will be given a unique code and may include information that can identify you. Information that can identify you or the blood samples may be kept permanently in a lab and database at CHOP.

We may not ask for your consent before using or sharing your identifiable specimens or data. You will not receive any results or financial benefit from the future research done on your specimens or data. We may share your identifiable specimens or data with outside researchers who will use them for future research.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.Please indicate whether you will allow your data or samples to be used for future research.

If consent is in person, please put your initials next to one of the following choices:

If verbal consent is obtained, the investigator will initial the subject's choice:

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

_____ (initials) YES, my identifiable data and specimens 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 child's health information as discussed above. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

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

(for subjects consented by telephone)

_____

Name of Subject

The research study and consent form was explained to:

_____ _____

Person Providing Consent

Relation to subject:
☐ Parent ☐ Legal Guardian

The person who provided consent confirmed that all of their questions had been answered and they agreed to their child's or the adult's participation in this research study.

They confirmed that they were legally authorized to consent to their child's or the adult's participation.

They agreed to let CHOP use and share their child's or the adult's health information.

_____ _____

Person Obtaining Consent

Signature of Person Obtaining Consent

_____

Date

STUDY SUMMARY SIGNATURE PAGES

For Subjects with Limited English Proficiency

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

Name of Subject

Name of Authorized Representative

Relation to subject:
☐ Parent ☐ Legal Guardian

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

By signing this form, you are indicating that you have answered the 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 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: