University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: The RHINO Study (Hospitalized with Pneumonia)

Formal Study Title: *Identifying the burden of hospitalization due to Rhinovirus (RV) in children and mechanisms of pathogenesis using airway molecular profiling*

Lead Researcher: *Ellen R. Wald, MD, 608-263-8543, 600 Highland Ave, Madison, Wisconsin 53792*

Institution: *University of Wisconsin – Madison*

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

We are conducting this study at the University of Wisconsin to study all of the viruses that cause colds and infection of the lungs in children. Rhinovirus is the most common cause of the common cold and it also causes infection of the lungs. There are 169 different RVs and we don't know which ones cause the more serious infection of the lungs. We are doing this study to find out which RVs cause the more serious infections. It is possible that if we can learn which RVs cause more serious infection, we will be able to prevent it with a vaccine or develop a treatment.

We invite your child to take part in this research study because your child has been admitted to American Family Children's Hospital (AFCH) with an infection that may be caused by RV. We expect your child's participation in this study will end before their 18th birthday. The study team will not collect any data from your child's medical record on or after their 18th birthday without your adult child's written consent.

What will my child need to do in this study?

The research team will ask you to allow the study team to review your child's medical chart and perform two nose swabs on your child. One swab will collect a sample right in the front of the nose, and the other swab will collect a sample from the middle of the nose. If your child's care team collects any lung or airway samples during their hospital stay, the study team will work with the care team to gather any leftover samples for research purposes. Around the time we get leftover samples, the study team will also

collect more nasal swabs from your child. The study also includes a one-time optional blood draw and a one-time optional cough sample of mucus from the chest.

We expect that your child will be in this research study for the time they are in the hospital, until they are discharged.

You can find detailed information about the study procedures in the section called **If my child takes part in the study, what will they do?**

What are some reasons I might – or might not – want my child to be in this study?

You may want your child to be in this study if you are:	You may NOT want your child to be in this study if you:
• Comfortable having researchers ask questions about your child's health. • Willing to have your child's nose swabbed. • Interested in contributing to scientific knowledge even though your child won't benefit directly from the study.	• Want to be in a study that might help improve your child's own health. • Are nervous about having your child's nose swabbed.

Does my child have to be in the study?

No, you do not have to enroll your child in this study. Taking part in research is voluntary. If you decide not to enroll your child in this study, your choice will not affect your child's healthcare or any services they receive. There will be no penalty to you or your child. You or your child will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When your child takes part in a research study, they are helping to answer a research question. Study tests and procedures are not for your child's health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at 608-228-4940.

If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns and assist in resolving any complaints.

If my child takes part in the study, what will they do?

(1) If your child takes part in this study, as soon as possible after admission to the hospital, a study team member will perform **two nasal swabs** on your child. This procedure is done while your child is in their hospital bed. One swab would be inserted into the front part of your child's nose for just a few seconds, gently rotated, and then removed. A second swab would be inserted into the middle part of your child's nose for just a few seconds, gently rotated, and then removed. The two swabs will then be sent to the laboratory to determine which viruses might be present and how your child is responding to them.

If your child's care team collects any lung or airway samples during their hospital stay, the study team will work with the care team to **gather any leftover samples for research purposes**. Around the time we get leftover samples, the study team will also collect **more nasal swabs** from your child.

Genetic testing: Some of the tests we will perform on your child's nose samples will be genetic testing, which is done on their DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be. We will be looking at which genes in your child's nose are turned on or off by the virus.

(2) The study team will also **verbally ask you and your child some questions** about your child's health and basic demographic information.

(3) We will **review your child's medical chart throughout their hospital stay** to see the progress they have made.

(4) You will have the choice later in this consent form to opt in or out of your child providing a **one-time blood sample of less than ½ a teaspoon**. Whenever possible, we would collect the blood sample at the same time your child is getting blood drawn for their clinical care so that an extra poke is not needed.

(5) You will have the choice later in this consent form to opt in or out of your child providing a **one-time cough sample of mucous from the chest.** This procedure will be performed by a Respiratory Therapist who is experienced at doing this test. Your child would be given a breathing treatment to open up the airway shortly before the procedure. Then your child would be given another breathing treatment with a salt water solution to encourage a deep cough. A suction tube may need to be passed through the nose to collect the mucous from the airway if your child is not able to cough it up.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your child's physical health that includes your child's name or other information that can identify your child, like date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your child's health
- Information currently in your child's medical records as well as information added to their medical records during the course of this study. This information could include medical history; diagnosis; lab test results or medical imaging. We will get this information from your child's health care providers.

What happens if I say yes, but I change my mind later?

Your child can leave the research at any time. If you choose to have your child leave the study, your choice will not affect your child's healthcare or any services your child receives. No matter what decision you make, and even if your decision changes, there will be no penalty to you or your child. Your child will not lose medical care or any legal rights. If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Your authorization for researchers to use your child's protected health information (PHI) will last until the research study is done and then indefinitely. However:

- You can choose to take back your authorization for researchers to use your child's health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about your child.
- If you take back your authorization, your child will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Ellen Wald, at 600 Highland Avenue, Madison, Wisconsin 53792.

Will being in this study help my child in any way?

Being in this study will not help your child directly. Your child's participation in the study may benefit other people in the future by helping us learn more about how often RV causes serious infections in the lung.

What are the study risks?

- Physical risks – there may be slight discomfort from the performance of nose swabs, sneezing, watering of the eyes or a small amount of bleeding.

- Psychological risks – The verbal questionnaires may make you or your child feel uncomfortable.
- Privacy risks - The other risk of taking part in this study is that your or your child's study information could become known to someone who is not involved in performing or monitoring this study. We will take many precautions to keep your and your child's health information private.

Who has access to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, as described in this consent form.

However, we cannot promise complete confidentiality. We will share information with individuals or organizations identified in this consent form. Federal or state laws may also permit or require us to show information to university or government officials and to study sponsors responsible for carrying out or monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as the Human Research Protection Program, and the Food and Drug Administration.

The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means we will not share any information that would identify you as a participant in the study, even if the police or courts ask to look at the data we have collected.

We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once we share your identifiable health information outside UW-Madison, the HIPAA Privacy Rule may no longer protect it. However, we try to make sure that everyone who sees your health information keeps it confidential.

We will share information and samples collected for this study with researchers or organizations outside UW-Madison, including University of Washington, Seattle and the Benaroya Research Institute in Seattle.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Will information from this study go in my child's medical record?

Your child's medical record might say that they participated in this study, and a copy of this consent and authorization form might go in their medical record. None of the results from this study will go in your child's medical record.

Will my child's information and samples be used in other research?

This study is collecting information and samples from your child. We would like to make your child's information and samples available for other research studies that may be done in the future without additional consent from you. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions. Your information and/or samples may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your information and samples indefinitely. To get your information and/or samples, future researchers must seek approval from this institution and review by an IRB may be required.

Your child's name and other information we think could identify them will be removed from any information and samples your child provides before they are shared with other researchers. Researchers cannot easily link your identifying information to the information and/or samples. However, there remains a possibility that someone could identify your child. There is also the possibility that people who are not supposed to might access your child's information and/or samples. In either case, we cannot reduce the risk to zero.

Participating in this study means you agree to share your child's information and samples. You can change your mind later, but researchers might still use your child's information and/or samples if they have already been shared or have been de-identified and can't be removed. If you do not want your child's information and samples used for other research studies, you should not allow your child to participate in this study.

Because genomic data and health information from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect genomic data and health information from research studies. We will put genomic data and health information from this study in a federal database or in other public scientific resources to make the information broadly available. Data will be available for a wide range of research not limited to health, such as research about population origins or ancestry and health-related research. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your child's genomic data and health information may be used for research that you disagree with or would not choose to be involved in. We will share the data from this study in a database that requires researchers to request access and receive permission to use the data for a specific research project. This is called "controlled access." Only genomic summary results, a

summary of the information generated from hundreds, or thousands, of research participants, would be shared in a database that does not require permission.

Will I receive the results of research tests?

Most tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or unexpected findings.

Can my child be removed from the research without my agreement?

The person in charge of the research study can remove your child from the research study without your approval. Possible reasons for removal include:

- your child's health changes and the study is no longer in their best interest
- your child does not follow the study rules or no longer meets the requirements to be in the study
- the study is stopped by the sponsor or researchers

What else do I need to know?

Information about genetic research

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurance companies or health plan administrators from requesting or requiring genetic information of you or your family members or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments.

Will my child receive anything for participating?

If you agree to have your child take part in this research study, we will pay you $50 for your time and effort. If you choose to have your child contribute an optional blood sample, you would receive an additional $10. If you choose to have your child contribute an optional cough sample, you would receive an additional $40. See "Optional study activities" section below for more information.

This payment will be included to help offset time/cost expenses for this study. This payment is considered taxable income. If payment to an individual exceeds more than $600 in one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) on a 1099 (Miscellaneous Income) form. You will be sent a 1099 MISC tax form from the University of Wisconsin-Madison and a copy will be sent to the IRS. Study staff will discuss this with you before your participation in the study will begin, including the amount available during your time in this study.

The University of Wisconsin uses a third-party system to provide these stipends. Ensure you read the participant handouts related to receiving stipends. You will only be reimbursed for the study activities you complete, as detailed below.

Permission to communicate about the study by email
We are requesting your email address so we can use it to communicate with you and answer any questions you may have. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study team at 608-228-4940. You do not have to provide your email address to participate in this study.

How many people will be in this study?
We expect about 670 people will be in this research study

Who is funding/supporting this study?
This research is being funded by the National Institutes of Health.

Optional study activities

Diagnosing precisely what type of bacteria or virus causes pneumonia is very difficult. We are collecting different types of samples to better be able to identify the cause of your child's illness. This part of the consent form is about two additional research activities that you can choose to have your child take part in. Your child can still take part in the main study even if you say "no" to these activities. The optional activities will not help your child directly.

If you opt in to the blood sample and/or cough sample, the clinical team may give infants oral sucrose (Sweet-Ease) for their comfort. This is at the discretion of the treating provider as part of routine clinical care. Therefore, Sweet-Ease is not considered a study drug.

Blood Sample

As soon as possible, we will draw an additional sample of blood (less than ½ teaspoon), and whenever possible, we will collect the blood sample when your child receives a blood draw for their clinical care. The blood will analyzed using a test called Polymerase Chain Reaction, or PCR. This type of test is a little better than ordinary blood cultures at finding some germs (bacteria) that cause pneumonia.

The purpose of the blood test is to increase the likelihood that we can find out exactly what germ is causing your child's pneumonia.

- We will try to have the additional blood drawn when another sample is required for clinical care so your child does not need to have an extra poke.
- If the sample is drawn as an extra poke, it may cause temporary pain and possible bruising.

Place your initials next to one of the following options:

____Yes, I agree to have my child give a blood sample for research purposes.

____No, I **do not** agree to have my child give a blood sample for research purposes.

Cough Sample

As soon as possible, a Respiratory Therapist would come to your child's hospital room and give them a breathing treatment to open up the airway shortly before the cough procedure. Then your child would be given another breathing treatment with a salt water solution to encourage a deep cough. A suction tube may need to be passed through the nose to collect the mucous from the airway if your child is not able to cough it up.

If you opt in to having an induced sputum sample done, your child will receive three medications for this procedure. They will receive small amount of a topical anesthetic in their nose called lidocaine to numb the area. They will be asked to breathe in a medication called albuterol to open up the airways. They will then receive a salt water (also known as "saline") breathing treatment to make them produce a deep cough.

These are potential side effects of these medications:

Lidocaine – Allergic reactions can occur but are very rare. An allergic reaction could cause rash, swelling or low blood pressure. Drowsiness or other nervous system problems are very rare but have been reported.

Saline – Can cause a cough. This is why we give it.

Albuterol – Can cause jitteriness, dizziness or make your child more excited. It can sometimes increase the heart rate and make the heart pound harder.

The purpose of the cough test is to increase the likelihood that we can find out exactly what germ is causing your child's pneumonia.

Place your initials next to one of the following options:

____Yes, I agree to have my child give a cough sample for research purposes.

____No, I **do not** agree to have my child give a cough sample for research purposes.

____Not Applicable, my child cannot give a cough sample since they have poorly controlled asthma and/or a known allergy to lidocaine, any "-caine" anesthetic, or albuterol.

Agreement to participate in the research study: Child participants

You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child's participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

When parents/guardians agree to participate in the optional induced sputum collection, a second parent/guardian signtuare is required below.

Signature of a second parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of person obtaining consent and assent | Date

Printed name of person obtaining consent

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Second Signature

- ❑ A second parent/guardian signature was NOT required since they did not consent to the optional inducd sputum.
- ❑ A second parent/guardian signature was required and obtained since they did consent to the optional inducd sputum.

The following witness line is to be signed only if this consent form is read aloud to a participant unable to read.

My signature below documents that the information conveyed in the consent process was accurately communicated in the language spoken by the participant and that the participant's questions were answered.

Signature of witness | Date

Printed name of person witnessing consent process

Agreement to participate in the research study: Reconsent as adult

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

The following witness line is to be signed only if this consent form is read aloud to a participant unable to read.

My signature below documents that the information conveyed in the consent process was accurately communicated in the language spoken by the participant and that the participant's questions were answered.

Signature of witness	Date
Printed name of person witnessing consent process	