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 (Younger Community Group)

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 they are between 12 and 36 months old, are generally healthy, and get care from UWHealth.

What will my child need to do in this study?

The research team will ask you to come into the research clinic for an in-person study visit to collect two nose swabs and answer verbal questions about your child's health and demographics. Then we will want to obtain two nose swabs and your responses to a brief online questionnaire any time your child is sick, as well as four times a year when they are well. One nose swab is collected from the front of the nose, and the second nose swab is collected from the middle of the nose. The nose swabs can be collected by families at home, with or without the support of the study team via virtual visit. Or you may bring your child for an in-person visit so that the study team can collect the nose swabs.

We expect that you and your child will be in this research study for about three years.

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, either by a study team member or by family at home. • Willing to participate in the study for three years. • 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 608-890-3840 or email RHINOstudy@pediatrics.wisc.edu.

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) Enrollment Visit (30-60 minutes, at University Hospital)

If your child takes part in this study, the study team will verbally review inclusion and exclusion criteria with you to confirm your child is eligible to join the study. Next, the study team will verbally ask you questions about your child's health and demographics. The study team will demonstrate and perform two nasal swabs on your child. We will ask you to hold your child still while the study team swabs their nose. One swab will be inserted into the front part of your child's nose for just a few seconds, gently rotated, and then removed. The second swab will be inserted into the middle part of your child's nose for just a few seconds, gently rotated, and then removed. The study team will deliver the two swabs to the laboratory, and the swabs will be analyzed to determine if any viruses are present, as well as how your child is responding to the viruses.

During this visit, the study team will also provide verbal and written instructions about surveillance and sick sample collection and survey completion (see details below). The study team will send you home with sample collection and prepaid, self-addressed mailing materials, if you feel comfortable collecting samples from your child at home. The study team will also give you the option to bring your child to a UW Health Hospital or Clinic for the study team to collect nasal samples.

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) Virtual Post-Enrollment Check-in Visit (10-15 minutes, telephone or video call)

About one month after your first visit (and no later than 3 months after enrollment), the study team will check in with you via phone or video call at a time that you can schedule and plan for. This brief virtual visit an opportunity for you to ask any questions you have after being in the study for a few weeks. If you'd like, the study team can also use this time to observe you collecting a nasal sample at home to make sure you feel comfortable with the process.

(3) Annual Check-in Visits (30-60 minutes, at University Hospital)

You will be asked to bring your child for an in-person study visit after their first and second years in the study. The purpose of this annual check-in visit is to provide you

with more home testing supplies, review sample collection techniques, confirm your contact information is all current, and answer any questions you may have.

(4) 3 Years of Surveillance Sample Collection (15 minutes, up to 12 times)
Four times a year during specified surveillance months (February, April, September, and December), two nasal swabs need to be collected from your child when they are healthy. These swabs may be collected by caregivers at home or by a study team member at a UW Health hospital or clinic. At each timepoint, the study requires two nose swabs—one from the front of the nose and one from the middle of the nose. We can only collect surveillance samples during these surveillance months if/when children have been free of respiratory symptoms for at least two weeks before sampling.

Caregivers may collect samples at home, either independently or with the support of the study team via virtual visit. Families will also have the option to bring their child for in-person visits so that a member of the study team can collect the nasal samples. When caregivers collect samples at home, you will either mail samples to the study team in prepaid, self-addressed mailing containers, or you can drop samples off to a study team member. The study team will be available to you by phone and email to coordinate sample collection and delivery.

Each time a surveillance sample is collected, the caregiver will also complete a very brief REDCap survey easily accessible through a link on the study's website. The survey will collect information about sample collection (i.e., date, time, etc.) and your child's present health.

(5) 3 Years of Sick Sample Collection (24-48 hours after symptoms start; 15 minutes each time your child gets sick)

At the Enrollment Visit, you will receive instructions about what to do when your child develops respiratory symptoms (runny nose, stuffed nose, sore throat, cough, fever, etc.). The study team will remind you of these instructions throughout your child's 3-year study participation. We will ask you to watch for respiratory symptoms and collect two nose swabs 24-48 hours after symptoms begin.

Families may collect samples at home, either by themselves or with the support of the study team with a virtual study visit. Families will also have the option to bring their child for in-person visits so that a member of the study team can collect the nasal samples. When caregivers collect samples at home, they will either mail samples to the study team in prepaid, self-addressed mailing containers, or they can drop samples off to a study team member.

Each time a sick sample is collected, the caregiver will also complete a brief online survey easily accessible through a survey link on the study's website. The survey will collect information about sample collection (i.e., date, time, etc.) and your child's present symptoms.

Submitting this online survey will alert the study team to your child's illness, and the study team will know to look out for nose swabs.

(6) Sick Follow-up Online Survey (5 minutes each time your child gets sick)

When you submit a Sick Sample Collection Survey, the study team will schedule a 7-10-Day Follow-Up Survey link to be emailed to you about 7 days after sick sample collection. The Follow-Up Survey will need to be completed 7-10 days after sample collection, and it will ask you for information about your child's illness and recovery. Doctors and nurses on the study team are available to you to answer questions.

(7) As-Needed Visits (30-60 minutes, at University Hospital or by telephone or video call)

If the study team notices any issues with the quality of the nasal swab samples, they may request that you and your child schedule and complete a visit to review the sample collection process. Depending on what the issue is with the samples, the study team may ask you to come to University Hospital for an in-person visit, or they may schedule and conduct a virtual visit (by telephone or video call).

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 they receive. 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 child's 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 information we collect for this study will go in their 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
- you do not follow the study rules or your child 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 I receive anything for my child participating?
If you agree to take part in this research study, we will pay you according to the Reimbursement Table below over three years for your time and effort. The total amount will depend on the number of sick and surveillance samples that your child provides over their three years in the study.

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.

VISIT	REIMBURSEMENT	TIME
Enrollment Visit	$50	30-60 minutes
Surveillance Sample & Survey (Up to 12 total)	$20 each	15 minutes each time
Sick Sample & Survey (As needed, for each respiratory infection)	$20 each	15 minutes each time
Completion Bonus For finishing the 36-month study period	$50	N/A

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 608-890-3840 or

email rhinostudy@pediatrics.wisc.edu. 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.

Agreement to participate in the research study

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.

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 (e.g., child is under the age of 7 years old).

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