The Microbes and Respiratory Illnesses Study

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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 MARI Study

Formal Study Title: The Microbes and Respiratory Illnesses Study

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Key Information

The information in this section is to help you and your child 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 a study at the University of Wisconsin looking at the relationship between rural and suburban children and their responses to common cold illnesses (also called viral respiratory illnesses). This study is called the Microbes and Respiratory Illnesses (MARI) Study. Children growing up on farms are exposed to many types of microbes that could be beneficial. We think that increased exposure to certain types of microbes early in life helps to develop a healthy immune system and reduce the risk for severe common cold illnesses, breathing problems, and allergies.

We invite you and your child to take part in this research study because your child is between the ages of 4 and 12 and is part of the Madison-area community, with or without asthma.

What will my child and I need to do in this study?

The research team will ask your child to come into the research clinic for an in-person study visit to collect biological samples (nasal samples, blood, saliva) and questionnaire data sometime over the summer. Then, starting the first week of September, we will ask your child to collect weekly nasal swabs at home and complete a paper diary about illnesses for the month. There will be an optional follow-up visit done in-person at the research clinic for a subset of families. We will discuss the optional visit more with you and your child during your visit.

We expect that you and your child will be in this research study for about 2 months.

You can find detailed information about the study procedures in the section called **If my child and I take part in the study, what will we do?**

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

It is unlikely there will be any direct medical benefit to you or your child for participation in this study. Even if the study does not help you or your child directly, the information we collect about the relationship between rural and suburban children during common colds could lead to new strategies to prevent these illnesses in the future. This may be highly valuable for many families outside of this study. Some people also find great satisfaction in advancing medical information and potentially helping others.

This study is not a substitute for your child's regular medical care. Your child should continue to see their regular doctor.

You and your child may want to be in this study if you are:	You and your child may NOT want to be in this study if you:
Comfortable having researchers ask questions about your and your child's medical and allergy/asthma history. Your child is willing to give nasal samples, blood and saliva samples for research tests. Willing to participate in the study for about 2 months. Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	Want to be in a study that might help improve your child's own health. Your child is nervous about giving blood samples or getting nasal swabs. May not have time to complete the illness diary for one month.

Do my child and I have to be in the study?

No, you and your child do not have to be in this study. Taking part in research is voluntary. If you and your child decide not to be in this study, your choice will not affect your healthcare or any services you or your child receive. There will be no penalty to you or your child. You and your child will not lose medical care or any legal rights. You and your child 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 you and your child take part in a research study, you and your child 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 or your child have questions, concerns, complaints, or think that participating in the research has hurt your child, talk to the study team at 608-890-3840 or email **maristudy@show.wisc.edu**.

If you or your child have any questions about your child's 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. Staff will work with you and your child to address concerns about research participation and assist in resolving problems.

If my child and I take part in the study, what will we do?

If you and your child choose to participate in this study, the researchers will ask you to provide information (including dates of birth and addresses) and biological specimens at a baseline visit done in-person at the research clinic. Then during the month of September, you will assist your child in collecting a weekly nasal swab and a daily illness diary at home. See Table 1 below for the visit schedule.

Table 1: Schedule of MARI Study Procedures	Timing of Visit	June-August	Sept Wk 1	Sept Wk 2	Sept Wk 3	Sept Wk 4	Sept/Oct Wk 5	October - November
		Baseline Visit	Home	Home	Home	Home	Home	Optional Sub-studies
Procedure / Biospecimen								
Eligibility		X						
Consent/Assent		X						
Questionnaires		X						X
Illness Diary		X	X	X	X	X	X	
Blood		X						X
Saliva (DNA)		X						
Nasal Filter Paper		X						
Nasal Swabs		X	X	X	X	X	X	X
Phone Call			X		X		X	

A brief description of the types of information researchers will collect from you and your child is below:

- **Demographics Collection**: Demographic information will be collected and will include (but is not limited to) name, address, date of birth, email address, phone number, etc.

- **Questionnaires**: We will ask you to complete questionnaires and other forms about you and your child. You will be able to complete them on a computer or tablet, by mail, over the phone, or in person.
  - Examples of information that we will collect includes**:**
    - Age, race, birth dates, sex, language, household information including physical address
    - Household environment and exposures to pets and smoke
    - Child and family health history and medications
    - Illness/symptom diary collected each day during the month of September
    - Allergy and asthma history

- **Samples:** We will ask to collect some samples from your child. Types of samples we will collect include:

  Blood: A blood sample will be collected by a trained staff member to test for allergies. The amount of blood collected will depend on your child's weight and will range from approximately two to four teaspoons. The area inside their elbow will be wiped down with alcohol prior to placing the needle in the vein. A medication to numb the skin may be placed on the skin before the needle is inserted. This may reduce the pain your child might feel. The use of this cream is optional. If you would like to use this cream, it must be on the child's skin 30-60 minutes before the blood is taken.

  Nasal Sampling: We will collect several samples of cells and mucus from your child's nose. This will be done by the study team at the baseline in-person visit. Researchers are interested in looking at the types of cells, the types of proteins and viruses, and environmental contaminants in the nose.
    - **Nasal Swabs:** Nasal cells and mucus will be collected by putting a tiny swab (the size of a Q-tip) in the nose. The swab is then removed from the nose. During the baseline visit, the study team will teach you and your child how to collect these swabs at home for the weekly collection. You will be given the materials to take home with you to be able to collect the nasal swabs at home and mail it back to the study site.
    - **Nasal Filter Paper:** Nasal secretions will be collected by inserting an absorbent strip into your child's nose for one minute.

  Saliva (spit): We will collect a saliva sample from your child. Your child's saliva will be collected by either spitting in a tube or by having a study team member, you or the child hold 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.

  Genetic Testing: Some of the tests we will perform on your child's saliva and nasal samples will be genetic testing, which is done on your 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.

As part of this study, we may examine the variation in your child's DNA. RNA is genetic material that carries instructions from DNA for controlling the building of proteins. We may examine the amount of RNA produced in the saliva your child provides.

The laboratories that are processing 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 your child or other information obtained from your child's samples will not be given to you, your family or your doctor.

- **Follow-up Phone Calls:** The study team will call you at the start of September, midway through and at the end to make sure you and your child have everything you need to collect the weekly nasal swab and complete the daily illness diary. We will use this check-in to get updated contact information and answer any questionnaires about the collections for September. These calls should not last more than 15-20 minutes.

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

You and your child's name, address, and birthdate
Results of tests or procedures done as part of the study
Things you tell the researchers about your child's health

What happens if I say yes, but my child or I change our minds later?

You and your child can leave the research at any time. If you and your child choose to leave the study, your choice will not affect your healthcare or any services you or your child receives. No matter what decision is made, and even if your decision changes, there will be no penalty to you or your child. You and your child will not lose medical care or any legal rights.

If you choose to leave the study, any information or samples that were shared before you left the study will continue to be used. If your family decided to have samples banked for future research, they will not be destroyed unless you request that we do so. If your family decided not to have samples banked, we will destroy any remaining samples collected during your participation after our study is closed. We may ask you why you are leaving the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Your authorization for researchers to use you and your child's protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use you and 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 you or your child.
- If you take back your authorization, you and 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, James Gern, MD at 600 Highland Ave, CSC K4/918, Madison, WI 53792.

What are the study risks?

Questionnaires

Less Likely - You or your child may find some of the questions too personal or repetitive. You or your child may feel fatigued from answering the questions. You and your child may skip any question on the questionnaire or an entire questionnaire that you do not wish to answer.

Rare - There is also a chance that you and your child's answers may be read by others outside of the study. Neither your or your child's name is put on the questionnaires.

Blood Collection

Likely - The risk of having blood taken may include pain, bleeding, or bruising.

Less Likely - There is a small risk of infection at the site where the needle entered the skin. Lightheadedness and fainting rarely occur for non-fasting blood draws.

Nasal Swab Collection

Likely – The nasal swabs will be uncomfortable, and your child may have a brief nosebleed, sneezing, watering eyes, runny nose or postnasal drip. These symptoms will go away soon after the procedure is over.

Nasal Filter Paper Collection

Likely - The nasal filter paper will be slightly uncomfortable, and your child may have some sneezing, watering eyes or runny nose. This discomfort will go away when the procedure is over.

Saliva Collection

There are no known risks with saliva collection.

Genetic Analysis

For genetic analysis, it is unlikely but possible that in the future someone could trace the genetic information back to your child, or a blood relative. Even without your name or other identifiers, your child's genetic information is unique, like a fingerprint. 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.

General Risks from Participation

There may be some risks that are currently not known. There is a risk that your child's information could become known to someone not involved in this study. All efforts will be made to keep your personal information private and confidential. You and your child will be identified in the study by a code. Personal information from your and your child's records will not be released without your written permission.

Procedures in this research study may involve risks that are not possible to predict. You and your child will be informed of any new risks that may be identified during the study. Please ask your study clinician or the study staff to explain any procedures or risks that you do not understand.

Privacy and Confidentiality

By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others. Your confidentiality cannot be guaranteed in these circumstances.

What happens to the information collected for the research?

We have strict rules to protect your child's personal information and protected health information (PHI). We will limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify your child as a participant in the study.

However, we cannot promise complete confidentiality. Federal or state laws may require us to show study information to university or government officials responsible for monitoring research studies, such as the U.S. Office for Human Research Protections and the National Institute of Allergy and Infectious Diseases.

Authorizing the research team to use your child's PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information and biospecimens that we collect during this study for other research, or share it with other researchers without additional consent from you.

We will share information and samples collected for this study with researchers or organizations outside UW-Madison, including researchers at the University of Chicago, Vanderbilt University Medical Center, John's Hopkins, and Oklahoma State University.

Because data 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 data from research studies. We will put data from this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in. We will not share your child's name, birth date, or other information that could directly identify them.

Your child's study information such as results of the nasal swab analysis or questionnaire data 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 label the information in a way that could identify your child. We will not share your child's name, birth date, or other information that could directly identify them.

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?

A medical record may be created for you if you do not already have one. Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. None of the information we collect for this study will go in your medical record.

Will my child or 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 and your child will not be informed of any test results or unexpected findings.

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

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

- you and your child are lost to follow up meaning we are not able to contact you by telephone, email or mail
- the investigator no longer believes participation is in the best interest of you and your child
- your child does not tolerate the home collection of nasal samples and completing of home diaries

What else do I need to know?

Will my child or I receive anything for participating?

A subject stipend for completed study visits will be provided. This stipend will be included to help offset time/cost expenses for this study (research study visits to the UWHC). This stipend 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 trial 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 visits you complete, as detailed below.

VISIT	REIMBURSEMENT	TIME
Baseline Visit	$75	1.5 hours
September Week 1	$25	30 minutes
September Week 2	$25	30 minutes
September Week 3	$25	30 minutes
September Week 4	$25	30 minutes
September/October Week 5	$25	30 minutes
Optional Follow Up Visit	$25	30 minutes

As a participant in this study, you may have travel arrangements provided for you. The University of Wisconsin uses a third-party system to arrange payment for travel and transportation for study participants to and from scheduled study visits.

As a participant in this study, you, or family/caregivers of a participant may request:

Transportation

Mileage will be determined by using an internet-mapping program and reimbursement will be calculated at the current IRS standard business mileage rate
Parking Reimbursement: Up to ($20 USD) per study visit day

Permission to communicate about the study by email

We are requesting your email address so we can communicate study reminders or changes with you. 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 **maristudy@show.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 350 children total will be in this research study. This includes 250 children from the Madison-area Community at UW Madison.

Who is funding this study?

This research is being funded by the National Institutes of Health (NIH).

Optional study activities

This part of the consent form is about additional research activities that you and your child can choose to take part in. You can still take part in the main study even if you say "no" to these activities. The optional activities will not help you directly, and we will not tell you the results or put the results in your medical record.

Storage of Samples and Information for Possible Future Research Studies

After processing samples from this study, they might also be helpful for future research studies. We are asking your permission to store any leftover samples and data collected from you and your child at UW-Madison in what is called a "biobank." This biobank is called the Morris Institute of Respiratory Research (MIRR) Biorepository. This could include:

From the child: blood, nasal swab and filter paper, saliva
Information such as health information collected from the research study

The leftover samples would be coded with a randomly-generated number so they cannot be identified by anyone outside of our study team. If we share samples and information with other investigators for future research studies, they will not be able to figure out which samples and information are yours. Only the study team will maintain a link between your samples and your identifiable information.

You and your child do not have to participate in the biobank to be part of this study. If you do not agree, any remaining leftover samples not used in this study will be destroyed.

If you agree, this is what will happen with the stored leftover samples:

- The samples and information collected may be used in other research studies. We do not know exactly what studies the stored samples may be used for. The possible future research studies may benefit other people by helping other investigators learn more about allergies. There will be no direct benefit to you or your child from possible future studies that will be done with your samples or information.
- The samples and information may be shared with other investigators at the UW-Madison and outside the University.
- The samples could be stored for many years. You or your child can request to have your samples and information removed from the biobank by contacting the study team at any time. To do so, send your request in writing to the study team at the address on Page 1.
- Some possible future research studies could include genetic tests on the DNA from the blood samples. You can agree to allow your child's samples to be stored but not agree to allow genetic testing.

If you agree to allow possible genetic tests with your child's samples, it is unlikely, but possible that in the future someone could trace the genetic information back to your child, or a blood relative. Even without your name or other identifiers, your child's genetic information is unique, like a fingerprint. 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.

There may be other risks about sharing your child's genetic information that we don't know about right now. This is because the field of genetics is moving forward very quickly, and because we plan to keep your child's samples for an unknown period of time until they are used.

Consent for storage of leftover samples and data for possible future research studies in the biobank at UW-Madison:

1. I give my permission to store my child's samples and data in the biobank for possible future research studies.

_____**YES** I give my permission to store my child's samples and data in the biobank for possible future research studies.

_____**NO** I do **NOT** give my permission to store my child's samples and data in the biobank for possible future research studies.

2. I give my permission to store my child's samples and data in the biobank for possible future research studies including genetic studies.

_____**YES** I give my permission to store my child's samples and data in the biobank for possible future research studies including genetic studies.

_____**NO** I do **NOT** give my permission to store my child's samples and data in the biobank for possible future research studies including genetic studies.

Future Contact

We would like your permission to contact you in the future. We may contact you as a follow-up to this study or we may contact you to invite you and/or your child to take part in future studies. If you agree, we will keep your name, contact information, and a note that you participated in this study with a secure and confidential recruitment list. Your contact information will only be available to members of this study team. You can be taken off the recruitment list at any time by contacting the study team at 608-890-3840 or email **maristudy@show.wisc.edu** or by letting us know you no longer wish to participate if contacted in the future. If you would like to be added to the recruitment list, **initial** by your choice of "YES" or "NO" for the following study activity:

_____**YES** I agree to be contacted in the future as a follow-up to this study or for future studies for either my child or me. The best way(s) to contact me is:

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

Follow-Up Study Visit

If you agree, we may invite your child back to the research clinic after September for a follow-up visit to collect an additional nasal swab and/or another tube of blood. The additional samples will be used to look for antiviral responses and antibodies after viral infection. The subset of children selected for an additional nasal swab or additional tube of blood will be determined by the Investigators and study team based on which group

the child belongs to (Traditional agrarian community, Madison with asthma or Madison without asthma) and willingness to complete the procedure. If you agree and if your child is eligible for the follow-up study visit, the study team will reach out after the September collection period has ended to schedule the follow-up visit. You and your child may participate in both the optional blood collection and optional nasal swab collection, if selected. Your child will be reimbursed for their time and effort with an additional $25 for the follow-up visit. This visit is expected to take approximately 30 minutes.

Please **initial** by your choice of “YES” or “NO” for the following study activity:

1. I give my permission for my child to participate in the Optional Follow-Up Study Visit for **blood collection** if selected:

_____ **YES**, my child may participate if selected

_____ **NO**, my child may **NOT** participate if selected

2. I give my permission for my child to participate in the Optional Follow-Up Study Visit for **nasal swab collection** if selected:

_____ **YES**, my child may participate if selected

_____ **NO**, my child may **NOT** participate if selected

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

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

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

Assent

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

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent and assent