Site Name: _____ **Principal Investigator**: _____

Project Title: Prematurity and Respiratory Outcomes Program (PROP)

PARENTAL INFORMED CONSENT FORM

Participant's Name: _____

Title: Prematurity and Respiratory Outcomes Program (PROP)

Investigator:	Name
Address:	xxxxxxxxxxx
	Xxxxxxxxx
Office #:	xxx-xxx-xxxx
24 Hour #	xxx-xxx-xxxx
Sponsor:	The National Heart Lung and Blood Institute (NHLBI), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH)

Thank you for taking the time to read this consent form when so much is happening to your baby. We know it is a difficult time for you.

Why am I being asked to have my baby participate in this study?

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

We are asking that your baby take part in this study because she/he was born earlier than expected and may develop breathing problems.

What is the purpose of this research study?

Breathing problems may develop in premature babies who are born early. Breathing problems may last a short time (during their hospital stay in the Neonatal Intensive Care Unit (NICU) or Intensive Care Nursery (ICN)), or longer (after discharge and through the first year of life and beyond). The purpose of this study is to collect information about how breathing and lung health changes over the first year of life in premature babies. This study will enroll 750 premature babies.

How long will my baby be in the study?

Your baby will be in the study during the entire time that she/he is in the hospital and then for about 1 year after she/he is discharged. The entire study will take about 4 years to complete.

What does the study involve?

We will collect information from your baby's medical record, perform physical examinations and tests that evaluate breathing, collect specimens, and conduct interviews with you.

Before the study begins, the study doctors will review your medical records to obtain your pregnancy history and review your labor and delivery information. Your baby's medical record will be reviewed to see if she/he is eligible for this study.

If you agree to have your baby take part in this study and the study doctors agree that your baby is able to participate, she/he will have the following tests and procedures during hospital stay in the NICU/ICN:

IN HOSPITAL PROCEDURES

Health Information During Hospitalization

During your baby's stay in the hospital, information will be recorded in her/his medical chart. The study staff will collect information for this research study from your baby's medical chart. This will include information about your baby's feedings and growth, medication use, oxygen use, breathing assistance and brain scans, if applicable.

Airway Secretions

If your baby has a breathing tube in place, a sample will be collected from her/his airway between 3 -14 days of age. This is collected through the breathing tube already in place and is obtained by suctioning through the breathing tube, which is part of routine care. The sample will be collected at the time your baby is due for routine suctioning of the breathing tube. It will be stored for future testing.

Urine Collection

We will collect 4 urine samples. To collect urine from your baby, the nurses will place cotton balls in his/her diaper. This is a routine way to collect urine from preterm babies. The urine will be stored for future testing.

Two samples will be collected during the first week after enrollment. The third sample will collected a week later. The fourth sample will be collected when your baby is about 4 weeks old.

Saliva Collection (optional)

If you agree, your baby will have samples of saliva (spit) collected from the inside of her/his mouth for genetic (DNA) testing. This will be done by swiping a cotton swab inside your baby's mouth. It will be stored for future testing. If you choose not to participate in the DNA collection, it will not affect your baby's participation in the study.

When possible, saliva will be obtained from the mother and father of enrolled babies in the same manner. If you choose not to participate in the DNA collection it will not affect your baby's participation in the study.

BEFORE DISCHARGE FROM THE NICU OR ICN

Before discharge, the study staff will collect several different contact phone numbers from you that will help us follow your baby after she/he is discharged.

Breathing Tests

At the time of discharge from the hospital, the doctor may conduct the following breathing tests to find out how much oxygen your baby needs. Your baby will have these tests done if she/he is breathing the air in the room without help, or receives a small amount of extra oxygen.

Oxygen reduction test "to" room air:

This test will be done if your baby is using a small amount of oxygen flowing from nose prongs to help her/him breathe. This test involves slowly reducing the oxygen amount and air flow rate while continuously monitoring your baby to see how well this is tolerated. The test will be stopped right away if your baby's oxygen levels fall during the test.

Rib and stomach breathing motion measurements:

These tests are done to learn many things about the way your baby breathes. Flexible bands are placed snugly around the baby's chest and stomach to measure the amount of movement in the chest and stomach with each breath. These signals are used to provide information about how the lungs are working. A drug called albuterol, used to relax and widen the airways, will be given to your baby. This drug is given as mist that your baby will breathe in by a mask held near his/her face. Shortly after this drug is given, the test will be repeated to see if this drug makes it easier for your baby to breathe and improves lung function.

Oxygen levels while sleeping and eating:

These tests will be done using the oxygen sensor your baby wears all the time to record any changes in your baby's oxygen levels while sleeping and eating.

AFTER DISCHARGE FROM THE NICU OR ICN

The study staff will contact you to schedule an interview about your baby's health, at approximately 3, 6, 9, and 12 months after your baby is discharged. A focused questionnaire will be asked over the telephone by the clinical site staff at a time that is convenient for you.

Follow-up Phone Interviews

The study staff will ask you questions about your baby's health, breathing symptoms, and illnesses. You will be asked about hospitalizations, emergency department and doctor visits, breathing medications, nutrition and exposure to smoking, kerosene heaters, and pets.

The study staff will collect information about some hospitalizations by checking medical records. You may be asked to sign a medical record release form, if this applies to your baby.

12 MONTH CLINICAL VISIT AND TESTS

Your baby will come to the office for a follow-up visit at 12 months. A complete physical examination will be done.

Physical Exam

Your baby will have a physical exam that includes weight and length, vital signs, breath sounds, oxygen saturation and observation of breathing patterns.

What are the risks of taking part in this research study?

Potential Risks

Taking part in a research study may involve risks or side effects. You should talk about these risks with the study doctor.

Breathing Tests

There may be mild discomfort from the bands placed around your baby's chest and stomach to measure the chest when it rises and falls during breathing. The bands must fit snugly. The study staff will monitor your baby continuously for discomfort during the test.

The drug used during the breathing test (albuterol) is called a bronchodilator. It is used to relax the airway muscles to make breathing easier. This drug may increase your baby's heart rate for a short while. Your baby will be observed continuously during the time that this drug is given and the testing time. If this happens, it will last for only short time because this is not a long acting drug. The use of albuterol is not usual practice and is being done for the purpose of this breathing test.

Sample Collection

Suctioning of the airway through the breathing tube is part of routine care. A small amount of salt water will be used for suctioning to help clear the secretions and to obtain the sample from the breathing tube.

The collection of urine and saliva specimens poses no physical risks.

Confidentiality

Collection of research information could pose the risk of revealing sensitive information. Your baby's privacy is important to us. To limit the risk of disclosing the information we collect, we will ask questions, collect health information and perform study procedures in a private setting away from other patients or people who are not involved in this study. Confidentiality will be maintained by using a unique code number instead of using your baby's name, birth date, medical record number or address. In addition, the data will be stored in locked files available only to the study staff or the doctor. All future references to the file will be made using the code number.

What are the risks involved in allowing future use of genetic specimens and information?

The main risk is that someone could get access to the data we have stored. If that data suggested something serious about the parent's health or the baby's health, it could be misused. For example, it could be used to make it harder to get or keep a job or insurance. There are laws against this kind of misuse, but they may not give full protection. We believe that the chance of these things ever happening is extremely small. However, we cannot make guarantees. You and your baby's privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Your baby's name or any other personally identifying information will NOT be used in any published reports from future research performed on your specimens.

Are there any benefits to taking part in this study?

There may or may not be a direct medical benefit to your baby if she/he takes part in this study. Some of the tests done as part of this study may help the doctors taking care of your baby know more about your baby's need for oxygen or if the drug used to open the airways makes it easier for your baby to breath.

We hope that what we learn in this study may help us better understand breathing problems of premature babies and lead to a better treatment in the future.

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

You may decide not to participate in this study. This will not affect your care or your baby's care at this hospital. Your baby will receive the same health care even if you do not participate in the study.

Will confidential health information be collected as part of this study?

Yes. We need to collect personal health information to conduct this study and we will keep it confidential as required by law. A detailed list of the personal health information that we will collect and how it will be shared is described in a separate form for you to review and sign (site specific HIPAA document). In order to protect your baby's health information, we will give this information a unique code number when we share it with other researchers outside of this institution. The key to this code will be kept in a locked file or a password-protected computer file in the study team's locked office.

We will do our best to keep your baby's health information private. However, we cannot guarantee total privacy. We may share research information about your baby with the following groups. These include the following institutions:

- The National Heart, Lung and Blood Institute (NHLBI) and the National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH)
- Your institution's Institutional Review Board or Office of Human Research (groups that review the ethics of research)
- University of Pennsylvania, which is managing all of the study data
- University of North Carolina, which is scoring the breathing tests
- An NIH-approved safety board
- Researchers and data centers approved by the National Institutes of Health

All efforts will be made to remove any personal (identifying) information about your baby prior to sharing research information.

The results of this study may be shown at meetings or published in journals so other doctors and health professionals learn about the study. We will keep your baby's identity private in any publication or presentation about the study.

Use of your baby's and your information and specimens in future studies

Your baby's and your information and specimens may be useful for other research studies. Your baby's information and specimens will only be used again if an ethics committee called the Institutional Review Board allows it. These committees may require that research staff contact you again before more research is done using your baby's and your information and specimens. However, the committees may allow research without contacting you again if you and your baby's health

information is kept private. You may also tell us that you do not want us to use your baby's information in future studies.

What will be done with my baby's and my specimens?

Your specimens will be sent to special labs for testing and storage at the University of California and Vanderbilt University. Your specimens may also be stored for future research in a special facility called a specimen repository. The specimen repository will be under contract to the National Institutes of Health (NIH) and will store your specimens in a secure facility.

Specimens will only be provided through a review process to qualified investigators for acceptable research. Specimens may be shared with scientists from private research companies and may lead to the development of commercial products. You will not receive any compensation if your specimens lead to the development of a commercial product. You and your healthcare provider will not receive any results from the future research done on your specimens. The researchers that are part of this study and the specimen repositories will take steps to prevent any misuse of your specimens and research information.

What if you want your baby to leave the study after she/he begins?

You can have your baby leave the study at any time or ask that your baby's health information not be used. If you ask that we no longer collect your baby's health information, then your baby will have to leave the study.

If you do not want us to collect, use or share your health information anymore, you must inform the study doctor in writing. You must clearly state that you will not allow us to use and share your baby's health information anymore. We will then ask you to sign a "Withdrawal of Study Participation and Consent/Authorization" form.

Even if you take back your permission for us to use your baby's information, we may still use the information about your baby that we collected before you left the study. We do this because we need to know what happens to everyone who starts a research study, not just those who stay in it.

Will there be any costs to you?

There will be no costs for any of the tests or examinations for research purposes (specimen collection, breathing tests and physical exam at 12 months). These are paid for by the research study.

Will you be paid for taking part in this study?

You will receive $XX for each completed follow-up call and $XX for the completed visit at Month 12. We will provide you with parking and travel costs for the Month 12 visit.

What if you have questions about the study?

If you have questions about study procedures or your baby's participation, call xxx-xxx-xxxx to reach the study doctor, xxxxxxx. You may also talk to your own doctor if you have questions or concerns.

If you have questions about your rights as someone taking part in a research study at xxxxx or if you have questions or complaints about a study, you can talk to a person at the Office of xxxxxx at xxx-xxx-xxxx.

What happens if your baby is injured during the study?

If you feel that your baby has been injured because of taking part in the study, it is important that you inform the study doctor, Dr. XXXXXXXXX at xxx-xxx-xxxx. Or, you can contact the Office of Human Research, at this institution, at xxx-xxx-xxxx.

If your baby is injured as a result of being in this study, treatment will be available. The costs of treatment may be covered by the Medical Center/University depending on a number of factors. The Medical Center/University does not normally provide any other form of compensation for injury. For further information about this, you may call the Office of Human Research, at this institution, at xxx-xxx-xxxx.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your or your baby's usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your baby's identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at xxx or elsewhere; however, XXX will not provide free care or compensation for lost wages.

Clinicaltrials.gov

A description of this study will be available on www.clinicaltrials.gov, as required by U.S. Law. This web site will not include information that can identify you. In the future, the web site will include a summary of the results. You can search this web site at any time.

Site Name: _____ **Principal Investigator**: _____

Project Title: Prematurity and Respiratory Outcomes Program (PROP)

Study Contact Information

_____ has described to you what will be done, the risks, and benefits involved, and can be contacted at _____.

SIGNATURE PAGE

A copy of this consent form will be given to you. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about your baby.

The person being considered for this study is unable to consent for himself/herself because she/he is a minor. By signing below, you are giving your permission for your baby to be included in this study.

I hereby grant permission for my child _____ to take part in this research study.
Baby's Name (please print)

Printed Name Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
Printed Name Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
Printed Name	Signature of Person Obtaining Consent	Date

Site Name: _____ **Principal Investigator**: _____

Project Title: Prematurity and Respiratory Outcomes Program (PROP)

OPTIONAL STUDIES

Participation in additional studies is optional. These studies will not require additional visits.

Please initial and reply to the statements below. This is not a consent form for the additional studies listed below.

I agree to allow my baby's and my specimens to be stored and used for future research. ..... __ YES __ NO

I agree to allow a sample of my baby's saliva to be taken for possible future research and genetic testing. ..... __ YES __ NO

If you are the biological mother, you agree to allow a sample of your saliva to be taken for possible future research and genetic testing. ..... __ YES __ NO

If you are the biological father, you agree to allow a sample of your saliva to be taken for possible future research and genetic testing. ..... __ YES __ NO

I agree to discuss the 1 Year Lung Function test. ..... __ YES __ NO

I agree to be contacted about future research. ..... __ YES __ NO

Printed Name Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
Printed Name Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
Printed Name	Signature of Person Obtaining Consent	Date