CONSENT FOR A CHILD TO BE A SUBJECT IN MEDICAL RESEARCH AND AUTHORIZATION TO PERMIT THE USE AND SHARING OF IDENTIFIABLE MEDICAL INFORMATION FOR RESEARCH PURPOSES

TITLE **Efficacy of Tympanostomy Tubes for Children with Recurrent Acute Otitis Media**
Screening Phase

INVESTIGATORS: Alejandro Hoberman, M.D. 412-999-3277

Evening/Week-end Coverage: **(412) 999-EARS (3277)**

Source of Support: National Institutes of Health

What is this study about and why is it being done?
We are asking you and your child to take part in our research study because he/she has had at least one ear infection. Two out of every 10 children have multiple ear infections. These ear infections can be treated with antibiotics, but in some cases, placement of ear tubes is considered. This procedure is not the best answer for every child and some children improve without having tubes placed in the ears. We are doing this study to determine which children are most likely to benefit from ear tubes.

In Part 1, the screening phase, we identify children who might develop multiple ear infections in the future. Recurrent ear infections are defined as 3 ear infections in 6 months or 4 in the past 12 months. We would like to follow your child over time and have our study team examine his/her ears and confirm at least one ear infection. Children with recurrent ear infections will be asked to participate in the Part 2 of the study. You can participate in Part 1 without participating in Part 2.

What are my child and I being asked to do?
About 2000 children in Pittsburgh, Washington, DC, and Bardstown, KY between the ages of 6 and 35 months will be enrolled in this part of the study. If you enroll your child, we will ask you about your child's medical history and current medications. A general physical exam will be done. We will document the appearance of the eardrum at every visit. You can call us on the study cell phone anytime (412-999-3277). We will see your child anytime you feel he/she may have an ear infection. We will arrange a study visit within 2 days of any new symptom of an ear infection. If your child has an ear infection s/he will be treated as we would normally treat an ear infection with a standard prescription for antibiotics. The treatment is not part of the study. This visit should take about 30 minutes. About five days after each infection, we will ask you to complete a short form on your phone about the symptoms your child is having. If your phone does not accept emails, we will call you on Day 5. The phone call will not take more than 10 minutes. We will continue to follow your child for one year or until s/he has met our definition of recurrent otitis media.

Screening period - Enrollment visit
1. Identify children with ear infections
2. Explain that we would like to follow him/her for the next year to determine whether s/he develops more ear infections 3. Discuss that we will assess and manage episodes of ear infections and prescribe treatment, as necessary.

Sick visits
1. A child is seen due to new, continuing or worsening symptoms An ear examination will be done with photos of the ear drum if possible. 2. We will prescribe antibiotics as necessary for ear infections as standard care (not research).

What are the benefits and risks of participating in this research study?

Risks

Examination

There are no study procedure or study medications as part of this research. The risks are those associated with performing an ear examination and obtaining digital photos of the eardrum. Some children are uncomfortable holding still for the examination.

Confidentiality

Rarely (<1%), there is a risk of loss of confidentiality. All of the study data will be stored in locked file cabinets that are kept in the research area and computer records are password protected. Electronic data entries will be stored on a secure server that requires an account with a password in order to obtain access. .Every staff member has their own unique password. All specimens and electronic diary entries will only have the patient study identification number on them. Identifying codes that could be used to link your child with this identification number will be kept in a locked file cabinet in the research office.

Benefits

In this study all children have the potential for benefit. Study participants may benefit from early detection and appropriate antibiotic treatment of ear infections with close clinician monitoring of their symptoms. If your child is sick or is worsening or not improving they can be evaluated without delay and treated as needed. You will have 24-hour access to the study physicians who will arrange a study visit, within 24 hours, if indicated. This investigation will provide indirect benefit to children who experience recurrent ear infections because this study will help us to determine which children may benefit from having tubes placed in the ears.

May I refuse to give my permission for the use of my child's medical information for the purpose of this research study?

Your permission to use and share your child's medical information for the purpose of this research study is completely up to you. However, if you do not provide your permission, your child will not be allowed to be in this study.

What alternatives are available to my child if I don't give my permission for him/her to participate in this study?

You may choose not to be a part of the study and have usual clinical care as determined by your health care provider. Participation in this study is up to you. Choosing not to participate in this study will not affect you or your child's present or future relationship with the Children's Hospital of Pittsburgh or any UPMC hospital or affiliated health care provider of the University of Pittsburgh.

What if my child's doctor is one of the investigators for this research study?

If your child's physician is involved as an investigator in this research study, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

What if there is new information while my child is in this study?
If any information is learned that might affect your willingness to have your child continue to be in this study, you will be informed.

What costs will be associated with permitting my child to participate in this research?
You will not be charged for any study visits while your child is a participant in this study. Your child's ear infection will be treated as standard care and the cost of the medication will be covered by your child's health insurance or by you; the medication is not part of the research study. If your child develops a yeast diaper rash, we will prescribe an antifungal cream. You or your insurance company will be charged for any procedures or treatment performed for your child's routine medical care. To help cover any expenses such as transportation or time off from work, we will provide a WePay debit card: $15 at study entry; $15 for any sick visit.

How will my child's privacy rights be protected?
Under the Health Insurance Portability and Accountability Act (HIPAA), your child's private health care information cannot be used for the research purposes of this study without your permission. You will be informed of the specific uses and disclosures of your child's medical information for the purpose of this research study and who will have access to your child's health information.

What uses of my child's medical information will this research involve?
This research study will involve the recording of existing medical information as well as medical information that will become available while your child participates in this study. From this material, report forms will be prepared so that your child's medical information, such as prior treatments, medical history, diagnosis, age, gender (male or female), and ethnic origin can be compared to that of other children participating in this research. If the results of this study are published, information concerning your child will be in a form such that he/she cannot be identified.

This information will be reported to the NIH. We will store and process the information about your child using a computer. Your child's personal identity (name, address, and other identifiers) will remain confidential. In the database, your child will only be referred to by a study identification number. Only the study staff will be able to link the code number to your child's name. The NIH or regulatory authorities may directly access your child's medical records in order to determine the accuracy of the reported data. These representatives will observe professional secrecy and keep your child's identity confidential to the extent permitted by law.

Will participation in this research result in medical information being placed in my child's medical records?
Your child's participation in this study will result in specific research related health information being placed in the Children's Hospital of Pittsburgh medical chart, outpatient chart, or research record. A letter will be sent to your child's primary care provider with information about their study participation and the letter may be added to your medical records. It will include a phone number for your care provider to contact the study if needed.

Who will have access to my child's medical information related to his/her participation in this research study?
In general, research records are kept confidential. Each computer has a password only available to the study staff. Paper records are stored in locked cabinets and computerized records are password

protected. There are, however, some disclosures of your child's research-related medical information that may occur. In addition to Dr. Hoberman and his research staff, the following persons may have access to your child's identifiable private health information related to your child's participation in this research study.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your child's identifiable medical information) related to your child's participation in this research study for the purposes of (1) fulfilling orders made by the investigators, for hospital and health care services (e.g. laboratory tests, diagnostic procedures); (2) addressing correct payment for tests and procedures; and/or (3) for internal hospital operations (i.e. quality assurance).

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your child's identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. Authorized representatives of the NIH and the Office for Human Research Protections (OHRP) may review and/or obtain your child's identifiable medical information for the purpose of monitoring the accuracy and completeness of the research data, for performing required scientific analyses of the research data, and reanalysis of the research data at a later date and to be sure that the research is being conducted according to the guidelines of each institution. While these organizations have provided their assurance that they will not release your child's identifiable medical information to anyone else, the Children's Hospital of Pittsburgh cannot guarantee this. In unusual cases, the investigators may be required to release your child's research information in response to a court order. Research investigators may be required under Pennsylvania law to report any suspicion of child abuse to child protection services. If the investigators learn that you or someone with whom you are involved is in serious danger of potential severe harm, they may need to warn those who are in danger and contact other agencies to ensure safety.

May I have access to my child's medical information resulting from participation in this research study?

In accordance with the Children's Hospital of Pittsburgh's Notice of Privacy Practices document which you have been provided, you are allowed to look at information (including information resulting from your child's participation in this research study) contained within your child's medical records unless specifically stated.

May I stop my child's participation in this study and may I withdraw my permission for the use of my child's medical information for the purpose of this research study?

You have the right to stop your child's participation in this study at any time. Your child's participation in the study may also be discontinued without your consent, by your doctor, the NIH or the Office for Human Research Protections, if based on their judgment it might improve your child's medical care or if you fail to follow the study schedule. Your child will receive the same quality of care at this hospital whether or not he/she is in the study. Additionally, you may withdraw, at any time, your permission for the use of your child's medical information for the purpose of this research study. Of course, if you withdraw your permission for the use of your child's health information, your child may no longer participate in this research study. To the extent that researchers have already used your child's health information in data analysis and/or scientific publication, this information cannot be withdrawn. Any publication of information will be such that your child's information will not be identifiable. If you decide to withdraw your permission, you should notify the study doctor in writing along with the date of your decision. Your decision to

withdraw your permission for the use of your child's private health information will have no effect on your or your child's current or future medical care at Children's Hospital of Pittsburgh, UPMC or affiliated health provider, or the University of Pittsburgh.

For how long will the investigators be permitted to use my child's identifiable health information?

Dr. Hoberman and his study staff will be permitted to use your child's identifiable health information indefinitely. Any information shared with those who are not members of the research team will be in coded, de-identified form.

Will there be any compensation if my child is injured or becomes ill as a result of participating in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Voluntary Consent and Authorization

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my child's rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). Dr. Hoberman 412-999-3277 will be available for questions about this research, my child's rights, and any possible research-related injury. I will receive a signed copy of this consent form.

_____
Printed Name of Child (Research Subject)

I understand that, as a minor (age less than 18 years), the above named child is not permitted to participate in this research study without my consent. Therefore, by signing this from I give my consent for his her participation in this research study.

_____ _____
Parent's Name (print) Relationship to Participant (Child)

_____ _____
Parent's Signature Date

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered and we will always be available to address future questions as they arise. I further certify that no component of this protocol was begun until after this consent form was signed.

_____ _____
Signature of Investigator Date

_____ _____
Printed Name of Investigator Role in Research Study