

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Tina V. Hartert, MD, MPH

Revision Date: 1/30/2026

Study Title: The Wheezing, Asthma and Viral Effects on Epithelial Structure and Function (WAVES) Study

Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You/your child are being asked to take part in this research study because you are planning to become pregnant, or you are currently pregnant, and will be receiving your care at Vanderbilt. During this study, you/your child will be asked to complete questionnaires, complete in-person visits which we try to coordinate with prenatal and well-child visits, and which will include measurement of height and weight and collection of biological samples. During your child's first year of life when respiratory infection rates are high, you will also be asked to answer brief respiratory symptom surveys about your child and provide nasal samples from your child.

These study activities will be done on a computer or tablet, by mail, over the phone, virtually and/or in person.

You/your child will be in this study for up to five years or longer if the study is extended and you agree to continue.

During your/your child's study participation, you may feel fatigued from answering some of the questionnaires. There will also be some minimal pain from the blood draws and some discomfort from the nasal collections. These risks are described in more detail in the "Side effects and risks that may occur if you/your child take part in this study" section of this consent form. While you/your child will not receive any direct benefit from participating in this study, the information collected from you/your child may help improve the health of children.

You/your child do not have to be in this research study. You can stop being in this study at any time for any reason. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your/your child's medical records will contain a note saying you/your child are in a research study and may contain some research information about you/your child. Anytime you authorize to receive your/your child's medical record will also get this information.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Previous studies have found that early-life environmental factors, such as pollution, viruses, and bacteria, contribute to the development of asthma and allergies. We are doing this research because there continues to be a strong need to understand the role of environmental factors on children's respiratory health, including the causes of asthma and allergies. This is an observational study, which means we are not asking you/your child to change your medications and we will not be giving you/your child a study drug.

What will happen and how long will you/your child be in the study?

If you decide to participate in this research study with your child, the study team will ask you to provide information (including dates of birth and addresses) and biological samples while you are pregnant, at the

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approximate time your baby is born, and beyond. For the first year of your child's life, you will have a study visit every two months by phone, virtually, and/or in person, to provide information and specimens from you/your child, and after 1 ½ years study visits will only be once a year. We try to coordinate these visits with your regularly scheduled well-child visits. If your child is born prior to 34 weeks, you/your child will not continue in the study after the birth.

Other health information: We will review your child's medical records and ask you questions regarding your child's health, including respiratory infections and growth information. You will also be asked to sign a release of medical information so we can get information on any healthcare visits for respiratory illnesses your child received outside of Vanderbilt during this time.

Procedures to be followed:

Biospecimen collection and questionnaires: Each test or activity is scheduled for a specific visit. If you miss the visit, or do not complete a test or activity during a specific visit, it may be done at a later time or at home with a home collection kit. These visits may also be split into multiple visits, if necessary. In person visits will occur during the prenatal (pregnancy) period, a perinatal (delivery) period, and following delivery at 2-, 4-, 6-, 12-, 18- months, and once a year at ages 2-, 3-, 4- and 5-years. These visits may take up to 1 hour to complete. During your child's first year of life, you will receive biweekly, 2–5-minute, electronic surveys to assess for respiratory illness symptoms. This will be done while respiratory syncytial virus (RSV) is circulating, which is typically during the winter. If your child has illness symptoms, a nasal sample will be collected in-person, a home visit or remotely.

Some parts of the study visits may be completed on a computer/tablet, by email, over the phone, cell phone, in person, and/or virtually. If any samples are lost, damaged, or need to be repeated, we may ask you and/or your child for more samples. If any of the tests are found to be invalid, we may ask you and/or your child to return to repeat the test.

Measurements and physical exam: During study visits measurement assessments such as weight, height and head circumference may be collected. This is typically collected from the medical chart, but if not done as part of your or your child's routine medical care, the research staff will take these measurements. If during your child's first year of life they meet the study criteria for a respiratory illness, our research staff may do a physical exam during an in-person or home visit. This may include measuring your child's breathing rate, looking at the chest during breathing, and listening to your child's breathing with a stethoscope, and a brief survey (5-10 minutes) may be conducted asking about your child's symptoms and any treatment.

Questionnaires: We will ask you to complete questionnaires and other forms about you/your child. Questionnaires may be completed on a computer/tablet/smart phone, by mail, over the phone, in person, and/or virtually. We may also collect information from your/and your child's medical records.

Examples of information that we may collect include:

- Demographic information to include (but is not limited to) name, address, former address, date of birth, email address, phone number, etc.
- Dates of birth, race, sex, gender, language, household information, and jobs
- Your child's development and behavior
- Childcare, other children in the home, and school attendance
- Household environment and exposures to chemicals, drugs, and smoke
- Your health care and diet while pregnant
- Child and family health history, medications, immunizations (vaccines), and health insurance status
- Things that may cause stress in your and your child's life, relationships with family and other people, and what your neighborhood is like.
- How your child behaves, what his/her daily life is like, what he/she eats, how he/she sleeps, and how healthy your child is overall
- Use of tobacco, alcohol, and drugs

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Email Addresses: We are requesting your email address so we can communicate study visit reminders or changes with you. Your email will also be used to send secure online study survey links to you for completion. We ask that you please avoid sending sensitive, detailed personal information about your health by unsecured email. You do not have to provide your email address to participate in this study. You may also request, at any time, that your email no longer be used to communicate about the study, without any loss or penalty.

Physical Exam: Physical examinations may include height, weight, head and waist circumference. This may be obtained from the medical chart or measured on you at the prenatal visit and may be measured on you/your child during in-person visits.

Skin Barrier Function: We will ask to measure skin barrier function using a wand that is passed over the skin several times. We may measure this on your child at the 24-, 36-, 48-, and 60-month visits. The wand measures trans-epidermal water loss (TEWL), the amount of water that naturally evaporates through skin to the environment. It also measures stratum corneum hydration (SCH), which represents the amount of water present in skin.

Biological Samples: We will ask to collect biological samples from you/your child. We will collect samples during an in-person study visit, during your already scheduled OB/clinic appointment, during a pediatric appointment, or during an in-person home visit. We may also give you instructions and supplies to collect certain samples at home

Researchers will use the data and samples to study your/your child's surroundings and experiences, such as chemicals, smoke, and what you eat. We may also look at things in your/your child's body, such as hormones, genes, germs, and whether you and/or your child have been exposed to medicines or drugs.

Types of biological samples we will collect include:

Blood: Blood samples will be obtained from you/your child to study things like cells, proteins, and other substances that can affect health.

- We may draw up to 3½ tablespoons of blood from you during the prenatal visit to look at the numbers and types of cells in your blood. The area inside your elbow (or other appropriate area) will be cleaned prior to the blood draw.
- We may collect up to 2 tablespoons of blood from the umbilical cord after your child's birth. When your child is 1-, 2-, 3-, and 5-years of age, we will draw up to 2 tablespoons of blood. The site of the blood draw will be cleaned prior to the blood draw. A topical numbing cream may be used, if your child is of age, and will be placed on the skin before the blood draw to reduce the pain your child might feel. The use of this cream is optional. If you would like to use this cream, we will place it on your child's skin at the start of the visit 30-60 minutes before the blood is taken. If blood cannot be collected by a typical blood draw on your child, we may collect blood using other appropriate means such as from a finger or heel stick or capillary collection device.

Saliva (spit): We will collect saliva samples from you during the prenatal visit and from your child during one of the regularly scheduled visit(s). Saliva may also be collected at home using the provided collection kit and instructions. Your saliva will be collected by you spitting in a tube. Your child's saliva will be collected by holding a cotton swab in your child's mouth for 1-2 minutes. These samples will be used to look at genes (DNA) in relationship to health if you agree to genetic and genomic testing (detailed later in the consent form).

Placenta Collection: We will collect the placenta after childbirth. The study staff will also photograph the placenta prior to processing the tissue. Researchers are interested in studying the placenta to look at things such as signs of inflammation and environmental exposure

Breast Milk: If you are breast feeding, we will ask you to collect a sample of your breast milk (either in person or at home using a collection kit) when your child is about 2-months old, and again when your child is about 12-months old. The sample should be about 7 tablespoons, but can be less, if it needs to be. Researchers will measure things like signs of inflammation and other environmental exposures.

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Urine Collection: We will collect urine from you during the prenatal visit and from your child during the 4-month and 2-year visits to look for things like signs of inflammation and environmental exposures. Urine may also be collected at home using a collection kit that will be provided to you.

Stool Collection: We will ask you to collect a stool sample during the prenatal visit and from your child during the perinatal, 2-, 4-, 6-month, 1-year, 1½-year, and 2-year visits to examine things such as the bacterial and fungal content of your/and your child's stool. Stool can be collected at home or during an in-person visit using the provided collection kit and instructions. Your child's meconium (first stool sample) will also be collected while you are still in the hospital after your child's birth. If sample collection while you are still in the hospital is not possible, the samples may be collected during a separate visit shortly after your child's birth.

Skin Swab Collection: We may collect skin swab samples from you during the prenatal visit and from your child at the perinatal, 2-, 4-, 6-months, 1-, 2-, 3-, 4-, and 5-year visits. This is done by taking a swab and passing it over the front of your/your child's arms multiple times to gather skin cells. More than one swab may be collected. Researchers are interested in looking at the bacteria normally present on your/your child's skin. If sample collection while you are still in the hospital is not possible, the samples may be collected during a separate visit shortly after your child's birth.

Nasal Sampling: We will collect several samples from your child's nose at the perinatal, 2-, 4-, 6-month, 1-, 1½-, 2-, 3-, 4-, 5-year visits. We may also collect nose samples from you during the prenatal visit. If sample collection while you/your child are still in the hospital (perinatal visit) is not possible, the samples may be collected during a separate visit shortly after your child's birth. Researchers are interested in looking at things like the types of cells, substances that can be measured in these samples, and environmental exposures.

- **Nasal Swab Collection:** Nasal cells from you/your child will be collected by putting a tiny brush or soft swab (the size of a Q-tip) in the nose and moving it gently in and out for approximately 4 seconds.
- **Nasal Wash:** A nasal wash is collected by introducing 2 ml (or half of a teaspoon) of a sterile salt - water solution into the nose using a bulb syringe and gently suctioning it out. This sample will only be collected at in-person or home visits by our trained research staff.
- **Nasal Filter Paper:** Nasal secretions will be collected from you/your child by inserting absorbent strips (like a small piece of tissue paper) into you/your child's nose for up to 2 minutes. The nasal filter paper can also occur at home using the provided collection kit, which will include detailed instructions, and a trained research team member will also be available to provide instructions on the collection.

Side effects and risks that you can expect if you take part in this study:

Questionnaires: You may find some of the questions too personal or repetitive. You may feel fatigued from answering the questions. You may skip any question on the questionnaire or in-person that you do not wish to answer.

Blood Collection: This can cause minimal pain and may sometimes cause bruising. Topical numbing cream, which is optional, may cause minimal side effects. Side effects of the topical numbing cream include paleness or redness at the area where the cream is applied, rash, burning sensation, and allergic reaction. To reduce the risk of reactions from the topical numbing cream, the least amount of cream necessary to numb the skin will be applied. If a capillary blood draw device is used, the adhesive may cause skin irritation.

Nasal samples: The nasal samples may cause minimum discomfort and, rarely, some mild bleeding.

Placenta, Breast Milk, Cord Blood, Urine, Stool, Skin Swab, Skin Barrier Function, and Saliva: There are no known risks or discomforts related to these procedures.

Confidentiality: Although we will take steps to protect your/your child's confidentiality, there is the risk that information about you/your child may become known to others. There is a small chance that there could be a loss of confidentiality, meaning someone sees your/your child's information when they do not have permission. To lower this risk, we will use special codes to label samples, questionnaires, forms, and other information

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instead of names. However, we cannot completely remove this risk. Also, it is possible that in the future someone could figure out how to use the health or genetic information to identify individuals or their close biological relatives. The risk of this happening is very small. You/your child will be notified if any new risks are identified during identify individuals or their close biological relatives. The risk of this happening is very small. You/your child will be notified if any new risks are identified during this study.

Good effects that might result from this study:

There may be no benefit to you/your child. You/your child's participation in the study may help us learn things about health and may benefit children in the future, including your children and grandchildren.

Taking part in this study will not improve you or your child's health right now, nor will it change anything about your or your child's current medical care.

Payments for your time spent taking part in this study or expenses:

Session	Estimated time commitment for surveys	Estimated time commitment for visits	Compensation Totals (i.e., combined total for surveys and visits)
Consent	<1 hour		\$50
Prenatal	<35m	<1 hour	\$175
Perinatal		30-45m	\$125
2mo	<15m	20-30m	\$125
4mo	<15m	30-40m	\$125
6mo	<20	<20m	\$125
12mo	<20	~45m	\$125
18mo	<20	~20m	\$125
2y	<15m	~45m	\$125
3y	<15m	~45m	\$125
4y	<15m	~45m	\$125
5y	<15m	~45m	\$125
First-year biweekly respiratory illness surveys during RSV season	<5 minutes per survey		\$5 for each survey completed, which can include up to 12 or more surveys. In addition to compensation for each survey, if 85% or more of these biweekly surveys are completed you will receive an additional \$50 reward.
First-year in-person visit for respiratory illness (may include survey, exam and specimen collection)		30-40m	\$50 per visit
First-year respiratory illness remote/parent collection and survey		20m	\$25 per visit

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You will be compensated for your/your child's time and effort in completing the study visits. You will only be compensated for the visits you complete. If significant travel is required to attend the in-person visit, you may be compensated for your travel costs up to \$75. If any samples are lost, damaged or need to be repeated, we may ask you to come in for an additional in-person visit. You will receive \$25 for this additional in-person visit. You will receive an additional \$10 for each home collection kit you complete and return to the study team. You may also receive additional compensation in the form of meal/food vouchers or other additional gifts valued under \$200 total throughout the duration of the study.

We may ask for your Social Security number and address before you are compensated for taking part in this study. You may also be participating in other studies at Vanderbilt University or Vanderbilt University Medical Center. If the total compensation you receive for participating in these studies is more than \$600, the amount may be taxable and will be reported to the Internal Revenue Service (IRS).

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt or the National Institutes of Health (NIH) to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the National Institutes of Health (NIH) to give you money for the injury.

Who to call for any questions or in case you are injured:

If it is an emergency, call 911 or go to an emergency room. If you should have any questions about this research study, or if you feel you or your child have been hurt by being a part of this study, please feel free to contact a study team member at 615-322-4444. If you cannot reach the research staff, you may call the study doctor, Dr. Hartert, at 615-936-1010 or the 24-hour contact number at 615-322-2386.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at 615-322-2918 or toll free at 866-224-8273.

Reasons why the study doctor may take you out of this study:

The researchers may take you/your child out of the study without your consent at any time. Reasons why you/your child may be removed from the study include, but are not limited to, the following:

- If your child is born prior to 34 weeks, you/your child will not continue in the study after birth.
- Your or your child's health changes, and the study is no longer in your or your child's best interest.
- You or your child do not follow the study rules or no longer meet the requirements to be in the study.
- The study is stopped by the researcher, Vanderbilt, or the NIH, National Institutes of Health who is funding this research.

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What will happen if you decide to stop being in this study?

You can change your mind at any time and stop you/your child from being in the study. This will not change your regular medical care or your child's regular medical care in any way. You/your child can also take a break at any time during the study and come back later. If you/your child decide to leave the study, we will keep all the information and samples we have collected up to that point. We will continue to use and share the information and samples you/your child provided unless you ask us not to do so. If you change your mind, we ask that you contact Dr. Tina Hartert in writing and let her know by using the contact information provided in this form. At that time, we will stop using the information and any remaining samples. We may not be able to get back information or samples already given to other researchers or placed in research databases.

Confidentiality:

The National Institutes of Health (NIH) and/or Vanderbilt may share your/your child's information with others or use it for other research projects not listed in this form. The National Institutes of Health (NIH), Vanderbilt, Dr. Tina Hartert, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you or your child for the use or transfer of this information.

This study has support from the National Institutes of Health (NIH). We will make every effort to keep your/your child's personal information private and confidential.

Your/your child's study information is protected by a Certificate of Confidentiality.

Certificate of Confidentiality

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases.

The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you or your child may be made available to others to use for research. To protect your/your child's privacy, we will not release your or your child's name. You or your child will not receive any benefit as a result of the tests done on your or your child's samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems. Your/your child's samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you or your child.

At any time, you may ask to have your sample destroyed. You should contact Dr. Tina Hartert at 615-936-1010, 615-322-3412, or in writing: Tina Hartert, MD, MPH, 2525 West End Avenue, Suite 450, Nashville, TN 37203 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Study Results:

We may publish and present what we learn from this study, but none of this information will identify you or your child directly without your permission. We share these publications with our study participants through annual newsletters.

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Routine lab tests planned for this study will generate study results. If we believe that the information is of urgent medical importance or is clinically significant, meaning the results may require follow-up with your or your child's primary care doctor, we will share this information with you. The study team will notify you with the results and obtain your permission to share them with your child's doctor.

If important new findings come up during the course of the study that might change your/your child's decision to be in this study, we will give you information about those findings as soon as possible. Since this is a research study, we do not provide medical care. You should always talk to your or your child's doctor if you have questions or concerns about your and/or your child's health.

Normal and abnormal study results: The results of select studies will be provided to you. This information and intention to inform will be included in the consent form for each test. Furthermore, if we inform your or your child's healthcare provider, we will obtain your permission, and this will be detailed in this consent form.

In regard to the Complete Blood Count (CBC) results, we may inform you of an abnormal result for your child that is deemed clinically significant by the study doctor or designee within two weeks of determination. Study results that fall in the category of critical range (as determined by the reference lab used by each study site) will be communicated to you and your child's healthcare provider as soon as possible.

Any study results communicated to the you or your healthcare provider will be done via phone or letter, or by fax to your healthcare provider.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your/your child's private health information (PHI).

By signing this document, you agree that your/your child's health care providers (including Vanderbilt University Medical Center and others) may release your/your child's private health information to us, and that we may use any and all of your/your child's information that the study team believes it needs to conduct the study.

Your/your child's private information may include things learned from the tests or procedures described in this form, as well as information from your/your child's medical record, or state health information (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your/your child's private health information include the researchers and their staff. Additionally, we may share your/your child's information with other people at Vanderbilt, for example if needed for your/your child's clinical care or study oversight. By signing this form, you give permission to the research team to share your/your child's information with others outside of Vanderbilt University Medical Center. This may include the NIH, who is providing the funding for this study, and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, and other agents and contractors used by the study team. We try to make sure that everyone who sees your/your child's information keeps it confidential, but we cannot guarantee that your/your child's information will not be shared with others. If your/your child's information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization/ consent form, but if you do not, you may not join the study.

How long will your information be used or shared?

Your/your child's Authorization for the collection, use, and sharing of your/your child's information does not expire. Additionally, you agree that your/your child's information may be used for similar or related future research studies.

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What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator, Dr. Tina Hartert, in writing at 2525 West End Avenue, Suite 450, Nashville, TN 37203 to let her know. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your /your child's authorization. We will not tell you/your child the results of these optional activities, and we will not put any of these results in your or your child's medical record.

Taking part in the optional activities will not cost you or your child anything.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of the consent form to keep.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, I freely and voluntarily choose to take part in this study, and I give permission for my child to take part in this study.

Date: _____ Signature of parent/guardian
MM/DD/YY

Date: _____ Signature of person obtaining consent
MM/DD/YY

_____ Printed Name of person obtaining consent

_____ Title of person obtaining consent

Time: _____ AM/PM/Military

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Consent for Genetic Research

Genetic Testing: Genetic and Genomic testing is optional. This section details what is involved with genetic and genomic testing. Here is a description of the genetic and genomic testing and what is unique about it: If you agree, several of the tests we will perform on you/your child's biospecimens will be genetic testing, which is done on DNA, RNA, or both. DNA carries the genetic instructions for the cells that make up your body. RNA is the material that carries instructions for making proteins in the body.

We may conduct a genome-wide association study (GWAS) to scan the genes of many people. This helps find genetic differences associated with people's health.

Genes tell your body how to do things like form your spine, or what color your eyes should be. While much of the DNA is the same between individuals, differences or changes in the DNA can lead to differences in how you look and how your body works, (e.g., eye color, blood type, risk for cancer).

As part of this study, we may examine the variation in your/your child's DNA. RNA is genetic material that carries instructions from DNA for controlling the building of proteins. Thus, we may also examine the amount of RNA produced in the samples you/your child provide.

If you agree to the optional testing, the DNA and RNA from your/your child's samples will be treated like the rest of the samples and testing involved in this study and may be sent to and shared with researchers outside of Vanderbilt to answer the scientific questions described above. The data may be published in scientific journals. When the data are shared with the ones who are providing the funding or publishers, it will not be shared in any way that can identify you/your child personally. Data shared with the ones who are providing the funding or publishers may be used by other researchers outside of Vanderbilt, but only data that cannot identify you or your child personally will be used.

The laboratories that are processing your/your child's genetic information are research facilities and do not have the ability to provide genetic test results or genetic counseling. Genetic information about you/your child or other information obtained from your/your child's samples will not be given to you, your child, your family, or your doctor. No one else (like a relative, boss, or insurance company) will be given your/your child's results.

Genomic Data Sharing (GDS): Genomic data can be useful for many kinds of research. For that reason, organizations like the National Institutes of Health (NIH) have created large databases that collect genomic data generated by research studies and make this information available to other researchers. We will share genomic data from this study in one of these federal databases or in other public scientific resources to make the information broadly available for a wide range of research.

Your/your child's individual genomic data and health information will go into a controlled-access NIH- supported research database. This means that only researchers who apply for and get permission to use the information for a specific research project will have access to the information. We will not share your or your child's name, birth date, or other information that could directly identify you or your child. Researchers approved to use information in the database will agree not to try to identify you or your child.

Although these protections will be in place, there is still a small chance that someone could identify you or your child from the genomic information and that the information could potentially be used to discriminate against or stigmatize participants, their families, or groups.

You may withdraw consent for research use of genomic data at any time without penalty or loss of benefits to which you/your child are otherwise entitled by contacting Dr. Hartert in writing and letting her know by using the contact information provided in this form. The genomic data will be withdrawn from the research database, if possible, but data already distributed cannot be withdrawn. Also, if your/your child's identity was removed from the biological samples, we will not be able to locate and destroy them.

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Tina V. Hartert, MD, MPH

Revision Date: 1/30/2026

Study Title: The Wheezing, Asthma and Viral Effects on Epithelial Structure and Function (WAVES) Study

Institution/Hospital: Vanderbilt University Medical Center

Another kind of genetic data we will share with federal databases are genetic summary results based on genomic data from hundreds or thousands of people. Genetic summary results might show how different genes are associated with different traits or diseases across many participants in a dataset, or how often certain gene changes are seen across participants from many studies. This information will be available online through a public database that anyone can access. Genetic summary results do not include any individual-level data, and the risk of anyone identifying you or your child from summary results is very low.

Risks: Research has already shown that some populations are more likely to develop certain diseases than others. For example, sickle cell anemia is more common in people of African, African American, or Mediterranean heritage. By participating in this research, your/your child's genetic information could help researchers find out if members of a specific population are at greater risk for specific diseases. Some people have been concerned that this information could be used to stereotype all members of a population group, even if not everyone in that group is at risk for the disease common in their racial or ethnic heritage.

The DNA and RNA samples and information sent to other researchers will not include personal information like your/your child's name or birthdate. However, even without your/your child's name or other identifiers, genetic information is unique to you, like a fingerprint. Scientists expect that over the next few years, researchers will be able to look at your/your child's genetic information and be able to trace the data back to you/your child (and potentially to your blood relatives). However, as a condition of using this data, researchers are asked to agree that they will not try to re-identify individuals.

It is possible that we will learn about unexpected health information based on your and/or your child's DNA. Because the evaluation of your/your child's DNA will be done in a research setting, this will not be shared with you, your child or your/your child's doctor. However, because some genetic variants are highly predictive of later disease development, there are concerns that genetic information could lead to discrimination for jobs or insurance.

An additional risk of giving samples for this research may be the release of your/your child's name that could link you/your child to the stored samples and/or the results of the tests run on your/your child's samples. To prevent this, these samples will be given a code. The name that belongs to the code will be kept in a locked file and/or a computer with a password. Only Dr. Hartert and study staff will have access to your/your child's code and name.

Laws help protect your/your child's genetic information. Health insurance companies and group health plans may not use your or your child's genetic information when making decisions regarding your/your child's eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when deciding to hire, promote, or fire you or when setting the terms of your employment. These laws do not apply to use of genetic information for other types of insurance (such as life, disability, or long-term care). Your/your child's sample will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

I read the Genetic and Genomic Testing and Genomic Data Sharing sections.

- A study staff member explained to me the purpose of the optional study activity, what may happen during the study, the risks, and the benefits.
- Please initial "YES" or "NO" for the following optional study activities for both you and your child:

YOUR SAMPLES:

Blood/tissue sample used in gene research for this study:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing as part of this study for **MY** samples.

_____ **NO:** I do NOT agree to allow genetic and genomic testing and genomic data sharing as part of this study for **MY** samples.

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Institution/Hospital: Vanderbilt University Medical Center

Blood/tissue sample stored/shared for future gene research in lung and respiratory diseases:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research in lung and respiratory diseases for **MY** samples.

_____ **NO:** I do NOT agree to allow genetic and genomic testing and genomic data sharing to be stored/shared for future gene research in lung and respiratory diseases for **MY** samples.

Blood/tissue sample stored/shared for future gene research for other health problems:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.) for **MY** samples.

_____ **NO:** I do NOT agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.) for MY samples.

CHILD'S SAMPLES:

Blood/tissue sample used in gene research for this study:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing as part of this study for **MY CHILD's** samples.

_____ **NO:** I do NOT agree to genetic and genomic testing and genomic data sharing as part of this study for **MY CHILD's** samples.

Blood/tissue sample stored/shared for future gene research in lung and respiratory diseases:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research in lung and respiratory diseases for **MY CHILD's** samples.

_____ **NO:** I do NOT agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research in lung and respiratory diseases for **MY CHILD's** samples.

Blood/tissue sample stored/shared for future gene research for other health problems:

_____ **YES:** I agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.) for **MY CHILD's** samples.

_____ **NO:** I do NOT agree to allow genetic and genomic testing and genomic data sharing be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.) for **MY CHILD's** samples.

FUTURE CONTACT:

_____ **YES:** I agree to be contacted in the future as a follow-up to this study or for future studies.

Preferred method of contact:

Phone (provide contact number): _____

Text (provide cell number): _____

Email (provide email address): _____

_____ **NO:** I do NOT agree to be contacted in the future as a follow-up to this study or for future studies.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY:

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, I freely and voluntarily choose to take part in this study, and I give permission for my child to take part in this study.

If you decide not to take part in this research study, it will not affect your or your child's treatment, payment or enrollment in any health plans or affect your or your child's ability to get benefits. You will get a copy of this form.

Date (MM/DD/YY)

Signature of parent/guardian

Date (MM/DD/YY)

Signature of person obtaining consent

Printed Name of person obtaining consent

Title of person obtaining consent