UNIVERSITY of ROCHESTER MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
DIVISION OF NEONATOLOGY
BOX 651
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-2972

CONSENT ADDENDUM

Subject's Name: _____

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigator: Gloria Pryhuber, MD Department of Pediatrics, Division of Neonatology
Mary Caserta, MD Department of Pediatrics, Division of Inf. Diseases

Office Number: (585) 275-6672, 585-275-5948

24 Hour Number: 585-275-2972

Study Coordinator: Elizabeth Werner, MPH

Office Number: (585) 273-2322

Sponsor: The National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH)

Introduction and Summary of Procedures

You are participating in the research study named above. Some of the information provided when you originally agreed to participate has changed. This consent addendum describes optional procedures that are now part of the study and provides important information to help you decide if you want to participate in this new part of the study. All other aspects of the study remain the same. Please read this form carefully and ask questions about anything that is not clear before you agree to continue participating or at any time.

Previously you and your child agreed to allow the study team to collect 2-5 cc of blood (1/2 – 1 teaspoon, approximately) at our 3 year study visit. We have found two additional tests we would like to do at the 3 year visit that will involve collecting an additional amount of blood for research about allergies These tests involve checking for possible allergies to certain foods and inhaled particles (e.g. ragweed or pollen). Unlike the rest of the tests we do, we will give your child's pediatrician access to the results as well as a letter of interpretation from a Pediatric allergist. In order to do these tests, we will need to collect more blood than we originally asked permission for, a total of 2-10 cc of blood (approximately 1/2 to 2 teaspoons). Although we will obtain a larger sample, we plan to collect the additional blood from the same needle poke (venipuncture) and at the same time as the originally planned blood draw.

Similar to what was done at the 1 year visit, we would also like to collect samples of mucus and stool from your baby's nose and throat and rectum by small, soft nylon swabs. We would also like to collect on a swab a sample of saliva (spit) from your baby to estimate the baby's passive exposure to products of cigarette smoke. In addition, we will ask you to complete the

breathing follow-up surveys with a few additional questions related to food, other allergy symptoms and environmental exposures. If you do not agree to allow us to collect these additional samples and data then we will complete the study visit as described to you originally without the extra blood and swab samples.

Risks of Participation

In regard to the collection of an additional volume of blood, we do not anticipate any additional risk for you or your child if you choose to allow your child to participate in this new portion of our study.. As we indicated in the original parent permission form there are some risks associated with drawing blood such as: potential discomfort, infection, bruising and/or bleeding where the needle is inserted for drawing blood. These risks do not change with the extra amount of blood drawn and we will continue to take every precaution to reduce these risks of the blood draw. Staff experienced and qualified in the care of children will perform every blood draw. Nose/Throat, stool sampling and saliva collection will be done as previously in the study by trained study nurses or practitioners and presents no risk to your child. Collecting these samples may cause temporary, mild discomfort.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Gloria Pryhuber at (585) 275-2972

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

As always, your participation in this study is voluntary. You are free to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you agree to continue taking part in this study, please sign and date this consent form below.

Signature/Dates

Child's Name: _____ **Child's Birth Date:** ____/____/_____

Please Complete:

Parent Permission For Infant Participation
I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a copy of this form for my records and future reference. I hereby voluntarily agree to allow my child to take part in this study.

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

I agree to allow my child's samples to be stored and used for future research.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Person Obtaining Consent/Permission
I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

Print Name and Title: _____

Signature: _____ **Date:** ____/____/_____

UNIVERSITY of ROCHESTER MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-6672

CONSENT/PARENTAL PERMISSION FORM

Full Term Follow-Up Permission (DMID #12-0012)

Infant Name: _____

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigator: Mary Caserta, MD Department of Pediatrics, Division of Inf. Diseases
Gloria Pryhuber, MD Department of Pediatrics, Division of Neonatology

Office Number: (585) 275-6672, (585) 275-5948

24 Hour Number: 585-275-2972

Study Coordinator: Gerry Lofthus, PhD, CCRC
Elizabeth Werner, MPH

Office Number: (585) 275-8149, (585) 273-2322

Sponsor: The National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH)

Introduction

This form is being given to you to invite you and your child to participate in a combined research study sponsored by two institutes of the NIH and designed to better understand how respiratory infections in infancy impact breathing.

Thank you for taking the time to read this consent form. This form describes what you may expect if you decide to allow your child to be in the research program. A research staff member will explain the study to you. Please also carefully read this permission form that describes the study and what you may expect if you decide to participate. Ask the person who brought it to you any questions that may help you to decide whether or not to join the study program.

Participation in this study is voluntary; it is your choice. Your decision to join or to not join the study will not affect the quality of care given to you and your infant.

Special protections are required when the research involves minors and this research has incorporated those requirements to further protect children in research.

Why You Are Being Asked to Participate

Babies born prematurely are more likely to develop trouble with their breathing, especially with respiratory (lung) infections and irritants, in the first few years after birth. However, healthy term infants can also develop breathing problems following respiratory (lung) infections in the first two years of life. You are being asked to have your child take part in this study because your child is / is expected to be an infant born at full term. Your child will also provide comparison information to help to understand premature infants.

Purpose of Study

Breathing problems may develop in babies who are born prematurely, or less commonly in babies who are born at full term, following respiratory (lung) infections. Breathing problems may last a short time or longer after an infection through the early years of life. For some preterm babies the breathing problems begin after they leave the hospital Neonatal Intensive Care Unit (NICU). This research is designed to benefit babies in the future by gaining new knowledge about how and why these breathing problems occur. The purpose of this study is to collect information about how breathing and lung health changes over the first three years of life in babies who are born prematurely and at full term, how respiratory (lung) infections and the immune system may be involved, and how these changes may impact future breathing problems up to three years of life.

Description of Study Procedures

You have already provided permission for your baby to participate in the Prematurity and Respiratory Outcomes Program (PROP), which involves collecting medical information, blood, saliva (spit), urine and stool samples, nose/throat swabs, and doing breathing tests during your baby's hospitalization and for approximately 1 year after they have been discharged. This follow-up study will expand upon the PROP study; therefore the information collected for the PROP study will also be used for this study.

After discharge from the hospital, we will ask that you bring your baby to clinic once each month for one year and then again at three years of age. In some cases, these visits will also coincide with PROP study visits, in which case study procedures will only be completed once for both studies.

We will ask that when your child has cold symptoms during the first two years at home, that you keep track of their symptoms on a scoring sheet that we will provide and explain to you. We will also provide you with a thermometer to take your baby's temperature at these times. If the symptom score is greater than 3, we will ask that you call the study team. We may ask that you bring your child to us to complete a study visit, or that we meet you at your doctor's office or emergency room for nose/throat and stool samples.

We will ask for information about the baby's pediatrician and contact information for you that will help us to follow your baby's health after leaving the hospital.

We will also ask for your permission for extra, **optional** parts of the study. You do not have to agree to these for your baby to take part in the main study. These parts are identified as "optional" below.

The following sections describe the study procedures in more detail.

Health Information

The study staff will collect information recorded routinely in your (the baby's mother) and your baby's medical charts. This will include information about pregnancy and delivery, race, ethnicity, education, tobacco and alcohol use, your baby's growth and feeding, medication use, or any other testing done as part of routine care.

Blood Sampling

We will ask for four blood samples. You will be asked to allow us to use a sample of blood that is routinely taken from the placenta/umbilical cord after the birth of your baby. This sample was / will be collected after your placenta was/is delivered, separated from the baby, and discarded.

Prior to discharge and at one and three years of age, we will collect 2-5 cc of blood (1/2 – 1 teaspoon, approximately) either by drawing from a vein or by heel stick in order to evaluate changes in the immune system from birth.

Saliva (Spit) Sampling
We will ask you (the baby's mother) to give us a sample of saliva (spit) soon after delivery to estimate the baby's passive exposure to products of cigarette smoke before their delivery. A sample of saliva (spit) will also be collected from your baby at six months and one year of age to estimate the baby's passive exposure to products of cigarette smoke.

Nose/Throat/Stool Swabs
Our immune systems adjust to the bacteria (germs) that normally live in our nose, mouth and stool. When a baby is born prematurely, the germs in the stool can be different than what develops in full term babies. We would like to determine how premature baby airway and stool bacteria differs from full term baby airway and stool bacteria, and if these differences change the immune system as well as the health of the lung. We will use a small, soft swab to collect samples of mucus from your baby's nose and throat. We will also sample your baby's stool using a small rectal swab. These samples will be collected once during hospitalization and then once per month in the first year of life and at any sick visits during the first two years of life.

Physical Exam
Shortly after you start the study and at each study visit, a physical exam will be completed. In some cases only weight and height will be measured. At other visits, for example the 6 month, 1 year and 3 year visits, we will conduct a more thorough physical exam, including a lung exam.

Breathing Tests (RIP tests)
At three different times during this study, we will conduct the following breathing tests to find out how well your baby's lungs are working. These tests will be done while still in the hospital soon after birth, and at one and three years of age. The test we will complete is called the "Respiratory Inductive Plethysmography" or RIP. To complete this test, flexible bands are placed snugly around your infant's chest and stomach and then we measure the amount and timing of movement in the chest and stomach with each breath. If the chest and stomach move together and how far they each move tell us about how the lungs are working. A medication (albuterol) that relaxes and opens the airways will then be given to your infant. This medication is commonly used in our NICU with babies born prematurely and in children with asthma. The drug is given as a mist that your infant will breathe in by a mask held near his/her face. Shortly after the dose is given, the test measuring the amount of movement in the chest and stomach with each breath will be repeated to see if this drug makes it easier for your infant to breathe.

Interviews, Surveys & Review of Need for Medications and Hospitalization
Before you and your baby are discharged, we will also ask you to complete a short interview. The interview will ask questions about your family's medical history and your home environment.

At each study visit, we will ask you questions about your baby's health, medications, breathing symptoms and any hospitalizations, emergency room visits and doctor visits. In some cases, we will ask additional questions about your baby's nutrition, vaccines, reflux symptoms and exposure to smoking, kerosene heaters, and pets.

If your baby needs to be back in the hospital, the study staff will collect information about your baby's hospitalization by reviewing medical records. The study staff may also review your baby's medications from your pediatrician's and pharmacy records. You may be asked to sign separate authorizations to release your baby's hospital, pediatrician and pharmacy records.

For one or more of the monthly visits, you may suggest that we come to your home if coming to clinic is not possible for you. If the research team comes to your home they are required to report

information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher must also report, based on information provided by you or observed during the research visit at your home, if you appear to present a danger of harm to others or to yourself, if there is a reasonable concern.

Summary of Study Procedures:

Birth/Delivery/ Discharge	Monthly: 1-11 Months (11 visits, less than 30 min each)	1 Year of Age (1 visit, 2 hours)	Sick Visits Through 2 Years of Age (Up to 6 visits per year, less than 30 min each)	3 Years of Age (1 visit, up to 2 hours)
	Interview & Survey	Interview & Survey	Interview & Survey	Interview & Survey
Cord Blood, Blood Sample at Discharge		Blood Sample		Blood Sample
Maternal Saliva	Infant Saliva at 6 months	Infants Saliva		
Physical Exam	Physical Exam	Physical Exam	Physical Exam	Physical Exam
Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	
Rectal Swab	Rectal Swab	Rectal Swab	Rectal Swab	
Breathing Tests		Breathing Tests		Breathing Tests

Optional Study Procedures:

DNA Sampling

One goal of this study program is to look at genes (DNA) and how they affect lung health and disease in premature babies. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body functions. They can also suggest a person's risk for certain diseases and how they will respond to treatment.

If you agree, samples of saliva (spit) will be collected by wiping the inside of your baby's mouth with a swab some time after birth. Tiny amounts of DNA will be isolated from the saliva and stored only for future testing for differences in genes that may affect lung health and disease. We will not tell you the results of any of the DNA testing because analysis will be done after the sample is no longer identified directly with you or with your baby. Research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to parents of infants like yours in the future.

In order to compare genes, we will also ask for a sample of saliva (spit) from the mothers and fathers of enrolled babies. This part of the study program is also optional. You do not have to agree to it. We will ask you separately at the end of this form whether or not you agree.

Future Research Studies

We currently know what questions to ask and what tests to do with the information and samples that you are allowing us to collect. But, we are learning more about premature babies everyday and as our knowledge grows, our questions change. At the end of this form, we will ask you whether you will allow us to keep the information and specimens we collected for long-term storage (10-20 years) for future research on conditions of newborn infants. This is optional; you do not have to agree to this for your baby to be in the main study. If you do not

agree to the storage and future use of your or your baby's biological samples, they will be recovered and destroyed at the completion of analysis of this study. The results of analyses performed on the samples prior to their destruction will remain with the study.

Your baby's specimens and information will only be provided for future research to qualified investigators for acceptable research (which may include genetic testing) determined through a formal review process. Specimens may be shared with scientists from private research companies and may lead to the development of commercial products. Only specimens that are de-identified will be shared with other investigators. This means that there won't be any identifiable information attached to the specimen. You and your healthcare provider will not receive any results or financial reimbursement 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.

If you decide now that your and your baby's samples can be kept for future research, you can change your mind at any time. A written withdrawal of consent should be submitted to the study team. Then the samples not already used for research will be destroyed if they can be identified. The results of analyses performed on the samples prior to their destruction will remain with the study.

Number of Subjects

Approximately 250 children, 100 term and 150 pre-term babies, will be enrolled in this study at the University of Rochester.

Duration of Study

Your baby will be in the study during the entire time that she/he is in the hospital and then until about 3 years of age, counted from your baby's due date. There may be circumstances, such as failure to attend follow-up visits, under which the investigator may end your participation in the study prior to the usual end of the study. We will do our best to notify you of this decision. We will also provide to you any significant new findings developed during the course of the research that may affect your willingness to continue to participate,

Risks of Participation

Taking part in a research study involves possible risks and side effects. You are encouraged to talk to the study doctor if you have any concerns.

Blood Collection: There are some risks associated with drawing blood. Your infant may experience discomfort, infection, bruising and/or bleeding where the needle is inserted for drawing blood. However, we take every precaution to reduce these risks of blood draws. Staff experienced and qualified in the care of children will be provided for every blood draw.

Sample Collection: Nose/Throat and stool sampling will be done by trained study nurses or practitioners and presents no risk to your child. Collecting these samples may cause temporary, mild discomfort.

Breathing Test: There may be mild discomfort or irritation from the bands placed around your infant's chest and stomach to measure them as they rise and fall during breathing. The bands must fit snugly. An infant may become uncomfortable during the testing, although this has never been reported. Since the test is done when the baby is in quiet sleep, the bands will not prevent the baby from falling asleep naturally. The study staff will monitor your infant for discomfort during the test. Your baby will wear the soft bands for approximately 2 hours.

The medication used during the breathing test, called a bronchodilator, may relax the airway to make breathing easier. This drug will increase your baby's heart rate for a short while. We will observe your baby continuously while the drug is given and during the testing time to follow, as well as, for 30 minutes after the test has been completed. We will also call you by phone the following day to check on the baby.

Samples of Blood, Nose/Throat and Stool: There is a chance that someone who was not supposed to have it could get access to these samples. Your infant's specimens will be kept in secure facilities at the University of Rochester. If you agree, your specimens may also be stored for future research at the University of Rochester or, at the end of the study, in a special facility called a specimen repository that is under contract to the National Institutes of Health (NIH). The samples will be marked only with a study identification number in order to do our best to protect your infant's privacy. Once the samples are stored for future research, after the analyses for this study are completed, they will no longer be linked to you or your infant and so will not be able to be selectively destroyed if you chose later to not allow future use.

Collection of Information: There is a chance that someone who was not supposed to have it could get access to your baby's information because it is collected together. We will do everything we can to prevent this from happening. We will do our best to keep your baby's information safe and not send any information that isn't needed to anyone else.

DNA Specimen (optional): There is a chance that someone who was not supposed to have it could get access to the gene data we store. If that data suggested something serious about the parent's health or the infant'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 infant's privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Your infant's name and any other personally identifying information will NOT be used in any published reports from this study and it will not be associated with any future research performed on the samples.

Future Research Studies (optional): Your baby's and your information and specimens may be useful for other research studies after the study is completed. There are no foreseeable additional risks to you or your baby from the storage and future use of the samples and data. If you agree, your baby's information and specimens will only be used again if an ethics committee called the Institutional Review Board allows it. The committee may allow this research without contacting you again if you and your baby's health information is kept private. However, the committee may require that research staff contact you again before more research is done using your baby's and your information and specimens. You may tell us that you do not want us to use or to contact you about using your baby's information in future studies.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you or any individuals. At most, the Website will include a summary of the study results. You can search this Website at any time.

Benefits of Participation

Your child might not benefit from being in this research study program. Some of the tests done as part of the study may help the doctors taking care of your baby to know more about your baby's breathing and his/her response to the drug used to open the airways to make breathing easier. If, during the physical examination or discussion of your baby's breathing, abnormal findings are identified, we will notify your pediatrician, which may allow earlier treatment. Findings from any future research using

samples or data will occur after identifiers are removed and so will not provide benefit to you or your child.

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

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

Sponsor Support
The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study.

Payments and Costs
Having consented to PROP, you will receive an educational book for your child at discharge and at the 3, 6, 9 and 12 month follow-up study visits. This study will also provide a book at 3 years of age. We will assist with scheduling and travel costs by providing compensation for each completed follow-up study visit ($20) that are in addition to the PROP visits already compensated, and for each completed study visit at 3 years of age ($60) for a total of $220. We will provide $20 for each visit when your child has symptoms of a respiratory infection, up to 12 visits in 2 years. We will also provide you with parking for each study visit.

There will be no costs to you for any of the tests or examinations done for research purposes (specimen collection and breathing tests). These costs are paid for by the research study.

Compensation for Injury
If you are directly injured by the procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and HIPAA Authorization
While we will make every effort to keep information we learn about you/your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of this information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your/your baby's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you/your baby that we either create or use as part of the research. This permission is called an Authorization. We will use your/your baby's research record, and related information from the medical record, results of clinically indicated laboratory tests (such as blood counts, cultures, electrolytes), results of brain imaging studies (MRI, head ultrasound), results of follow-up interviews, physical exams and tests, and other observations, both clinical and research, made while your baby takes part in this study

We will use your/your baby's health information to conduct the study and to determine research results. Health information is used to report results of research to sponsors and federal regulators. Federal law provides authority for certain individuals or groups to have access to the data collected in this study. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study

is completed. If you have not received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following institutions:

- The Department of Health and Human Services
- The National Institute of Allergy and Infectious Diseases (NIAID), The Eunice Kennedy Shriver National Institute of Child Health and Development, and the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) and/or their authorized designees.
- The University of Rochester and Highland Hospital, Including Research Ethics Review Boards
- An NIH-approved safety board and study monitors
- Researchers and data centers approved by the National Institutes of Health

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you/your baby will also be removed from the study. However, standard medical care and any other benefits to which you/your baby are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may be used and given to others.

As stated in the section on Voluntary Participation below, you can refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Persons

For more information concerning this research please contact the study coordinators, Gerry Lofthus at (585) 275-8149 or Elizabeth Werner at (585) 273-2322. If you feel your child has suffered a research-related injury, please contact Dr. Mary Caserta at (585) 275-6672 or Dr. Gloria Pryhuber at (585) 275-2972.

If you have any questions about your rights as a research subject, or any questions or concerns or complaints, you may contact the Human Subjects Protection Specialist at: University of Rochester Research Subjects Review Board, 601 Elmwood Avenue, Box 315, Rochester, NY 14642-8315. Telephone: (585) 276-0005. For long-distance, you may call toll free, (877) 449-4441. You may also call this number if you cannot reach the research staff or wish to talk to someone other than research staff.

Voluntary Participation

You have the right to ask, and have answered, any questions you may have about this research study. Having your child take part in this research study is your choice. You are free to withdraw your child at any time, for whatever reason, without risking loss of present or future care your child would otherwise expect to receive. No matter what decision you make, there will be no penalty or loss of benefit to which you and your child are entitled. In the event that you withdraw your child from this study, the information your child has already provided will be kept in a confidential manner.

"The authority to collect this information is under 42 USC 285f. This Federal code allows the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to conduct and support research."

Signature/Dates

Child's Name: _____ ***Child's Birth Date:*** ___/___/_____

Please Complete:

I agree to allow my baby's specimens to be stored and used for future research.	☐ Yes	☐ No	Initials:	

Parent Permission For Infant Participation

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a copy of this form for my records and future reference. I hereby voluntarily agree to allow my child to take part in this study.

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ___/___/_____
Signature

Birth Mother's Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name: _____

Subject Signature: _____ **Date:** ___/___/_____

Person Obtaining Consent/Permission

I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

Print Name and Title: _____

Signature: _____ **Date:** ___/___/_____

PERMISSION ADDENDUM – Genetic Testing (Optional)

Genetic Testing for the Infant:

Participation in additional studies is optional. These studies will not require additional visits. Please reply to the statements below.

I agree to allow my baby's specimens to be used for genetic testing.	☐ Yes	☐ No	Initials:

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Genetic Testing for the Birth Mother:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:

Subject Name: _____

Subject Signature: _____ Date: ____/____/_____

Genetic Testing for the Birth Father:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

UNIVERSITY of ROCHESTER MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-6672

CONSENT/PARENTAL PERMISSION FORM

Full Term Permission (DMID #12-0012)

Infant Name: _____

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigator: Mary Caserta, MD Department of Pediatrics, Division of Inf. Diseases
Gloria Pryhuber, MD Department of Pediatrics, Division of Neonatology

Office Number: (585) 275-6672, (585) 275-5948

24 Hour Number: 585-275-2972

Study Coordinator: Gerry Lofthus, PhD, CCRC
Elizabeth Werner, MPH

Office Number: (585) 275-8149, (585) 273-2322

Sponsor: The National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH)

Introduction

This form is being given to you to invite you and your child to participate in a research program designed to better understand how respiratory infections in infancy impact breathing.

Thank you for taking the time to read this consent form. This form describes what you may expect if you decide to allow your child to be in the research program. A research staff member will explain the study to you. Please also carefully read this permission form that describes the study and what you may expect if you decide to participate. Ask the person who brought it to you any questions that may help you to decide whether or not to join the study program.

Participation in this study is voluntary; it is your choice. Your decision to join or to not join the study will not affect the quality of care given to you and your infant.

Special protections are required when the research involves minors and this research has incorporated those requirements to further protect children in research.

Why You Are Being Asked to Participate

Babies born prematurely are more likely to develop trouble with their breathing, especially with respiratory (lung) infections and irritants, in the first few years after birth. However, healthy term infants can also develop breathing problems following respiratory (lung) infections in the first two years of life. You are being asked to have your child take part in this study because your child is / is expected to be an infant born at full term. Your child will also provide comparison information to help to understand premature infants.

Purpose of Study

Breathing problems may develop in babies who are born prematurely, or less commonly in babies who are born at full term, following respiratory (lung) infections. Breathing problems may last a short time or longer after an infection through the early years of life. For some preterm babies the breathing problems begin after they leave the hospital Neonatal Intensive Care Unit (NICU). This research is designed to benefit babies in the future by gaining new knowledge about how and why these breathing problems occur. The purpose of this study is to collect information about how breathing and lung health changes over the first three years of life in babies who are born prematurely and at full term, how respiratory (lung) infections and the immune system may be involved, and how these changes may impact future breathing problems up to three years of life.

Description of Study Procedures

If you agree to have your baby participate, we will collect medical information, blood, saliva (spit), mucus and stool samples, and do breathing tests during your baby's hospitalization after birth. During the first year of life, we will ask you to bring your baby back once each month for one year and then again at three years of age.

We will also ask that when your child has cold symptoms during the first two years at home, that you keep track of their symptoms on a scoring sheet that we will provide and explain to you. We will provide you with a thermometer to take your baby's temperature at these times. If the symptom score is greater than 3, we will ask that you call the study team. We may ask that you bring your child to us to complete a study visit, or that we meet you at your doctor's office or emergency room for nose/throat and stool samples.

Before discharge from the hospital, we will ask for information about the baby's pediatrician and contact information for you that will help us to follow your baby's health after leaving the hospital.

We will also ask for your permission for extra, **optional** parts of the study. You do not have to agree to these for your baby to take part in the main study. These parts are identified as "optional" below.

The following sections describe the study procedures in more detail.

Health Information

The study staff will collect information recorded routinely in your (the baby's mother) and your baby's medical charts. This will include information about pregnancy and delivery, race, ethnicity, education, tobacco and alcohol use, your baby's growth and feeding, medication use, or any other testing done as part of routine care. Details of research testing and information about your baby's participation in this study will be included in your baby's electronic medical record.

Blood Sampling

We will ask for four blood samples. You will be asked to allow us to use a sample of blood that is routinely taken from the placenta/umbilical cord after the birth of your baby. This sample was/ will be collected after your placenta was/is delivered, separated from the baby, and discarded.

Prior to discharge and at one and three years of age, we will collect 2-5 cc of blood (1/2 – 1 teaspoon, approximately) either by drawing from a vein or by heel stick in order to evaluate changes in the immune system from birth.

Saliva (Spit) Sampling

We will ask you (the baby's mother) to give us a sample of saliva (spit) soon after delivery to estimate the baby's passive exposure to products of cigarette smoke before their delivery. A sample of saliva (spit) will also be collected from your baby at six months and one year of age to estimate the baby's passive exposure to products of cigarette smoke.

Nose/Throat/Stool Swabs
Our immune systems adjust to the bacteria (germs) that normally live in our nose, mouth and stool. When a baby is born prematurely, the germs in the stool can be different than what develops in full term babies. We would like to determine how premature baby airway and stool bacteria differs from full term baby airway and stool bacteria, and if these differences change the immune system as well as the health of the lung. We will use a small, soft swab to collect samples of mucus from your baby's nose and throat. We will also sample your baby's stool using a small rectal swab. These samples will be collected once during hospitalization and then once per month in the first year of life and at any sick visits during the first two years of life.

Physical Exam
Shortly after you start the study and at each study visit, a physical exam will be completed. In some cases only weight and length will be measured. At other visits, for example the 6 month, 1 year and 3 year visits, we will conduct a more thorough physical exam, including a lung exam.

Breathing Tests (RIP tests)
At three different times during this study, we will conduct the following breathing tests to find out how well your baby's lungs are working. These tests will be done while still in the hospital soon after birth, and at one and three years of age. The test we will complete is called the "Respiratory Inductive Plethysmography" or RIP. To complete this test, flexible bands are placed snugly around your infant's chest and stomach and then we measure the amount and timing of movement in the chest and stomach with each breath. If the chest and stomach move together and how far they each move tell us about how the lungs are working. A medication (albuterol) that relaxes and opens the airways will then be given to your infant. This medication is commonly used in our NICU with babies born prematurely and in children with asthma. The drug is given as a mist that your infant will breathe in by a mask held near his/her face. Shortly after the dose is given, the test measuring the amount of movement in the chest and stomach with each breath will be repeated to see if this drug makes it easier for your infant to breathe.

Interviews, Surveys & Review of Need for Medications and Hospitalization
Before you and your baby are discharged, we will also ask you to complete a short interview. The interview will ask questions about your family's medical history and your home environment.

At each study visit, we will ask you questions about your baby's health, medications, breathing symptoms and any hospitalizations, emergency room visits and doctor visits. In some cases, we will ask additional questions about your baby's nutrition, vaccines, reflux symptoms and exposure to smoking, kerosene heaters, and pets.

If your baby needs to be back in the hospital, the study staff will collect information about your baby's hospitalization by reviewing medical records. The study staff may also review your baby's medications from your pediatrician's and pharmacy records. You may be asked to sign separate authorizations to release your baby's hospital, pediatrician and pharmacy records.

For one or more of the monthly visits, you may suggest that we come to your home if coming to clinic is a hardship for you. If the research team comes to your home they are required to report information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher must also report, based on information provided by you or observed during the research visit at your home, if you appear to present a danger of harm to others or to yourself, if there is a reasonable concern.

Summary of Study Procedures:

Birth/Delivery/ Discharge	Monthly: 1-11 Months (11 visits, less than 30 min each)	1 Year of Age (1 visit, 2 hours)	Sick Visits Through 2 Years of Age (Up to 6 visits per year, less than 30 min each)	3 Years of Age (1 visit, up to 2 hours)
	Interview & Survey	Interview & Survey	Interview & Survey	Interview & Survey
Cord Blood, Blood Sample at Discharge		Blood Sample		Blood Sample
Maternal Saliva	Infant Saliva at 6 months	Infants Saliva		
Physical Exam	Physical Exam	Physical Exam	Physical Exam	Physical Exam
Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	
Rectal Swab	Rectal Swab	Rectal Swab	Rectal Swab	
Breathing Tests		Breathing Tests		Breathing Tests

Optional Study Procedures:

DNA Sampling

One goal of this study program is to look at genes (DNA) and how they affect lung health and disease in premature babies. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body functions. They can also suggest a person's risk for certain diseases and how they will respond to treatment.

If you agree, samples of saliva (spit) will be collected by wiping the inside of your baby's mouth with a swab some time after birth. Tiny amounts of DNA will be isolated from the saliva and stored only for future testing for differences in genes that may affect lung health and disease. We will not tell you the results of any of the DNA testing because analysis will be done after the sample is no longer identified directly with you or with your baby. Research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to parents of infants like yours in the future.

In order to compare genes, we will also ask for a sample of saliva (spit) from the mothers and fathers of enrolled babies. This part of the study program is also optional. You do not have to agree to it. We will ask you separately at the end of this form whether or not you agree.

Future Research Studies

We currently know what questions to ask and what tests to do with the information and samples that you are allowing us to collect. But, we are learning more about premature babies everyday and as our knowledge grows, our questions change. At the end of this form, we will ask you whether you will allow us to keep the information and specimens we collected for long-term storage (10-20 years) for future research on conditions of newborn infants. This is optional; you do not have to agree to this for your baby to be in the main study. If you do not agree to the storage and future use of your or your baby's biological samples, they will be recovered and destroyed at the completion of analysis of this study. The results of analyses performed on the samples prior to their destruction will remain with the study.

Your baby's specimens and information will only be provided for future research to qualified investigators for acceptable research (which may include genetic testing) determined through a formal review process. Specimens may be shared with scientists from private research companies and may lead to the development of commercial products. Only specimens that are de-identified will be shared with other investigators. This means that there won't be any identifiable information attached to the specimen. You and your healthcare provider will not receive any results or financial reimbursement 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.

If you decide now that your and your baby's samples can be kept for future research, you can change your mind at any time. A written withdrawal of consent should be submitted to the study team. Then the samples not already used for research will be destroyed if they can be identified. The results of analyses performed on the samples prior to their destruction will remain with the study.

Number of Subjects

Approximately 250 children, 130 term and 150 pre-term babies, will be enrolled in this study at the University of Rochester,

Duration of Study

Your baby will be in the study during the entire time that she/he is in the hospital and then until about 3 years of age, counted from your baby's due date. There may be circumstances, such as failure to attend follow-up visits, under which the investigator may end your participation in the study prior to the usual end of the study. We will do our best to notify you of this decision. We will also provide to you any significant new findings developed during the course of the research that may affect your willingness to continue to participate,

Risks of Participation

Taking part in a research study involves possible risks and side effects. You are encouraged to talk to the study doctor if you have any concerns.

Blood Collection: There are some risks associated with drawing blood. Your infant may experience discomfort, infection, bruising and/or bleeding where the needle is inserted for drawing blood. However, we take every precaution to reduce these risks of blood draws. Staff experienced and qualified in the care of children will be provided for every blood draw.

Sample Collection: Nose/Throat and stool sampling will be done by trained study nurses or practitioners and presents no risk to your child. Collecting these samples may cause temporary, mild discomfort.

Breathing Test: There may be mild discomfort or irritation from the bands placed around your infant's chest and stomach to measure them as they rise and fall during breathing. The bands must fit snugly. An infant may become uncomfortable during the testing, although this has never been reported. Since the test is done when the baby is in quiet sleep, the bands will not prevent the baby from falling asleep naturally. The study staff will monitor your infant for discomfort during the test. Your baby will wear the soft bands for approximately 2 hours.

The medication used during the breathing test, called a bronchodilator, may relax the airway to make breathing easier. This drug will increase your baby's heart rate for a short while. We will observe your baby continuously while the drug is given and during the testing time to follow, as

well as, for 30 minutes after the test has been completed. We will also call you by phone the following day to check on the baby.

Samples of Blood, Nose/Throat and Stool: There is a chance that someone who was not supposed to have it could get access to these samples. Your infant's specimens will be kept in secure facilities at the University of Rochester. If you agree, your specimens may also be stored for future research at the University of Rochester or, at the end of the study in a special facility called a specimen repository that is under contract to the National Institutes of Health (NIH). The samples will be marked only with a study identification number in order to do our best to protect your infant's privacy. Once the samples are stored for future research, after the analyses for this study are completed, they will no longer be linked to you or your infant and so will not be able to be selectively destroyed if you chose later to not allow future use.

Collection of Information: There is a chance that someone who was not supposed to have it could get access to your baby's information because it is collected together. We will do everything we can to prevent this from happening. We will do our best to keep your baby's information safe and not send any information that isn't needed to anyone else. Individuals who have a reason to access your electronic medical record in the University of Rochester Medical Health System (Strong Memorial Hospital, Highland Hospital, URMC primary care and specialist physician offices, etc.) will know that your baby participated in this research study.

DNA Specimen (optional): There is a chance that someone who was not supposed to have it could get access to the gene data we store. If that data suggested something serious about the parent's health or the infant'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 infant's privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Your infant's name and any other personally identifying information will NOT be used in any published reports from this study and it will not be associated with any future research performed on the samples.

Future Research Studies (optional): Your baby's and your information and specimens may be useful for other research studies after the study is completed. There are no foreseeable additional risks to you or your baby from the storage and future use of the samples and data. If you agree, your baby's information and specimens will only be used again if an ethics committee called the Institutional Review Board allows it. The committee may allow this research without contacting you again if you and your baby's health information is kept private. However, the committee may require that research staff contact you again before more research is done using your baby's and your information and specimens. You may tell us that you do not want us to use or to contact you about using your baby's information in future studies.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you or any individuals. At most, the Website will include a summary of the study results. You can search this Website at any time.

Benefits of Participation

Your child might not benefit from being in this research study program. Some of the tests done as part of the study may help the doctors taking care of your baby to know more about your baby's breathing and his/her response to the drug used to open the airways to make breathing easier. If, during the physical examination or discussion of your baby's breathing, abnormal findings are identified, we will notify your pediatrician, which may allow earlier treatment. Findings from any future research using

samples or data will occur after identifiers are removed and so will not provide benefit to you or your child.

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

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

Sponsor Support
The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study.

Payments and Costs
You will receive an educational book for your child at discharge and at each follow-up study visit at 1 and 3 years of age. We will assist with scheduling and travel costs by providing compensation at your discharge visit and for each completed follow-up study visit ($20), and for each completed study visit at 12 and 36 months of age ($50 each), for a total of $340. We will also provide $20 for each visit when your child has symptoms of a respiratory infection, up to 12 visits in 2 years. We will provide parking for each study visit.

There will be no costs to you for any of the tests or examinations done for research purposes (specimen collection and breathing tests). These costs are paid for by the research study.

Compensation for Injury
If you are directly injured by the procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and HIPAA Authorization
While we will make every effort to keep information we learn about you/your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of this information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your/your baby's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you/your baby that we either create or use as part of the research. This permission is called an Authorization. We will use your/your baby's research record, and related information from the medical record, results of clinically indicated laboratory tests (such as blood counts, cultures, electrolytes), results of brain imaging studies (MRI, head ultrasound), results of follow-up interviews, physical exams and tests, and other observations, both clinical and research, made while your baby takes part in this study

We will use your/your baby's health information to conduct the study and to determine research results. Health information is used to report results of research to sponsors and federal regulators. Federal law provides authority for certain individuals or groups to have access to the data collected in this study. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have not received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following institutions:

- The Department of Health and Human Services
- The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) and/or their authorized designees.
- The University of Rochester and Highland Hospital, Including Research Ethics Review Boards
- An NIH-approved safety board and study monitors
- Researchers and data centers approved by the National Institutes of Health

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you/your baby will also be removed from the study. However, standard medical care and any other benefits to which you/your baby are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may be used and given to others.

As stated in the section on Voluntary Participation below, you can refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Persons

For more information concerning this research please contact the study coordinators, Gerry Lofthus at (585) 275-8149 or Elizabeth Werner at (585) 273-2322. If you feel your child has suffered a research-related injury, please contact Dr. Mary Caserta at (585) 275-6672 or Dr. Gloria Pryhuber at (585) 275-2972.

If you have any questions about your rights as a research subject, or any questions or concerns or complaints, you may contact the Human Subjects Protection Specialist at: University of Rochester Research Subjects Review Board, 601 Elmwood Avenue, Box 315, Rochester, NY 14642-8315. Telephone: (585) 276-0005. For long-distance, you may call toll free, (877) 449-4441. You may also call this number if you cannot reach the research staff or wish to talk to someone other than research staff.

Voluntary Participation

You have the right to ask, and have answered, any questions you may have about this research study. Having your child take part in this research study is your choice. You are free to withdraw your child at any time, for whatever reason, without risking loss of present or future care your child would otherwise expect to receive. No matter what decision you make, there will be no penalty or loss of benefit to which you and your child are entitled. In the event that you withdraw your child from this study, the information your child has already provided will be kept in a confidential manner.

"The authority to collect this information is under 42 USC 285f. This Federal code allows the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to conduct and support research."

Signature/Dates

Child's Name: _____ ***Child's Birth Date:*** ____/____/_____

Please Complete:

I agree to allow my baby's specimens to be stored and used for future research.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Parent Permission For Infant Participation

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a copy of this form for my records and future reference. I hereby voluntarily agree to allow my child to take part in this study.

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Birth Mother's Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

Person Obtaining Consent/Permission

I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

Print Name and Title: _____

Signature: _____ **Date:** ____/____/_____

PERMISSION ADDENDUM – Genetic Testing (Optional)

Genetic Testing for the Infant:

Participation in additional studies is optional. These studies will not require additional visits. Please reply to the statements below.

I agree to allow my baby's specimens to be used for genetic testing.	☐ Yes	☐ No	Initials:	

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Genetic Testing for the Birth Mother:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Subject Name: _____

Subject Signature: _____ Date: ____/____/_____

Genetic Testing for the Birth Father:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

UNIVERSITY of ROCHESTER MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
DIVISION OF NEONATOLOGY
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CONSENT/PARENTAL PERMISSION FORM

Preterm Follow-Up Permission (DMID #12-0012)

Subject's Name: _____

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigator: Gloria Pryhuber, MD Department of Pediatrics, Division of Neonatology
Mary Caserta, MD Department of Pediatrics, Division of Inf. Diseases

Office Number: (585)275-6672, (585) 275-5948

24 Hour Number: 585-275-2972

Study Coordinators: Elizabeth Werner, MPH
Gerry Lofthus, PhD, CCRC

Office Number: (585) 273-2322, (585) 275-8149

Sponsor: The National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH)

Introduction

This form is being given to you to invite you and your child to participate in a research program designed to better understand the infection and breathing problems of premature babies over their first three years of life.

Thank you for taking the time to read this consent form. This form describes what you may expect if you decide to allow your child to be in the research program. A research staff member will explain the study to you. Please also carefully read this permission form that describes the study and what you may expect if you decide to participate. Ask the person who brought it to you any questions that may help you to decide whether or not to join the study program.

Participation in this study is voluntary; it is your choice. Your decision to join or to not join the study will not affect the quality of care given to you and your infant.

Special protections are required when the research involves minors and this research has incorporated those requirements to further protect children in research.

Why You Are Being Asked to Participate

Babies born prematurely are more likely to develop trouble with their breathing, especially with respiratory (lung) infections and irritants, in the first few years after birth. You are being asked to have

your child take part in this study because your child is a premature infant who is already enrolled in the Prematurity and Respiratory Outcomes Program (PROP).

Purpose of Study

Breathing problems may develop in babies who are born prematurely. They may last a short time during their hospital stay in the Neonatal Intensive Care Unit (NICU) or longer (after discharge and through the early years of life). For some preterm babies the breathing problems begin after they leave the NICU. This research is designed to benefit babies in the future by gaining new knowledge about how and why these breathing problems occur. The purpose of this study is to collect information about how breathing and lung health changes over the first three years of life in babies who are born prematurely and at full term, how respiratory (lung) infections and the immune system may be involved, and how these changes may impact future breathing problems up to three years of life.

Description of Study Procedures

You have already provided permission for your baby to participate in the Prematurity and Respiratory Outcomes Program (PROP), which involves collecting medical information, blood, saliva (spit), urine and stool samples, nose/throat swabs and doing breathing tests during your baby's hospitalization and for approximately 1 year after they have been discharged. This follow-up study will expand upon the PROP study, therefore the information collected for the PROP study will also be used for this study.

After discharge from the NICU, we will ask that you bring your baby to clinic once each month for one year and then again at three years of age. The timing of your visits will be counted from your baby's due date. In some cases, these visits will also coincide with PROP study visits, in which case study samples and procedures will only be completed once for both studies.

We will ask that when your child has cold symptoms during the first two years at home, that you keep track of their symptoms on a scoring sheet that we will provide and explain to you. We will also provide you with a thermometer to take your baby's temperature at these times. If the symptom score is greater than 3, we will ask that you call the study team. We may ask that you bring your child to us to complete a study visit, or that we meet you at your doctor's office or emergency room for nose/throat and stool samples.

We will confirm information about the baby's pediatrician and contact information for you that will help us to follow your baby's health after discharge.

We will also ask for your permission for extra, **optional** parts of the study. You do not have to agree to these for your baby to take part in the main study. These parts are identified as "optional" below.

The following sections describe the study procedures in more detail.

Nose/Throat and Stool Swabs

At each visit (except at year 3), we will collect samples of mucus and stool from your baby's nose and throat and rectum using small, soft nylon swabs.

Follow-Up Interviews, Surveys & Review of Medications and Hospitalization

At each visit, will ask you questions about your baby's health, medications, breathing symptoms and any hospitalizations, emergency room visits and doctor visits. In some cases, we will ask additional questions about your baby's nutrition, vaccines, reflux symptoms and exposure to smoking, kerosene heaters, and pets.

If your baby needs to be back in the hospital, the study staff will collect information about your baby's hospitalization by reviewing medical records. The study staff may also ask to review your baby's medications from your pediatrician's and pharmacy records. You will be asked to sign separate authorizations to release your baby's hospital, pediatrician and pharmacy records as needed. Details of research testing and information about your baby's participation in this study will be included in your baby's electronic medical record.

Saliva (Spit) Sample
At 6 and 12 months of age, we collect on a swab a sample of saliva (spit) from your baby to estimate the baby's exposure to products of cigarette smoke.

Physical Exam
At each study visit weight and length will be measured. At some visits, for example the 6 month, 1 year and 3 year visits, we will conduct a more thorough physical exam, which will include a lung exam.

Breathing Tests (RIP tests)
At one and three years of age, we will complete the "Rib and Stomach Breathing Motion (RIP) test" to find out how well your baby's lungs are working as they get older. This is the same test that the PROP study will do just before discharge from the hospital. To complete the test, flexible bands are placed snugly around your infant's chest and stomach to measure the amount and timing of movement in the chest and stomach with each breath. If the chest and stomach move together and how far they each move tell us about how the lungs are working. A medication (albuterol) that relaxes and opens the airways will then be given to your infant. This medication is commonly used in our NICU with babies born early and in children with asthma. The drug is given as a mist that your infant will breathe in by a mask held near his/her face. Shortly after the dose is given, the test measuring the movement of the chest and stomach with each breath will be repeated to see if this drug makes it easier for your infant to breathe.

Blood Sample
At one and three years of age, we will collect 2-5 cc of blood (1/2 – 1 teaspoon, approximately) either by drawing from a vein or by heel stick in order to evaluate changes in the immune system from birth.

For one or more of the visits, you may suggest that we come to your home if coming to clinic is a hardship for you. If the research team comes to your home they are required to report information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher must also report, based on information provided by you or observed during the research visit at your home, if you appear to present a danger of harm to others or to yourself, if there is a reasonable concern.

Summary of Study Procedures After Discharge From the Hospital:

Monthly: 1-11 Months (11 visits, less than 30 min each) Plus potential visit near due date if discharged early.	**1 Year of Age (1 visit, 2 hours)**	**Sick Visits Through 2 Years of Age (Up to 6 visits per year, less than 30 min each)**	**3 Years of Age (1 visit, 2 hours)**
Interview & Survey	Interview & Survey	Interview & Survey	Interview & Survey
	Blood Sample		Blood Sample
Infant Saliva (at 6 months)	Infant Saliva		
Physical Exam	Physical Exam	Physical Exam	Physical Exam
Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	
Rectal Swab	Rectal Swab	Rectal Swab	
	Breathing Test		Breathing Test

Optional Study Procedures:

DNA Sampling

One goal of this study program is to look at genes (DNA) and how they affect lung health and disease in premature babies. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body functions. They can also suggest a person's risk for certain diseases and how they will respond to treatment.

If you agree, samples of saliva (spit) will be collected by wiping the inside of your baby's mouth with a swab some time before three years of age. Tiny amounts of DNA will be isolated from the saliva and stored only for future testing for differences in genes that may affect lung health and disease. We will not tell you the results of any of the DNA testing because analysis will be done after the sample is no longer identified directly with you or with your baby. Research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to parents of premature infants like you in the future.

In order to compare genes, we will also ask for a sample of saliva (spit) from the mothers and fathers of enrolled babies. This part of the study program is also optional. You do not have to agree to it. We will ask you separately at the end of this form whether or not you agree.

Future Research Studies We currently know what questions to ask and what tests to do with the information and samples that you are allowing us to collect. But, we are learning more about premature babies everyday and as our knowledge grows, our questions change. At the end of this form, we will ask you whether you will allow us to keep the information and specimens we collected for long-term storage (10-20 years) for future research on conditions of newborn infants. This is optional; you do not have to agree to this for your baby to be in the main study. If you do not agree to the storage and future use of your or your baby's biological samples, they will be recovered and destroyed at the completion of analysis of this study. The

results of analyses performed on the samples prior to their destruction will remain with the study.

Your baby's specimens and information will only be provided for future research to qualified investigators for acceptable research (which may include genetic testing) determined through a formal review process. Specimens may be shared with scientists from private research companies and may lead to the development of commercial products. Only specimens that are de-identified will be shared with other investigators. This means that there won't be any identifiable information attached to the specimen. You and your healthcare provider will not receive any results or financial reimbursement 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.

If you decide now that your and your baby's samples can be kept for future research, you can change your mind at any time. A written withdrawal of consent should be submitted to the study team. Then the samples not already used for research will be destroyed if they can be identified. The results of analyses performed on the samples prior to their destruction will remain with the study.

Number of Subjects

Approximately 150 premature and 100 full term children will be enrolled at the University of Rochester to participate in this study.

Duration of Study

Your baby will be in the study during the entire time that she/he is in the hospital and then until about 3 years of age, counted from your baby's due date. There may be circumstances, such as failure to attend follow-up visits, under which the investigator may end your participation in the study prior to the usual end of the study. We will do our best to notify you of this decision. We will also provide to you any significant new findings developed during the course of the research that may affect your willingness to continue to participate,

Risks of Participation

Taking part in a research study involves possible risks and side effects. You are encouraged to talk to the study doctor if you have any concerns.

Blood Collection: There are some risks associated with drawing blood. Your infant may experience discomfort, infection, bruising and/or bleeding where the needle is inserted for drawing blood. However, we take every precaution to reduce these risks of blood draws. Staff experienced and qualified in the care of children will be provided for every blood draw.

Sample Collection: Nose/Throat and stool sampling will be done by trained study nurses or practitioners and presents no risk to your child. Collecting these samples may cause temporary, mild discomfort.

Breathing Test: There may be mild discomfort or irritation from the bands placed around your infant's chest and stomach to measure them as they rise and fall during breathing. The bands must fit snugly. An infant may become uncomfortable during the testing, although this has never been reported. Since the test is done when the baby is in quiet sleep, the bands will not

prevent the baby from falling asleep naturally. The study staff will monitor your infant for discomfort during the test. Your baby will wear the soft bands for approximately 2 hours.

The medication used during the breathing test, called a bronchodilator, may relax the airway to make breathing easier. This drug will increase your baby's heart rate for a short while. We will observe your baby continuously while the drug is given and during the testing time to follow.

Samples of Blood, Nose/Throat and Stool: There is a chance that someone who was not supposed to have it could get access to these samples. Your infant's specimens will be kept in secure facilities at the University of Rochester. If you agree, your specimens may also be stored for future research at the University of Rochester or, at the end of the study, in a special facility called a specimen repository under contract to the National Institutes of Health (NIH). The samples will be marked only with a study identification number in order to do our best to protect your infant's privacy. Once the samples are stored for future research, after the analyses for this study are completed, they will no longer be linked to you or your infant and so will not be able to be selectively destroyed if you chose later to not allow future use.

Collection of Information: There is a chance that someone who was not supposed to have it could get access to your baby's information because it is collected together. We will do everything we can to prevent this from happening. We will do our best to keep your baby's information safe and not send any information that isn't needed to anyone else. Individuals who have a reason to access your electronic medical record in the University of Rochester Medical Health System (Strong Memorial Hospital, Highland Hospital, URMC primary care and specialist physician offices, etc.) will know that your baby participated in this research study.

DNA Specimen (optional): There is a chance that someone who was not supposed to have it could get access to the gene data we store. If that data suggested something serious about the parent's health or the infant'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 infant's privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Your infant's name and any other personally identifying information will NOT be used in any published reports from this study and it will not be associated with any future research performed on the samples.

Future Research Studies (optional): Your baby's and your information and specimens may be useful for other research studies after the study is completed. There are no foreseeable additional risks to you or your baby from the storage and future use of the samples and data. If you agree, your baby's information and specimens will only be used again if an ethics committee called the Institutional Review Board allows it. The committee may allow this research without contacting you again if you and your baby's health information is kept private. However, the committee may require that research staff contact you again before more research is done using your baby's and your information and specimens. You may tell us that you do not want us to use or to contact you about using your baby's information in future studies.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you or any individuals. At most, the Website will include a summary of the study results. You can search this Website at any time.

Benefits of Participation

Your child might not benefit from being in this research study program. Some of the tests done as part of the study may help the doctors taking care of your baby to know more about your baby's breathing and his/her response to the drug used to open the airways to make breathing easier. If, during the physical examination or discussion of your baby's breathing, abnormal findings are identified, we will notify your pediatrician, which may allow earlier treatment. Findings from any future research using samples or data will occur after identifiers are removed and so will not provide benefit to you or your child.

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

Alternatives to Study Participation

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

Sponsor Support

The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study.

Payments and Costs

You may recall that as a member of the PROP study, you will receive an educational book for your child at discharge and at the 3, 6, 9 and 12 month study visits. This study will also provide a book at 3 years of age. We will assist with scheduling and travel costs by providing compensation for each completed follow-up study visit ($20 each) that are in addition to the PROP visits already compensated, and for each completed study visit at 3 years of age ($60), for a total of $220. We will provide $20 for each visit when your child has symptoms of a respiratory infection, up to 12 visits in 2 years. We will also provide you with parking for each study visit.

There will be no costs to you for any of the tests or examinations done for research purposes (specimen collection and breathing tests). These costs are paid for by the research study.

Compensation for Injury

If you or your child is directly injured by the procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and HIPAA Authorization

While we will make every effort to keep information we learn about you/your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of this information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your/your baby's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you/your baby that we either create or use as part of the

research. This permission is called an Authorization. We will use your/your baby's research record, and related information from the medical record, results of clinically indicated laboratory tests (such as blood counts, cultures, electrolytes), results of brain imaging studies (MRI, head ultrasound), results of follow-up interviews, physical exams and tests, and other observations, both clinical and research, made while your baby takes part in this study

We will use your/your baby's health information to conduct the study and to determine research results. Health information is used to report results of research to sponsors and federal regulators. Federal law provides authority for certain individuals or groups to have access to the data collected in this study. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have not received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following institutions:

- The Department of Health and Human Services
- The National Institute of Allergy and Infectious Diseases (NIAID), 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) and/or their authorized designees.
- The University of Rochester and Highland Hospital, Including Research Ethics Review Boards
- An NIH-approved safety board and study monitors
- Researchers and data centers approved by the National Institutes of Health

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you/your baby will also be removed from the study. However, standard medical care and any other benefits to which you/your baby are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may be used and given to others.

As stated in the section on Voluntary Participation below, you can refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Persons

For more information concerning this research please contact the study coordinator, Elizabeth Werner at (585) 273-2322. If you feel your child has suffered a research-related injury, please contact Dr. Gloria Pryhuber at (585) 275-2972.

If you have any questions about your rights as a research subject, or any questions or concerns or complaints, you may contact the Human Subjects Protection Specialist at: University of Rochester Research Subjects Review Board, 601 Elmwood Avenue, Box 315, Rochester, NY 14642-8315. Telephone: (585) 276-0005. For long-distance, you may call toll free, (877) 449-4441. You may also call this number if you cannot reach the research staff or wish to talk to someone other than research staff.

Voluntary Participation

You have the right to ask, and have answered, any questions you may have about this research study. Having your child take part in this research study is your choice. You are free to withdraw your child at any time, for whatever reason, without risking loss of present or future care your child would otherwise expect to receive. No matter what decision you make, there will be no penalty or loss of benefit to which you and your child are entitled. In the event that you withdraw your child from this study, the information your child has already provided will be kept in a confidential manner.

"The authority to collect this information is under 42 USC 285f. This Federal code allows the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to conduct and support research."

Signature/Dates

Child's Name: _____ **Child's Birth Date:** ____/____/_____

Please Complete:

I agree to allow my baby's specimens to be stored and used for future research.	☐ Yes	☐ No	Initials:	

Parent Permission For Infant Participation
I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a copy of this form for my records and future reference. I hereby voluntarily agree to allow my child to take part in this study.

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Birth Mother's Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

Person Obtaining Consent/Permission
I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

Print Name and Title: _____

Signature: _____ **Date:** ____/____/_____

PERMISSION ADDENDUM – Genetic Testing (Optional)

Genetic Testing for the Infant:

Participation in additional studies is optional. These studies will not require additional visits. Please reply to the statements below.

I agree to allow my baby's specimens to be used for genetic testing.	☐ Yes	☐ No	Initials:

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Genetic Testing for the Birth Mother:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

Genetic Testing for the Birth Father:
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

UNIVERSITY of ROCHESTER MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
DIVISION OF NEONATOLOGY
BOX 651
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-2972

CONSENT/PARENTAL PERMISSION FORM

Preterm Infant Permission (DMID #12-0012)

Subject's Name: _____

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigator: Gloria Pryhuber, MD Department of Pediatrics, Division of Neonatology
Mary Caserta, MD Department of Pediatrics, Division of Inf. Diseases

Office Number: (585) 275-6672, 585-275-5948

24 Hour Number: 585-275-2972

Study Coordinators: Elizabeth Werner, MPH
Gerry Lofthus, PhD, CCRC

Office Number: (585) 273-2322, (585) 275-8149

Sponsor: The National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH)

Introduction

This form is being given to you to invite you and your child to participate in a research program designed to better understand the infections and breathing problems of premature babies over their first three years of life.

Thank you for taking the time to read this consent form when so much is happening for your baby. We know it is a difficult time for you. This form describes what you may expect if you decide to allow your child to be in the research program. A research staff member will explain the study to you. Please also carefully read this permission form that describes the study and what you may expect if you decide to participate. Ask the person who brought it to you any questions that will help you to decide whether or not to join the study program.

Participation in this study is voluntary; it is your choice. Your decision to join or to not join the study will not affect the quality of care given to you and your infant.

Special protections are required when the research involves minors and this research has incorporated those requirements to further protect children in research.

Why You Are Being Asked to Participate

Babies born prematurely are more likely to develop trouble with their breathing, especially with respiratory (lung) infections and irritants, in the first few years after birth. You are being asked to have your child take part in this study because your child is a premature infant.

Purpose of Study

Breathing problems may develop in babies who are born prematurely. They may last a short time during their hospital stay in the Neonatal Intensive Care Unit (NICU) or longer (after discharge and through the early years of life). For some preterm babies the breathing problems begin after they leave the NICU. This research is designed to benefit babies in the future by gaining new knowledge about how and why these breathing problems occur. The purpose of this study is to collect information about how breathing and lung health changes over the first three years of life in babies who are born prematurely and at full term, how respiratory (lung) infections and the immune system may be involved, and how these changes may impact future breathing problems up to three years of life.

Description of Study Procedures

Your baby's doctors have agreed that your baby is able to participate in this study. If you agree to have your baby participate, we will collect medical information, blood, saliva (spit), mucus and stool samples, and do breathing tests during your baby's hospitalization. After discharge from the NICU, we will ask you to bring your baby back once each month for one year and then again at three years of age. The age will be counted from your baby's due date.

We will also ask that when your child has cold symptoms during the first two years at home, that you keep track of their symptoms on a scoring sheet that we will provide and explain to you. We will provide you with a thermometer to take your baby's temperature at these times. If the symptom score is greater than 3, we will ask that you call the study team. We may ask that you bring your child to us to complete a study visit, or that we meet you at your doctor's office or emergency room for nose/throat and stool samples.

Before discharge from the hospital, we will confirm information about the baby's pediatrician and contact information for you that will help us to follow your baby's health after discharge.

We will also ask for your permission for extra, **optional** parts of the study. You do not have to agree to these for your baby to take part in the main study. These parts are identified as "optional" below.

The following sections describe the study procedures in more detail.

Procedures Done During Your Baby's Stay in the Hospital:

Health Information During Hospitalization

The study staff will collect information recorded routinely in your (the baby's mother) and your baby's medical charts. This will include information about pregnancy and delivery, race, ethnicity, education, tobacco and alcohol use, your baby's growth and feeding, medication use, oxygen use, breathing assistance and brain scans, if they are done as part of routine care. Details of research testing and information about your baby's participation in this study will be included in your baby's electronic medical record.

Blood Sampling

We ask for two samples of blood. If you decide to participate in this study, you will be asked to allow us to use a sample of blood that is routinely taken from the placenta/umbilical cord after the birth of your baby. This sample was collected after your placenta was delivered, separated from the baby, and discarded. If you decide you do not want to participate the sample will be destroyed. The second blood sample will be collected from a peripheral vein or by heel stick when your baby is healthy just prior to going home from the hospital. If your baby is not able to provide a blood sample before discharge we may ask you to bring your baby back to an outpatient blood-drawing lab to obtain this sample. As little as one half of a teaspoon, up to two

teaspoons of blood (no more than 3 ml/kg) will be collected for this sample, depending on your baby's size, red blood cell count (hematocrit) and ease of draw.

Saliva (Spit) Sampling
We will ask you (the baby's mother) to give us a sample of saliva (spit) soon after enrollment to estimate the baby's passive exposure to products of cigarette smoke before their delivery.

Nose/Throat/Stool Swabs
Our immune systems adjust to the bacteria (germs) that normally live in our nose, mouth and stool. When a baby is born prematurely, these bacteria can be different than what develops in full term babies. We would like to determine how premature baby airway and stool bacteria differs from full term baby airway and stool bacteria, and if these differences change the immune system as well as the health of the lung. We will use a small, soft swab to collect samples of mucus from your baby's nose and throat once per week, or every other week, while your baby is in the hospital. In the event your baby needs to have breathing tubes in place, we may collect the secretions suctioned out of their breathing tube instead of collecting the nose and throat samples. These secretions are suctioned out as part of their routine care and are normally thrown away. We will sample your baby's stool using a small rectal swab once per week while your baby is in the hospital.

Physical Exam & Interview
Shortly after when you start the study, and again when your baby is nearly ready to go home, a Pediatrician or a Pediatric Pulmonologist (lung specialist) will complete a physical exam. They will measure your baby's weight and length, listen to your baby's lung and watch how they breathe.

We will also ask you to complete a short interview. The interview will ask questions about your family's medical history and your home environment.

Breathing Tests
When your baby is nearly ready to go home, within about one week of discharge from the hospital or up to 41 6/7 weeks gestation, we will conduct a "Respiratory Inductive Plethysmography" or RIP. To complete this test, flexible bands are placed snugly around the infant's chest and stomach and then we measure the amount and timing of movement in the chest and stomach with each breath. If the chest and stomach move together and how far they each move tell us about how the lungs are working. A medication (albuterol) that relaxes and opens the airways will then be given to your infant. This medication is commonly used in our NICU with babies born early. The drug is given as a mist that your infant will breathe in by a mask held near his/her face. Shortly after the dose is given, the test measuring the movement of the chest and stomach with each breath will be repeated to see if this drug makes it easier for your infant to breathe.

Summary of Study Procedures During Hospitalization:

Birth	Enrollment	Weekly	Near Discharge (Approx 1 week Prior)
Cord Blood *			Blood Sample
	Saliva Sample (birth mother)	Nose / Throat / Rectal Swab	Breathing Tests
	Physical Exam		Physical Exam
	Saliva from Mother		Interview

* *Collecting discarded samples.*

Depending on how long your baby is in the hospital and their health status, not all of these procedures may be completed. The study team will discuss what procedures will/will not be completed throughout the course of the study.

Babies are sometimes transferred, with their parents' agreement, to other Rochester community hospitals. If your baby is transferred to one of these hospitals, these study procedures may be completed at that hospital. If your baby is discharged before some of these tests/procedures can be completed we may ask to come to your home to complete them.

Procedures After Discharge from the NICU:

Nose/Throat and Stool Swabs
We will collect samples of mucus and stool from your baby's nose and throat and rectum by small, soft nylon swabs monthly during the first year of life and at any sick visits during the first two years of life.

Follow-Up Interviews, Surveys & Review of Medications and Hospitalization
At each visit, will ask you questions about your baby's health, medications, breathing symptoms and any hospitalizations, emergency room visits and doctor visits. In some cases, we will ask additional questions about your baby's nutrition, vaccines, reflux symptoms and exposure to smoking, kerosene heaters, and pets.

If your baby needs to be back in the hospital, the study staff will collect information about your baby's hospitalization by reviewing medical records. The study staff may also ask to review your baby's medications from your pediatrician's and pharmacy records. You will be asked to sign separate authorizations to release your baby's hospital, pediatrician and pharmacy records as needed.

Saliva (Spit) Sample
At 6 and 12 months of age, we collect on a swab a sample of saliva (spit) from your baby to estimate the baby's passive exposure to products of cigarette smoke.

Physical Exam
At each study visit a weight and height will be measured. At some visits, for example the 6 month, 1 year and 3 year visits, we will conduct a more thorough physical exam, which will include a lung exam.

Breathing Tests (RIP tests)
Also at one and three years of age, we will repeat the breathing test described above that was done before NICU discharge to find out how well your baby's lungs are working as they get older.

Blood Sampling
At one and three years of age, we will collect 2-5 cc of blood (1/2 – 1 teaspoon, approximately) either by drawing from a vein or by heel stick in order to evaluate changes in the immune system from birth.

For one or more of the monthly visits, you may suggest that we come to your home if coming to clinic is a hardship for you. If the research team comes to your home they are required to report information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher must also report, based on information provided by you or observed during the research visit at your home, if you appear to present a danger of harm to others or to yourself, if there is a reasonable concern.

Summary of Study Procedures After Discharge From the Hospital:

Monthly: 1-11 Months (11 visits, less than 30 min each) Plus potential visit near due date if discharged early.	**1 Year of Age (1 visit, 2 hours)**	**Sick Visits Through 2 Years of Age (Up to 6 visits per year, less than 30 min each)**	**3 Years of Age (1 visit, 2 hours)**
Interview & Survey	Interview & Survey	Interview & Survey	Interview & Survey
	Blood Sample		Blood Sample
Infant Saliva at 6 Months	Infant Saliva		
Physical Exam	Physical Exam	Physical Exam	Physical Exam
Nose/Throat Swab	Nose/Throat Swab	Nose/Throat Swab	
Rectal Swab	Rectal Swab	Rectal Swab	
	Breathing Tests		Breathing Tests

Optional Study Procedures:

DNA Sampling

One goal of this study program is to look at genes (DNA) and how they affect lung health and disease in premature babies. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body functions. They can also suggest a person's risk for certain diseases and how they will respond to treatment.

If you agree, samples of saliva (spit) will be collected by wiping the inside of your baby's mouth with a swab some time after birth. Tiny amounts of DNA will be isolated from the saliva and stored only for future testing for differences in genes that may affect lung health and disease. We will not tell you the results of any of the DNA testing because analysis will be done after the sample is no longer identified directly with you or with your baby. Research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to parents of premature infants like you in the future.

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In order to compare genes, we will also ask for a sample of saliva (spit) from the mothers and fathers of enrolled babies. This part of the study program is also optional. You do not have to agree to it. We will ask you separately at the end of this form whether or not you agree.

Future Research Studies

We currently know what questions to ask and what tests to do with the information and samples that you are allowing us to collect. But, we are learning more about premature babies everyday and as our knowledge grows, our questions change. At the end of this form, we will ask you whether you will allow us to keep the information and specimens we collected for long-term storage (10-20 years) for future research on conditions of newborn infants. This is optional; you do not have to agree to this for your baby to be in the main study. If you do not agree to the storage and future use of your or your baby's biological samples, they will be recovered and destroyed at the completion of analysis of this study. The results of analyses performed on the samples prior to their destruction will remain with the study.

Your baby's specimens and information will only be provided for future research to qualified investigators for acceptable research (which may include genetic testing) determined through a formal review process. Specimens may be shared with scientists from private research companies and may lead to the development of commercial products. Only specimens that are de-identified will be shared with other investigators. This means that there won't be any identifiable information attached to the specimen. You and your healthcare provider will not receive any results or financial reimbursement 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.

If you decide now that your and your baby's samples can be kept for future research, you can change your mind at any time. A written withdrawal of consent should be submitted to the study team. Then the samples not already used for research will be destroyed if they can be identified. The results of analyses performed on the samples prior to their destruction will remain with the study.

Number of Subjects

Approximately 150 premature and 130 full term children will be enrolled at the University of Rochester to participate in this study.

Duration of Study

Your baby will be in the study during the entire time that she/he is in the hospital and then until about 3 years of age, counted from your baby's due date. There may be circumstances, such as failure to attend follow-up visits, under which the investigator may end your participation in the study prior to the usual end of the study. We will do our best to notify you of this decision. We will also provide to you any significant new findings developed during the course of the research that may affect your willingness to continue to participate,

Risks of Participation

Taking part in a research study involves possible risks and side effects. You are encouraged to talk to the study doctor if you have any concerns.

Blood Collection: There are some risks associated with drawing blood. Your infant may experience discomfort, infection, bruising and/or bleeding where the needle is inserted for drawing blood. However, we take every precaution to reduce these risks of blood draws. Staff experienced and qualified in the care of children will be provided for every blood draw.

Sample Collection: Nose/Throat and stool sampling will be done by trained study nurses or practitioners and presents no risk to your child. Collecting these samples may cause temporary, mild discomfort.

Breathing Test: There may be mild discomfort or irritation from the bands placed around your infant's chest and stomach to measure them as they rise and fall during breathing. The bands must fit snugly. An infant may become uncomfortable during the testing, although this has never been reported. Since the test is done when the baby is in quiet sleep, the bands will not prevent the baby from falling asleep naturally. The study staff will monitor your infant for discomfort during the test. Your baby will wear the soft bands for approximately 2 hours.

The medication used during the breathing test, called a bronchodilator, may relax the airway to make breathing easier. This drug will increase your baby's heart rate for a short while. We will observe your baby continuously while the drug is given and during the testing time to follow.

Samples of Blood, Nose/Throat and Stool: There is a chance that someone who was not supposed to have it could get access to these samples. Your infant's specimens will be kept in secure facilities at the University of Rochester. If you agree, your specimens may also be stored for future research at the University of Rochester or, at the end of the study, in a special facility called a specimen repository that is under contract to the National Institutes of Health (NIH). The samples will be marked only with a study identification number in order to do our best to protect your infant's privacy. Once the samples are stored for future research, after the analyses for this study are completed, they will no longer be linked to you or your infant and so will not be able to be selectively destroyed if you chose later to not allow future use.

Collection of Information: There is a chance that someone who was not supposed to have it could get access to your baby's information because it is collected together. We will do everything we can to prevent this from happening. We will do our best to keep your baby's information safe and not send any information that isn't needed to anyone else. Individuals who have a reason to access your electronic medical record in the University of Rochester Medical Health System (Strong Memorial Hospital, Highland Hospital, URMC primary care and specialist physician offices, etc.) will know that your baby participated in this research study.

DNA Specimen (optional): There is a chance that someone who was not supposed to have it could get access to the gene data we store. If that data suggested something serious about the parent's health or the infant'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 infant's privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. Your infant's name and any other personally identifying information will NOT be used in any published reports from this study and it will not be associated with any future research performed on the samples.

Future Research Studies (optional): Your baby's and your information and specimens may be useful for other research studies after the study is completed. There are no foreseeable additional risks to you or your baby from the storage and future use of the samples and data. If you agree, your baby's information and specimens will only be used again if an ethics committee called the Institutional Review Board allows it. The committee may allow this research without contacting you again if you and your baby's health information is kept private. However, the committee may require that research staff contact you again before more research is done using your baby's and your information and specimens. You may tell us that you do not want us to use or to contact you about using your baby's information in future studies.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you or any individuals. At most, the Website will include a summary of the study results. You can search this Website at any time.

Benefits of Participation

Your child might not benefit from being in this research study program. Some of the tests done as part of the study may help the doctors taking care of your baby to know more about your baby's risk of infection, or response to the drug used to open the airways to make breathing easier. If, during the physical examination or discussion of your baby's breathing, abnormal findings are identified, we will notify your pediatrician, which may allow earlier treatment. Findings from any future research using samples or data will occur after identifiers are removed and so will not provide benefit to you or your child.

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

Alternatives to Study Participation

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

Sponsor Support

The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study.

Payments and Costs

You will receive an educational book for your child when you are sent home from the NICU and for each follow-up study visit at 1 and 3 years of age. We will also assist with scheduling and travel costs

by providing compensation for your hospital discharge visit and for each completed follow-up visit ($20 each) and for each completed study visit at 12 and 36 months of age ($50 each), for a total of $340. We will also provide $20 for each visit when your child has symptoms of a respiratory infection, up to 12 visits in 2 years. We will also provide you with parking for each study visit.

There will be no costs for any of the tests or examinations done for research purposes (specimen collection and breathing tests). These are paid for by the research study.

Compensation for Injury

If you are directly injured by the procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and HIPAA Authorization

While we will make every effort to keep information we learn about you/your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of this information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your/your baby's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you/your baby that we either create or use as part of the research. This permission is called an Authorization. We will use your/your baby's research record, and related information from the medical record, results of clinically indicated laboratory tests (such as blood counts, cultures, electrolytes), results of brain imaging studies (MRI, head ultrasound), results of follow-up interviews, physical exams and tests, and other observations, both clinical and research, made while your baby takes part in this study

We will use your/your baby's health information to conduct the study and to determine research results. Health information is used to report results of research to sponsors and federal regulators. Federal law provides authority for certain individuals or groups to have access to the data collected in this study. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have not received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following institutions:

- The Department of Health and Human Services
- The National Institute of Allergy and Infectious Diseases (NIAID), and/or their authorized designees.
- The University of Rochester and Highland Hospital, Including Research Ethics Review Boards
- An NIH-approved safety board
- Researchers and data centers approved by the National Institutes of Health

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you/your baby will also be removed from the study. However, standard medical care and any other benefits to which

you/your baby are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may be used and given to others.

As stated in the section on Voluntary Participation below, you can refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Persons

For more information concerning this research please contact the study coordinator, Elizabeth Werner at (585) 273-2322. If you feel your child has suffered a research-related injury, please contact Dr. Gloria Pryhuber at (585) 275-2972.

If you have any questions about your rights as a research subject, or any questions or concerns or complaints, you may contact the Human Subjects Protection Specialist at: University of Rochester Research Subjects Review Board, 601 Elmwood Avenue, Box 315, Rochester, NY 14642-8315. Telephone: (585) 276-0005. For long-distance, you may call toll free, (877) 449-4441. You may also call this number if you cannot reach the research staff or wish to talk to someone other than research staff.

Voluntary Participation

You have the right to ask, and have answered, any questions you may have about this research study. Having your child take part in this research study is your choice. You are free to withdraw your child at any time, for whatever reason, without risking loss of present or future care your child would otherwise expect to receive. No matter what decision you make, there will be no penalty or loss of benefit to which you and your child are entitled. In the event that you withdraw your child from this study, the information your child has already provided will be kept in a confidential manner.

"The authority to collect this information is under 42 USC 285f. This Federal code allows the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to conduct and support research."

Signature/Dates

Child's Name: _____ **Child's Birth Date:** ____/____/_____

Please Complete:

I agree to allow my baby's specimens to be stored and used for future research.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Parent Permission For Infant Participation
I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a copy of this form for my records and future reference. I hereby voluntarily agree to allow my child to take part in this study.

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Birth Mother's Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

Person Obtaining Consent/Permission
I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

Print Name and Title: _____

Signature: _____ **Date:** ____/____/_____

PERMISSION ADDENDUM – Genetic Testing (Optional)

Genetic Testing for the Infant:

Participation in additional studies is optional. These studies will not require additional visits. Please reply to the statements below.

I agree to allow my baby's specimens to be used for genetic testing.	☐ Yes	☐ No	Initials:	

Parent/Guardian: _____ **Relationship to Child** _____
Print Name

Parent/Guardian: _____ **Date:** ____/____/_____
Signature

Genetic Testing for the Birth Mother:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

Genetic Testing for the Birth Father:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I have received (or will receive) a signed copy of this form for my records and future reference.

I agree to allow my saliva specimen to be used for genetic testing.	☐ Yes	☐ No	Initials:	
I agree to be contacted about future research.	☐ Yes	☐ No	Initials:	

Subject Name: _____

Subject Signature: _____ **Date:** ____/____/_____

DEPARTMENT OF PEDIATRICS
DIVISION OF NEONATOLOGY
BOX 651
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-2972

VERBAL CONSENT SCRIPT

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigators: Gloria Pryhuber, MD, Department of Pediatrics, Division of Neonatology
Mary Caserta, MD, Department of Pediatrics, Division of Inf. Diseases

24 Hour Number: (585) 275-2972

Study Coordinator: Elizabeth Werner, MPH, CCRC,

Office Phone Number: (585) 273-2322

Hi, my name is _____ from the University of Rochester's Department of Pediatrics. I am part of the study staff on a research study that your child enrolled into shortly after birth. Do you have a few minutes to speak with me about the study?

☐ If yes, continue below.
☐ If no, but the subject is interested in speaking, determine a better time to call back to discuss the study.
☐ If no, thank them for their time.

Your family completed the Infant Breathing and Immune Development study around the time your child turned 3. Since then we have developed a few more survey questions we would like to ask you about your family and your child. Would you be willing to answer these brief questions over the phone? It should only take about 10 minutes.

☐ If no, thank them for their time.
☐ If yes, tell them that you need to obtain consent to complete the survey over the phone and review with them a few facts about the study including:

Approximately 150 premature and 130 full term children were enrolled at the University of Rochester to participate in this study.

The risk of doing the survey over the phone is small but there is a chance that someone who was not supposed to have it could get access to your child's information. We will do everything we can to prevent this from happening. We will do our best to keep your child's information safe and not send any information that isn't needed to anyone else. Individuals who have a reason to access your electronic medical record in the University of Rochester Medical Health System (Strong Memorial Hospital,

Highland Hospital, URMC primary care and specialist physician offices, etc.) will know that your child participated in this research study.

The University of Rochester will make every effort to keep the information collected from you private. In order to do so, we will collect and store information in a secure manner. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study. There is no additional reimbursement for answering these questions over the phone and there are no costs to your family for participating in this part of the study.

Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled.

Does this sound like something you'd be willing to continue with?
☐ If yes, continue below.
☐ If no, thank them for their time.

Do you have any questions? Do you agree to participate in this study?
☐ Yes: Document oral consent below.
☐ No: Thank them for their time.

Name of Subject: _____

Parent/Guardian Name: _____

Person Obtaining Consent
I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date

DEPARTMENT OF PEDIATRICS
DIVISION OF NEONATOLOGY
BOX 651
601 ELMWOOD AVENUE
ROCHESTER, NY 14642
(585) 275-2972

VERBAL CONSENT SCRIPT

Title: Impact of Respiratory Virus Infections and Bacterial Microbiome Shifts on Lymphocyte and Respiratory Function in Infants Born Prematurely or Full Term

Investigators: Gloria Pryhuber, MD, Department of Pediatrics, Division of Neonatology
Mary Caserta, MD, Department of Pediatrics, Division of Inf. Diseases

24 Hour Number: (585) 275-2972

Study Coordinator: Elizabeth Werner, MPH, CCRC,

Office Phone Number: (585) 273-2322

Hi, my name is Dr. Mary Caserta (or Gloria Pryhuber) from the University of Rochester's Department of Pediatrics. I am the study doctor on a research study that your child enrolled into shortly after birth and is currently participating in. Do you have a few minutes to speak with me about the study?

☐ If yes, continue below.
☐ If no, but the subject is interested in speaking, determine a better time to call back to discuss the study.
☐ If no, thank them for their time.

Previously, you agreed to allow your child to complete a 3 year visit which included a study survey as well as a breathing test, swab samples, and a small blood test, just like what was done at one year of age. We have added allergy testing to this visit which we will provide to your child's pediatrician at no cost to you. I know you are very busy and we have not been able to complete the 3 year visit with you and wonder if there is something we can do to help you complete this? We can provide transportation or do the visit at your home. In addition, we could provide early evening or Saturday visits if that would be helpful. Do you want to complete the 3 year study visit? (if not, ask whether they would be willing to complete an expanded survey over the phone)

We have expanded the survey and added a few additional questions related to food, other allergy symptoms and environmental exposures.

☐ If no, thank them for their time.
☐ If yes, tell them that you need to obtain consent to complete the survey over the phone and review with them a few facts about the study including:

Approximately 150 premature and 130 full term children were enrolled at the University of Rochester to participate in this study.

The risk of doing the survey over the phone is small but there is a chance that someone who was not supposed to have it could get access to your baby's information because it is collected together. We will do everything we can to prevent this from happening. We will do our best to keep your baby's information safe and not send any information that isn't needed to anyone else. Individuals who have a reason to access your electronic medical record in the University of Rochester Medical Health System (Strong Memorial Hospital, Highland Hospital, URMC primary care and specialist physician offices, etc.) will know that your baby participated in this research study.

The University of Rochester is receiving funds from the National Institutes of Health (NIH) to conduct this study.

For completing this extended study survey, you will compensated $25 and your child will receive an educational book.

There are no costs for any tests or examinations done for research purposes. These are paid for by the research study.

Does this sound like something you'd be willing to continue with?

- ☐ If yes, continue below.
- ☐ If no, thank them for their time.

There are some additional things you should know about the study.

Again, The University of Rochester will make every effort to keep the information collected from you private. In order to do so, we will collect and store information in a secure manner. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled.

Do you have any questions? Do you agree to participate in this study?

☐ Yes: Document oral consent below.

☐ No: Thank them for their time.

Name of Subject:

_____

Parent/Guardian Permission:

_____

Relationship to Child:

_____

Person Obtaining Consent
I have read this form to the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. The subject has provided oral consent to participate in this study.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date