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| **RRH_Logo_CMYK_Line-01.jpg** | **1425 Portland Avenue Rochester, NY 14621- 3095** [**www.rochesterregional.org**](http://www.rochesterregional.org) |

**CONSENT TO TAKE PART IN A RESEARCH STUDY**

Name of Research Study: **A Study Evaluating Immunity to Acute Otitis Media and Nasopharyngeal Colonization in Healthy Children**

Name of Organization Sponsoring the Research Study: **Rochester General Hospital Research Institute and US Centers for Disease Control**

Name of Principal Investigator (Study Doctor): **Michael Pichichero, MD**

Address of Research Site: **Bay Creek Pediatrics, Newark Pediatrics or Finger Lakes Medical Association Geneva.**

Daytime Phone Number: **585-922-0970**24-Hour Phone Number: **585-922-0970**

**Y**our child has been asked to take part in a research study. First, we want you to know that taking part in a research study is entirely voluntary. Second, you need to know that there are important differences between being cared for in a research study and being cared for by your doctor outside of a research study:

* Outside a research study, you and your child's doctor have a great deal of freedom in making decisions about your child's health care.
* When you take part in a research study, the main goal is to learn things to help other patients in the future. The study team (your study doctor and the research staff that assist your study doctor) will follow the requirements for the research study.

Therefore, it's important that you understand the differences, if there are any, between the regular care your child gets from his/her doctor and what's involved in this research study. This consent document gives you important information about the research study. Please read this information carefully before deciding to let your child take part. No one can make your child take part and your child can stop at any time. If you choose to have your child take part in this research study, you will need to sign this consent document. You will receive a copy of the signed document for your records. This research study is being conducted for Rochester General Hospital Research Institute to who is sponsoring and will be paying for the conduct of the study.

**The following sections describe the research study. Please take as much time as you need to ask questions with your child's study team, with family and friends, or with your child's personal physician or other healthcare professional. The study team will answer any questions you have before you make a decision.**

1. **WHAT IS THE PURPOSE OF THE STUDY?**

Your child is being asked to take part in this research study because he/she has an ear infection and is between age 6 and 36 months old or is a healthy child 6 to 12 months of age.

Middle ear infections can cause a lot of pain and suffering for children. Some children have many ear infections, some have very few, and some children never, get ear infections.

The purpose of this study is to collect nose swabs, blood and ear fluid (biological samples) from children. We will collect samples over time to learn about ear infections in children. We will determine which types of bacteria live in the nose and cause ear infections, the immunity response that children make to the bacteria living in the nose, "colonization", the immunity response that children make after they have an ear infection, why the immunity response in some children is inadequate thereby resulting in repeated ear infections, and how the problem of ear infections might be treated better or prevented.

1. **HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?**

About 1100 children from Rochester, NY have taken part in this study over the past 11 years and we are extending the study for another 5 years, anticipating enrollment of another 500 children (about 100 children per year for 5 more years).

1. **HOW LONG WILL PARTICIPATION IN THE STUDY LAST?**

Your child may be in this study until he/she is 36 months old. Your child will need to visit the research site between 1 and 6 times during the study, depending on the age of your child, and additionally at any time when your child has an ear infection.

1. **WHAT WILL HAPPEN BEFORE THE RESEARCH STUDY BEGINS?**

If you decide to have your child take part in this study, we will ask you to sign this consent document before we do any study-related activities.

**5. WHAT WILL HAPPEN DURING THE RESEARCH STUDY?**

**Signing Up**

The study doctor will decide if your child is suitable for this research study. They will ask

about your child's health and examine him/her.

**Healthy Visits**

These visits can take place at 6, 9, 12, 15, 18, 24 and 30-36 months of age. For example, if your child joins the study at 15 months, they will have study visits at regular well child check-ups at age 15, 18, 24 and 30 —36 month old. At these visits the study doctor or nurse will:

* Ask about your child's health.
* Take 2 nose swabs.
* Nose wash with salt water.
* At 9 months and 24 months old check-ups, when a blood sample is routinely taken for a lead and anemia check we will take an extra ½-1 teaspoon of blood from a fingerstick or vein for study purposes.

**Ear Infection Visits**

If at any time you suspect your child may have an ear infection, they may come for a

sick visit. At a sick visit if your child has an ear infection the study doctor or nurse will:

* Ask about your child’s health.
* Examine your child to see if there is an ear infection.
* Take 2 nose swabs.
* Nose wash with salt water.
* Take a blood sample of about ½-1 teaspoon from a vein.
* Perform an ear tap of an ear infection is present.

An ear tap is used to take some fluid from your child's ear, to study the bacteria causing the ear infection.

The ear tap involves inserting a needle through your child's eardrum and withdrawing a sample of the infected fluid.

Before the ear tap, a numbing liquid is put into the ear canal with a special cotton plug, to numb the eardrum. Only people who are trained in doing ear taps will do the procedure. Ear taps relieve pain instantly.

The fluid will be used to find the bacteria causing the ear infection (if any). The ear infection will be treated according to standard care; this is not part of the study. Our research has shown ear taps result in more frequent first time cures and fewer ear infections and fewer children who go on to need ear tubes.

If your child requires the insertion of ear tubes because of repeated ear infections, he/she will remain in the study but instead of an ear tap when an ear infection occurs we will used a thin cotton swab to take a sample of the fluid draining from the ear tube.

The samples taken in this study will be used only for scientific research. The study staff, the sponsor, and its representatives will have access to the samples, which will be stored at a secure place chosen by the sponsor. Each sample will be labeled with a code, and not with your child's name, so that the lab staff testing the samples will not know who your child is. Some of the samples may be used for additional testing related to other studies about ear infections and the bacteria that cause them that may be taking place at the same time as this study. The samples will be stored indefinitely after the end of the study and then destroyed when they are no longer useful for research.

Your child's samples will not be identifiable to anyone in the research group. Only your study doctor will have a code to match your child's name and the samples that are taken for the research.

**6**. **WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF BEING IN THIS RESEARCH STUDY?**

Possible risks your child might experience from the nose swab, nose wash or blood draw include:

* Discomfort or pain.

Ear taps are done for research purposes only in this study, and would not normally be done for a child's first or second ear infection. Ear taps are indicated for repeated ear infections or treatment failures. Possible risks your child might experience from the ear tap include:

* Discomfort or pain.
* Bleeding from his/her ear.
* Injury to the small bones of the ear.

It is important that you tell your study doctor about all symptoms and side effects as soon as they happen if any occur. The phone numbers for the study team are on the first page of this document.

1. **WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?**

This research study is for research purposes only. You have no obligation to take part in this study. If you choose not to take part, your child would still receive standard medical care from your child's doctor.

1. **WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?**

Your child may receive benefit from the ear tap procedure such as relief from his/her ear pain. Also, our research shows that children who get an ear tap have 450% lower rate of repeated ear infections and 750% lower likelihood to receive ear tubes. Information learned from the study may help other children in the future.

1. **WHAT HAPPENS IF MY CHILD IS INJURED AS A RESULT OF TAKING PART IN THE RESEARCH STUDY?**

If your child experiences a research injury, the doctors of (location) Pediatrics and Rochester Regional Health will provide or arrange for medical treatment at no cost to you. Rochester Regional Health will cover the costs of this treatment. A research injury is any physical injury or illness caused by your participation in the study. If your child is injured by a medical treatment or procedure that he/she would have received even if he/she wasn't in the study that is not a research injury. Payment

for such things as lost wages, expenses other than medical care, or pain and suffering is not available. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

1. **IS BEING IN THE STUDY VOLUNTARY?**

Yes. Taking part in this research study is up to you. You may choose for your child not to take part. You can change your mind and withdraw (drop out) later. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could change your mind about your child taking part in this research study. Ifyou want your child to drop out, you should tell us. We will make sure he/she can end the study in the safest way. We will also talk to you about follow-up care, if needed.

The study doctor or the study sponsor may decide to take your child out of the study without your agreement if:

* Youdo not follow the directions of the study team;
* The study doctor decides that the study is not in your child's best interest;
* The study is stopped by the study sponsor, the institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the research to protect your rights), or by a regulatory agency;

If your child withdraws or is removed from the study, biological samples (for example, swab or ear fluid samples) that have been collected from your child can be withdrawn if they have not yet been analyzed or destroyed. If you want your child's samples withdrawn, you must tell the study team before or at the time your child leaves the study.

1. **WHAT WILL I HAVE TO PAY FOR IF MY CHILD TAKES PART IN THIS RESEARCH STUDY?**

There will be no charge to you for your child's participation in this study. The study-related procedures will be provided at no charge to you or your insurance company. You or your insurance company will be responsible for the costs of visits and procedures done as part of standard care.

1. **WILL I BE PAID FOR TAKING PART IN THIS STUDY?**

When samples are taken for the study, for your time and travel expenses related to your child's participation, you will receive a $25 gift card per healthy visit. If your child needs an ear tap, you will receive a $50 gift card, since this visit requires more of your time. You will also receive a $25 gift card for the follow up visits after an ear tap and ear infection visit.

1. **IF MY CHILD TAKES PART IN THIS RESEARCH STUDY, HOW WILL HIS/HER PRIVACY BE PROTECTED?**

Confidentiality of Records and HIPAA Authorization (Data Privacy Statement)

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your child's health information. Your child's health information is information that could be used to find out who your child is. For this research study, this includes information in your child's existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your child's health information will be used and who it will be given to ("disclosed") for this research study. It also describes privacy rights, including your right to see your child's health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your child's health information that are described in this Data Privacy Statement. If you do not want to allow these uses, your child should not participate in this study.

If you agree to let your child participate in the research study, your child's health information will be used and disclosed in the following ways:

The study doctor/investigator and staff will use your child's medical records and information created or collected during the study to conduct the study.

The study doctor/investigator and staff may send your child's study-related health information ("study data") **anonymously** to the National Institutes of Health (NIH), The US Food and Drug Administration (FDA), Centers for Disease Control and Prevention and/or pharmaceutical companies.

The study data sent by the study doctor/investigator to NIH, FDA, CDC or pharmaceutical companies does not include your child's name, address social security number, or other information that directly identifies him/her, thus it is anonymous. Instead, the study doctor/investigator assigns a numbering code to the study data. Some study data sent by the sponsor may contain information that could be used (perhaps in combination with other information) to identify your child (e.g. date of birth). If you have questions about the specific health information that will be sent by the sponsor, you should ask the study doctor/investigator.

The sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its vaccines in development and other tests and products relating to ear infections.

The sponsor may add your child's study data to data from other studies.in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.

Your child's study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the Rochester Regional Health Institutional Review Board overseeing this study at Rochester Regional Health.

Study data that does not directly identify your child may be published in medical journals or shared with others as part of scientific discussions.

Your child's original medical records, which may contain information that directly identifies them, may be reviewed by the sponsor, the Rochester Regional Health Institutional Review Board overseeing this study at Rochester Regional Health, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.

The sponsor works with business partners in vaccine and drug development. The sponsor may share your child's study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your child's study data in the same way as the sponsor.

The sponsor will not disclose personal health information to insurance companies unless required to do so by the law, or unless you provide separate written consent to do so.

Your child's medical records and study data may be held and processed on computers.

If research related procedures are performed within the Rochester Regional Health (RRI-1) (i.e. laboratory tests, imaging studies and clinical procedures), the results will be placed in your child's Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RRH staff who are not part of the research team.

Your child's health information may no longer be protected by HIPAA privacy rule once it is disclosed by your study doctor/investigator to these other parties.

You have the right to see and copy your child's personal health information related to the research study for as long as this information is held by the study doctor/investigator or Rochester Regional Health. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing written notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your child's personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of their personal health information to preserve the scientific integrity of the study. The sponsor will still use study data that was collected before you cancelled your authorization. If you cancel your authorization, your child will no longer be able to participate in the study. However, if you decide to cancel your authorization and - withdraw your child from the study, you will not be penalized or lose any benefits to which your child is otherwise entitled.

**Will My Authorization Ever Expire?**

This Authorization does not have an expiration date. The study team may need to correct or provide missing information about your child even after your child's study participation is over. The review of your child's medical records (described above) may also take place after the study is over.

**May I Look At My Study Information?**

You have a right to see and make copies of your child's medical records. However, to ensure the reliability of the study, you will need to wait to see your child's study records until the study is completed.

**14. WHO SHOULD I CONTACT ABOUT MY CHILD'S RIGHTS OR IF I HAVE QUESTIONS?**

Before you sign this document, you should ask questions about anything that you do not understand. The study team will answer your questions before, during, and after the study. If you do not think your question was fully answered or do not understand the answer, please continue to ask until you are satisfied.

If you have any concerns or complaints about this study or how itis being run, please do not hesitate to discuss your concerns with the study team. The phone numbers to reach the

study team are on the first page of this document. If you do not feel comfortable discussing your complaint with the study team, please contact the Investigational Review Board listed below.

If you have any questions about your child's rights as a research participant, or you would like to obtain information or offer input, or you wish to speak with someone **not** directly involved with the study, you should contact:

**IRB Administrator, Rochester General Hospital Investigational Review Board**

**1425 Portland Avenue, Rochester, NY 14621, phone: 585-922-5640**

**15. Conflict of Interest Statement**

The Rochester General Hospital is receiving payment from the Centers for Disease Control and Prevention (CDC) for conducting this study.

**16. SIGNATURES**

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I freely consent to have my child take part in this study. I do not give up any of my legal rights by signing this consent document. I understand that I will receive a signed and dated copy of this document.

Printed Name of Study Participant

Printed Name of Parent/Guardian

Signature of Parent/Guardian Date of Signature

(Please initial) I agree to the use of my child’s blood, middle ear fluid, nose swabs and nose wash for future research.

(Please initial) I do not agree to the use of my child’s blood, middle ear fluid, nose swabs and nose wash for future research.

**PERSON OBTAINING CONSENT**

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion Date of Signature

**WITNESS**

The parent/guardian has indicated to me that the research has been explained and the parent/guardian has read the consent and had an opportunity to ask questions and have them answered. In my judgement, the parent/guardian is signing this consent form voluntarily. (Study personnel may not act as a witness)

Printed Name of Witness

Signature of Witness Date of Signature