JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

RESEARCH SUBJECT INFORMED CONSENT DOCUMENT
RSV-SERONEGATIVE INFANTS AND CHILDREN, GROUP 1

TITLE:	Phase Ib Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-attenuated Respiratory Syncytial Virus Vaccine, LID/ΔM2-2/1030s, Lot RSV#010A, Delivered as Nose Drops to RSV-Seronegative Infants and Children 6 to 24 Months of Age
PROTOCOL NO.:	CIR335 IRB Protocol #20200975 IRB00011615
SPONSOR:	The National Institute of Allergy and Infectious Diseases (NIAID)
INVESTIGATOR:	Ruth A. Karron, MD Johns Hopkins Bloomberg School of Public Health (JHSPH) Center for Immunization Research (CIR) 624 N. Broadway, Hampton House Room 217 Baltimore, MD 21205
STUDY-RELATED PHONE NUMBER(S):	Ruth A. Karron, MD (410) 614-0319 (410) 955-1622 (410) 955-1624 Suzanne Woods, MSN, CRNP-P, CCRP (443) 813-0697 (24 hours)

RESEARCH CONSENT SUMMARY

You are being asked for your permission to allow your child to take part in a research study. This document provides a brief summary of this research. It describes the key information that we believe most people need to decide whether to give permission to allow your child to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you give permission for your child to take part is up to you.
- If your child does not take part, it won't be held against you or your child.

- Your child can take part now and drop out later, and it won't be held against you or your child.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will my child be in this research?

We expect that your child's taking part in this research study will last until she or he completes the post–RSV season visit in the calendar year following enrollment.

Why is this research being done?

Respiratory Syncytial Virus (RSV) is a virus that can cause breathing problems in children. At this time, there is no approved vaccine to prevent RSV illness.

The purpose of this research study is to look at the safety (side effects) of this study vaccine. In addition, scientists will look at the antibody response (germ fighters) to the vaccine in healthy children. This research study is testing an investigational vaccine.

What happens to my child if I give permission to take part in this research?

If you decide to have your child take part in this research study, the general procedures include daily temperature measurements and daily contacts for the first 28 days, administration of one dose of study vaccine or placebo delivered by nose drops, approximately 8 in-person visits, a physical examination, 6 clinical assessments, 4 blood samples, 4 nasal swabs and weekly contact during the RSV surveillance season.

Additional visits may occur if your child has any respiratory or febrile (fever) illness or ear infections. The illness visit will include a nasal swab and a clinical assessment. If a Stay at Home Order is put in place during the study or if your child is ill, we may replace in-person visits with remote research visits, and you may be asked to swab your child's nose and to mail the swab to us. We will show you how to do this, and we would provide the swabbing kit and a mailer. During a remote research visit, you may also be asked to measure your child's temperature and count your child's pulse and breathing rate.

Could being in this research hurt my child?

The most important risks or discomforts that your child may expect from taking part in this research include symptoms of runny nose, sore throat, cough, or other signs of a cold. It is also possible to cause a sinus infection, croup (infection of the upper airway with a barking cough), ear infection, fever, wheezing, or pneumonia.

Will being in this research benefit my child?

If your child receives the study vaccine, then it is possible that he or she may be protected against one type of RSV illness that is in the community. RSV illness protection should not be expected. If your child receives placebo, there is no direct benefit of protection against RSV.

Your child taking part in the study may help find a vaccine that works to prevent severe RSV illness. Such a vaccine may be of future benefit to babies and children in this country and the rest of the world.

What else should I know about this research?

All visits may take place at an agreed upon location, except on the day the study product is given. If your child is eligible, then the enrollment visit must take place at your child's primary medical practice or at one of the sites where emergency equipment is available. If a Stay at Home Order is put in place after your child has been enrolled, in-person visits, if required, may be replaced by remote research visits, and you may be asked to swab your child's nose and mail the swab to us. Any required blood draws will be collected in-person as soon as possible after the Stay at Home Order is lifted.

DETAILED RESEARCH CONSENT

Your child is being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

If you are being asked as the legally authorized representative, parent, or guardian to permit your child to take part in the research, "your child" in the rest of this form generally means the research subject.

What should I know about this research?

- Someone will explain this research to you.
- You are being asked to allow your child to be in a research study.
- This consent document is to help you decide if you want your child to join in the research study.
- Please read this consent document carefully and take as much time as you need.
- Taking part in this research is voluntary. Whether your child takes part is up to you.
- Your child should not join this research study until all of your questions are answered.
- The decision to join or not join the research study will not cause your child to lose any medical benefits.
- If you decide not to have your child take part in this study, your child's primary healthcare provider will continue to care for your child.
- If you allow your child to join, you may have your child quit at any time.
- There will be no penalty if you decide to have your child quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to have your child continue to be in the study.
- The goal of a research study is to learn things to help others in the future.
- This study involves an investigational (experimental) nose drop vaccine that is being tested to prevent respiratory syncytial virus (RSV) illness in infants and children.
- An investigational vaccine is one that has **not** been approved by the U.S. Food & Drug Administration (FDA).

- Throughout the consent, the investigational (experimental) nose drop vaccine is referred to as "study vaccine".
- In this study, your child may receive a salt-water placebo instead of the study vaccine.
- A placebo has no beneficial effect. A placebo is used in research as a study control. A study control group serves as a comparison group when the vaccine results are tested.
- Part of your child's medical records may become part of the research record.
- The study sponsor, government agencies, and other groups associated with this study may review or copy your child's research records. There will be a risk that your child's research records may be given to others without your permission.
- The Data and Safety Monitoring Board (DSMB) is an independent committee that will monitor the safety of this research study.
- If the study results become public, your child's identifiable information will not be used.

Why is this research being done?

Respiratory Syncytial Virus (RSV) is a virus (germ) that can cause breathing problems in children. Symptoms of infection with the virus may include:

- fever
- runny nose
- cough
- sore throat
- ear infection
- severe lung infections
- wheezing
- croup (barky cough with hoarseness)
- pneumonia (infection of the lungs)

At this time, there is no approved vaccine to prevent RSV illness.

Scientists at the National Institutes of Health (NIH) are developing a vaccine to prevent RSV illness in infants and children. This study vaccine is given as nose drops. The vaccine contains a live, weakened form of the virus. This study vaccine has been genetically modified.

The purpose of this study is to look at the safety (side effects) of this study vaccine. In addition, scientists will look at the antibody response (germ fighters) to the vaccine in healthy children. This research study is testing an investigational vaccine. The FDA has not licensed this vaccine. We have tested a very similar vaccine in adults and young children. There will be up to 81 infants and children taking part in this study.

Your child was chosen, and you are being asked to allow your child to be in this research study because your child is between 6 and 24 months of age.

How long will my child be in this research?

Your child will receive one dose of study vaccine, outside of the RSV season, and will remain on the study until your child completes the post–RSV season visit in the calendar year following enrollment.

What happens to my child if I give permission to take part in this research?

If you decide to have your child take part in this research study, the general procedures include daily temperature measurements and daily contact for 29 days, administration of one dose of study vaccine or placebo delivered by nose drops, approximately 8 in-person visits, a physical examination, 5 clinical assessments, 4 blood samples, 4 nasal swabs and weekly contact during the RSV surveillance season. Additional visits may occur if your child has any respiratory or febrile illness or ear infections. The illness visit will include a nasal swab and a clinical assessment. Illness visits may be done remotely or in-person. If the visit is done remotely, you may be asked to swab your child's nose and mail the swab to us. During a remote research visit, you may also be asked to measure your child's temperature and count your child's pulse and breathing rate.

SCREENING VISIT

If the screening was not already done under a separate screening informed consent, then the screening visit is to find out if your child may enter the study. This visit may take place at an agreed upon location. This visit will take about 1 hour and may include:

- reviewing and signing the study consent document and medical record release form
- completing a comprehension assessment
- obtaining your child's medical history
- offering topical numbing cream to decrease pain for the blood draw
- collecting about 1 teaspoon of your child's blood to test for antibodies against RSV
- a clinical assessment or physical examination

ENROLLMENT VISIT

If your child is eligible, then the enrollment visit must take place at your child's primary medical practice or at one of the sites where emergency equipment is available. We will follow all current CDC and local guidance regarding the use of personal protective equipment (PPE) during all study visits. We will give your child either one dose of study vaccine or one dose of placebo by nose drops. LID/ΔM2-2/1030s, study vaccine is investigational, which means that it is not approved by the Food and Drug Administration (FDA). Placebo is a saltwater nose drop without the study vaccine. Study doctors will compare results from children who receive placebo to the results of children who receive the study vaccine. Whether your child receives the study vaccine or placebo will be decided by chance (like tossing dice). Your child will have a 2 out of 3 chance of being given the study vaccine and a 1 out of 3 chance of being given the placebo. Neither you nor the study doctors, nurses, or staff will know whether your child received the study vaccine or placebo until the study ends. However, this information is available to the study doctor if needed in an emergency.

Your child's enrollment visit will take about 1 hour and may include:

- a complete physical examination including your child's temperature, heart rate, and breathing rate

- a blood draw if not enough blood was collected at the screening visit
- having your child lie on his or her back while receiving one dose of the study vaccine or placebo given by nose drops using a small syringe without a needle
- having your child continue to lie down for 1 minute after receiving study vaccine or placebo
- staying in the clinic for 30 minutes for observation after the study vaccine or placebo is given

You will also be getting:

- thermometers and a temperature card to record your child's temperature daily for 29 days (including enrollment day), and at any other time you are concerned about a fever.
- contact telephone numbers and information about when to call a study nurse or study provider. Study staff will be available 24 hours a day during the first 28 days after enrollment. During all other times, the study staff can answer your questions during regular business hours.

IN-PERSON STUDY VISIT DAYS
After your child is enrolled, the study staff will contact you daily for 4 weeks. There will be about 7 visits and 2 follow-up visits approximately 4 and 8 weeks after receiving vaccine or placebo.

Your child will have in-person study visits on days 5, 7, 10, 12, 28 and 56 days after enrollment. These visits will take place at an agreed upon location. If a Stay at Home Order is started during the study, you may be asked to do the nasal swabs, and the clinical assessments may be done by a remote research visit. During a remote research visit, you may also be asked to measure your child's temperature and count your child's pulse and breathing rate. Any required blood draws during a Stay at Home Order will be collected in-person as soon as possible once the order is lifted. Each visit will take about 30 minutes. The study visits on days 5, 7, 10, 12 after enrollment include:

- updating your child's health history since the last visit
- a clinical assessment including temperature, heart rate, and breathing rate
- swabbing your child's nose to check for study vaccine virus and other viruses

The study visits on days 28 and 56 after enrollment and will include:

- applying numbing cream before the blood draw to decrease pain (if requested)
- collecting about 1 teaspoon of blood to test for antibodies against RSV

NON-VISIT STUDY DAYS
After your child is enrolled, the study staff will be in contact with you for 24 non-visit day reports. On study days 1-29 when an in-person study visit is not completed, you will be reporting the daily temperature measurement and any illness symptoms.

ILLNESS VISIT STUDY DAY(S)
If your child has a fever, respiratory symptoms, or ear infection, then a remote or in-person illness visit may be scheduled. Each visit will take about 30 minutes and will include:

- updating your child's illness history
- a clinical assessment including temperature, heart rate, and breathing rate
- a nasal swab to check for study vaccine virus and other viruses

During a remote illness visit, you may be asked to do the nasal swab, and the clinical assessments may be done remotely during which we may ask you to measure your child's temperature and count your child's pulse and breathing rate.

RSV SURVEILLANCE SEASON
Your child's health will be monitored weekly for illness during the RSV surveillance season. If your child needs medical care for a fever, respiratory symptoms or an ear infection, we will do an illness visit with a remote or in-person clinical assessment and a nasal swab. If the visit is done remotely, you may be asked to do the nasal swab, to measure your child's temperature and count your child's pulse and breathing rate.

A blood sample will be collected after the RSV surveillance season. You may choose to have your child receive numbing cream before the blood draw to decrease pain. These samples are collected to check for antibody responses to RSV infection.

At the end of the research study you will be told if your child received the study vaccine or placebo.

If your child received placebo, it may be possible to be part of the study the next year if they meet all requirements.

What are my responsibilities if my child takes part in this research?
Your child cannot take part in this study if your child:

- has been previously diagnosed with wheezing more than once
- has been diagnosed with wheezing any time in the past 12 months
- lives in a house with people with weak immune systems
- lives with or is in a daycare room with babies younger than 6 months of age for the first 28 days after your child receives study vaccine or placebo
- had contact with a person diagnosed with COVID-19 disease or active SARS-CoV-2 infection within the past 10 days

Your child must wait 2 or 4 weeks after receiving routine vaccines before receiving the study vaccine or placebo. This will depend on which type of routine vaccine they received. Your child must not receive any of the following vaccines prior to receiving the study vaccine:

- the flu shot within 3 days prior, or
- any other non-live vaccine shot or rotavirus vaccine within the 14 days prior, or
- any live vaccine, other than rotavirus vaccine, within the 28 days prior, or
- another investigational vaccine or investigational drug within 28 days prior, or
- salicylate (aspirin) or salicylate-containing products within the past 28 days

In addition, after receiving the study vaccine or placebo, your child must:

- wait 14 days to receive a flu shot or live rotavirus vaccine
- wait 28 days to receive live vaccines other than live rotavirus vaccine
- not take part in any other investigational vaccine or drug studies for 56 days

If your child has any of the following events on the day your child is scheduled to receive the study product, then the administration of the study product will be deferred:

- fever (temporal [forehead] or rectal temperature of 100.4°F or more), or
- upper respiratory signs or symptoms (runny nose, cough, or pharyngitis) or
- nasal congestion significant enough to interfere with successfully giving vaccine or placebo, or
- ear infection

During the first 28 days after receiving the study vaccine, you are asked to measure your child's temporal (forehead) temperature daily. If your child's temperature is greater than or equal to 100.4°F then you are asked to measure your child's rectal temperature.

If your child has any of the following events during the first 28 days after receiving study vaccine, you are asked to contact the study nurse:

- fever (forehead or rectal temperature of 100.4°F or more), or
- any respiratory illness (such as runny nose, cough, sore throat, wheezing, or pneumonia)
- ear infection
- any serious injury or illness requiring hospitalization

If your child has any of the following events during the RSV surveillance portion of the study **and visits a health care provider**, you are asked to contact the study nurse:

- fever (forehead or rectal temperature of 100.4°F or more), or
- any respiratory illness (such as runny nose, cough, sore throat, wheezing, or pneumonia)
- ear infection
- any serious injury or illness requiring hospitalization

Could being in this research hurt my child?

RISKS OF THE STUDY VACCINE

- If the study vaccine is not weakened enough, then it may cause a runny nose, sore throat, cough, or other signs of a cold. It is also possible to cause a sinus infection, croup (infection of the upper airway with a barking cough), ear infection, fever, wheezing, or pneumonia.
- There is no specific medicine to treat RSV illness. If any symptoms occur, then your child will receive prompt medical care.
- The study vaccine virus could spread from your child to other people and may make them sick.
- The study vaccine could cause a severe allergic reaction. A severe reaction can cause hives, throat swelling, rapid heart rate, weakness, difficulty breathing, and death. These reactions are extremely rare, and we have never had this happen in our studies of live RSV vaccines.
- There may be other side effects or risks of the study vaccine that we do not know of yet. If we learn about any new side effects or risks while you are in the study, we will let you know, and you can then decide if you want to continue in the study.

RISKS OF NASAL SWAB

A nasal swab may cause brief discomfort and may rarely cause a nosebleed.

RISKS OF BLOOD DRAWING

Blood drawing can cause discomfort, bleeding, bruising, or a small risk of infection at the place where the blood is taken. Sometimes, blood drawing can cause older children to feel lightheaded or to faint. It can take more than one attempt to get blood from a child.

RISKS OF THE NUMBING CREAM (ANESTHETIC)

Possible side effects of the numbing cream include temporary skin discoloration on the places where the cream is placed. Skin rash, hives (an itchy rash), and rarely dizziness or sleepiness are reported.

RISKS OF OTHER VIRUSES

Your child may catch other germs that may cause illness during or after the study.

RISKS OF PRIVACY AND CONFIDENTIALITY BREACH

The information that identifies your child will not be given out to people who are not working on the study unless it is required by law or you give us permission. However, others who may see your child's information are the group of people who make sure that the study is being done as it should. The study sponsor, government agencies, and other groups associated with this study may review or copy your child's research records. There will be a risk that your child's research records may be given to others without your permission.

Will it cost me money to have my child take part in this research?

The sponsor, the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH, covers the costs of the study. There will be no costs to you or your health insurance for your child to take part in this study.

You may have unexpected expenses from allowing your child to be in the study. These expenses are discussed in the section "What if I am injured because of taking part in this research?".

Will being in this research benefit my child?

We cannot promise any benefits to your child from your taking part in this research. However, if your child receives the study vaccine, then it is possible that he or she may be protected against one type of RSV that is in the community. RSV illness protection should not be expected.

If your child receives placebo, there is no direct benefit of protection against RSV.

We cannot promise any benefits to others from your child taking part in this research. However, your child taking part in the study may help find a vaccine that works to prevent severe RSV illness. Such a vaccine may be of future benefit to babies and children in this country and the rest of the world.

What other choices do I have besides my child taking part in this research?

At this time, there are no licensed vaccines to protect against RSV illness. You may choose not to have your child take part in this study.

What happens to the information collected for this research?

All efforts within reason will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is or has been gathered or kept by the research staff. This includes data for research studies that can be traced back to your child. Using or sharing ("disclosure") of such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (providing "authorization") to the uses and sharing of your child's PHI. If you decide to let your child be in this research study, you are also agreeing to let the study team use and share your child's PHI as described below.

Your private information and your child's medical record, including laboratory results, may be shared with individuals and organizations that conduct or watch over this research, including:

- National Institutes of Health (NIH) and NIH contractors
- Legal counsel
- Food and Drug Administration (FDA)
- WCG IRB
- Data Safety and Monitoring Board (DSMB)
- Office for Human Research Protections
- Johns Hopkins University
- Centers for Disease Control
- Maryland Department of Health

Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.
We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. Maryland state law requires us to report certain diseases and information about child abuse. We cannot promise complete secrecy.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Suzanne Woods in writing and let her know that you withdraw your consent. Her mailing address is 624 N. Broadway, Room 212, Baltimore, MD 21205. At that time, we will stop getting any more data about your child, but the data we stored before you withdrew your consent may still be used for reporting and research quality.

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

At the end of the study, what we learn from the research may be used in a medical journal or used for teaching. Your child's name and other details about your child's health will not be used so that your child cannot be identified.

After the study is finished, you may review or request a copy of your child's research record.

Who can answer my questions about this research?

If you have any questions, concerns, or complaints about your child's participation in this study or any time you feel your child has a study-related injury or a reaction to the study vaccine, contact:

Dr. Ruth Karron at (410) 955-1624, (410) 955-1622 or (410) 614-0319
Suzanne Woods, MSN, CRNP-P, CCRP at (443) 813-0697 (24 hours)

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (855) 818-2289, or e-mail researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times.

What if my child is injured because of taking part in this research?

If your child is injured or gets sick because of being in this research study, then call Dr. Ruth Karron at (410) 955-1624, Suzanne Woods, CRNP-P at (443) 813-0697 (24 hours), or Johns Hopkins Office of Human Subjects Research at (888) 262-3242 or fax (410) 502-0584.

You should call if:

- you think you or your child has not been treated fairly
- your child has been hurt by joining the study
- you have any questions about the study

Either the study staff or Johns Hopkins Office of Human Subjects Research will answer your questions and help you find medical care for your child.

A study clinician can be reached during the study to treat your child for any short-term medical care resulting from participation in this research study. This short-term medical care will be provided through our contract with the NIH and will be at a facility determined by the research team and the NIH. The research team, the NIH, and the federal government will offer no long-term medical care or financial compensation for research-related injuries. You or your insurance company will be billed for payment of any such treatment or hospitalization. It is up to you to check with your insurance company before you start this study to find out what your insurance company will pay. Your health insurance company may not pay for these charges because your child is in a research study. Your child does not lose any legal rights by being in this study.

Can my child be removed from this research without my approval?

The sponsor or study doctors have the right to take your child out of the study at any time without your approval for any of the following reasons:

- it would be dangerous for your child to continue
- you do not follow study procedures as directed by the study doctors
- new information about the study vaccine safety is available
- it is in your child's best interest
- the FDA, study sponsor, or DSMB decide to end the study
- you are unable to keep your scheduled appointments

What happens if I give permission for my child to be in this research, but I change my mind later?

Your child joining this study is your choice. You may decide not to have your child join, or your child may leave the study at any time. You may decide not to allow your child to stay in the study after being told of changes in the research. Your choice will not result in any penalty or

loss of benefits to which you and your child are otherwise entitled. If you decide to have your child leave the study early:

- we ask that you tell the study staff
- we ask that your child stays in the safety evaluation until the end of the study even if sample collection is refused

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research. You may be asked to sign a new consent document if this happens.

Will my child be paid for taking part in this research?

You will receive the first check or gift card at the scheduled follow-up visit about 56 days after enrollment. This payment will include:

- $50 for enrollment visit
- $30 for each completed scheduled and unscheduled study visit
- $5 for each completed non-visit contact

You will receive the final payment at the visit after RSV-surveillance season. This payment is for activities during the RSV-surveillance season and will include:

- $5 for each weekly report to study staff
- $30 for the visit after RSV-surveillance season
- $30 for each illness visit
- $50 bonus if all study and RSV-surveillance season visits and contacts are completed

If you decide to take your child out of the study early, then you will only be paid for the study days that your child completed.

During the study, you or your child may receive:

- age-appropriate treats, books, or small toys (value less than $10)
- child safety seat educational materials
- referrals to certified car seat educators at community inspection stations
- certified lactation counseling services (if appropriate)
- bus tokens, taxi fare, or parking passes (as needed for study visits)

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

PHOTOGRAPHY PERMISSION (OPTIONAL)

We may take pictures of your child during the study. We may use these photos for our advertising flyers and sometimes in medical articles and presentations. Your child's name will not be used in any flyer, article, or presentation. People may be able to recognize your child in these photos. Once your child's photo is used in a flyer or article, you will not be able to take back your consent to use the photo.

Your child may take part in this research study without your agreement to have his or her photograph taken.

I will allow the research staff to take photos of my child.

Parent Initials _____ **Date** _____
month/day/year

SPECIMEN STORAGE PERMISSION (OPTIONAL)

If you agree, any unused blood and nasal swab specimens taken from your child will be stored. The unused specimens may be used for screening for future respiratory virus vaccine studies and research purposes. There will be no direct benefit to your child, but we may learn more about viruses that cause illness in children. The specimens will be labeled so that your child's name cannot be easily identified. Results from future research using your child's specimens will not be put in your child's medical or study records. The results may be included in medical papers and meetings, but your child's name will not be used.

Your child's specimens will not be sold, used for human genetic testing, or used to directly make products that will be for sale. You can change your mind at any time about allowing your child's unused specimen to be used for future screening and research by contacting the study staff in writing.

The nasal swabs, blood specimens, and data collected from your child during this study are important to science. You or your child will not own the specimens or data after you give it to the study. You will not receive any financial benefit from any product or idea created by the study investigators using the data or materials collected from you.

Your child may take part in this research study without your agreement to have his or her specimens stored for future screening and research. If specimen storage permission is not given, the specimens will not be used in the future for screening or research purposes and will be destroyed.

I will allow the use of my child's identifiable unused specimens for future screening and research as described above.

Parent Initials _____ **Date** _____
month/day/year

Statement of Consent

Assent of children is not required

Your signature documents your permission for the individual named below to take part in this research.

Signature of child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date & Time
Printed name of subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
Printed name of subject	Date
Signature of person obtaining consent	Date & Time