Department of Otolaryngology
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CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: Initiation of Acid Suppression Therapy Prospective Outcomes for Laryngomalacia

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What is the purpose of this research study?

- This study will help show if an acid reducer medication (famotidine or Pepcid) that is sometimes given to babies for laryngomalacia (LM) helps improve symptoms. We recently found there was a similar improvement between mild and moderate LM in patients who were on acid reducer medication and in patients who were not on acid reducer medication. However, since most infants were on an acid reducer medication, it is uncertain if these improvements are due to the medication or the natural resolution of LM.
- 160 patients will be randomly assigned (like flipping a coin) to be in either:
    A. prescribed famotidine (Pepcid) and receive speech language therapy (feeding therapy)
    B. or receive speech language therapy (feeding therapy) alone
- Participation is completely voluntary. It will not affect your child's care if you do not participate in the study.
- Speech language therapy (feeding therapy) with or without an acid reducer medication is the most common treatment for mild or moderate LM.

Who is being asked to participate in this study?

- 160 caregivers and their baby (6 months of age or younger) with mild or moderate laryngomalacia

What is the compensation or payment for participation?

- There is no compensation for participation.

What are my child and I being asked to do?

- You will be informed at your consult appointment if your child qualifies for the study based on symptoms and the scope performed.
- You will be asked to fill out the Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R) with 12 questions and the Pittsburgh Airway Symptom Score (PASS) with 10 questions at the consult and the follow-up appointment in 1 to 4 months.
- If your child qualifies for the study, they will be randomly assigned to receiving speech language therapy (feeding therapy) with or without famotidine (Pepcid). This means there is an equal change of either getting or not getting the famotidine (Pepcid). This medication is FDA-approved and is currently used to treat symptoms of laryngomalacia in children.
- Based on which group your child is randomly assigned to, you will be provided instructions on the dose of medication for your child
- Your child will also see a speech-language pathologist (SLP) on the day of your child's appointment.
- The study will not pay for your medications – you would purchase these medications just as you would if you were not enrolled in this study.
- You will be asked to give your child the medicine prescribed. Please consult your child's doctor with any change in medication or if you believe your child should stop taking the medication. The decision to prescribe any medication will be up to your child's physician.

- You will be asked to return to your child's Ear, Nose, and Throat (ENT) doctor in 1 to 4 months to check on your child. Please call the scheduling number provided or make a follow-up appointment at the consult.
- If you do not have a follow-up appointment for your child in 3 months, you will be sent an email to the email address on file with a link to take the two surveys (I-GERQ-R and PASS) electronically about your infant's current symptoms. If the surveys are not filled out electronically, a paper copy of the surveys will be mailed two weeks after the email to your home address on file with a postage paid envelope to return to the research office. If the surveys are not returned from the email link or paper copy, a researcher will call you to follow-up. You may take the surveys over the phone at this time or request another survey link or paper copy.
- For all medical questions please call the ENT nurse line at 411-692-5460, option 4 or send your doctor a virtual message.
- Neither you, nor your insurance, will be charged for this research. You will be charged for any procedures performed for your child's routine medical care.

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

- The medication being evaluated in this study is famotidine (Pepcid). Pepcid is a Histamine-2 blocker that works by lowering the amount of acid the stomach produces by blocking the histamine receptors (Pepcid.com).
- Some babies suffer from acid reflux. The benefit of taking famotidine (Pepcid) is to prevent more inflammation in your child's airway.
- The infrequent risks of famotidine (Pepcid) include worsening airway or dysphagia (swallowing) symptoms, increased risk for necrotizing enterocolitis (NEC), bone fractures, agitation or irritability, headache, vomiting, somnolence (drowsiness), anorexia (loss or lack of appetite for food), candidiasis (yeast fungal infection), and/or the inability to tolerate the medication. To decrease the risk of complications, give the medications as prescribed.
- Speech language therapy (feeding therapy) will be provided by a speech-language pathologist (SLP) at the consult appointment. The benefit of having this evaluation is to assess if your child has a swallowing or feeding disorder and will identify a treatment for adequate nutrition and optimal feeding. The infrequent risks include choking and the inability to tolerate a change in feeding (bottle nipple change).
- As with any research study involving a medicine, there may be problems or side effects that are currently unknown. Some of these unknown risks could be permanent, severe, or life-threatening. You will be quickly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate.
- The risk of collecting private health information may be a breach of confidentiality. We will do everything possible to protect your privacy and confidentiality, but no method of electronic storage is perfectly safe; therefore, absolute confidentiality cannot be guaranteed.
- The risks of completing surveys are breach of confidentiality, feeling uncomfortable answering the questions, and finding them cumbersome.

What are the alternatives to my child participating in this study?

- The alternative to participating is to follow the advice of and/or work with your child's doctor for LM management.

What should I know about the medical information you will be using?

- We are also asking for your authorization for the researchers listed at the top of this document to look at your child's medical records. We will look for things like age, race, zip code, insurance, primary language, diagnoses, ENT clinic information, ENT-related outcomes and any complications. This is needed to measure any differences in those taking famotidine (Pepcid) or not. This authorization is good for an unlimited amount of time.

Who will know that my child is in this research study?

- All physicians recruiting for the study and the researchers listed on the top of this form will know that your child is in this research study. Representatives from the UPMC Children's Hospital of Pittsburgh will have access to the medical record, including for billing and auditing purposes. The University of Pittsburgh Office of Research Protections may review your child's identifiable research information to make sure this study is

being done correctly. In unusual cases, the investigators may be required to release identifiable information related to your child's participation in this study in response to an order from a court of law. If we learn that your child or someone with whom they are involved is in serious danger or potential harm, we will inform the appropriate agencies. De-identified medical information may be shared with researchers who are conducting similar research. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US law. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time. However, you will not be notified about your child's individual research results.

How will my child's privacy rights be protected?

- A possible risk is that someone not on this form may see your child's information. However, paper records will be in a locked file in a locked office. Also, electronic information will be kept on a password-protected computer behind the UPMC firewall.
- Electronic records will be de-identified with linkage codes to help protect confidentiality.
- Per University of Pittsburgh policy, all research records must be maintained at least 7 years following final reporting or publication of a project. For projects involving children, records must be maintained for 5 years past age of majority (age 23 per PA state law) after study participation ends.

What happens if I decide that I no longer want my child to be in this study?

- At any time, you can decide to no longer be a part of the study. You can withdraw your authorization for us to use your child's identifiable medical information. To formally withdraw your consent for participation in this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Withdrawing from this study will not affect your child's care. When your child reaches age 18, your permission is no longer valid.

Can the study physician decide my child should no longer participate in the study?

- A study physician may decide that your child should not continue in the study for safety or other healthcare-related reasons. An example might be if she or he has an allergic reaction to the medication, or if there are other significant side effect or risks to your child's health from the medication. Another reason would be if the physician decides your child would benefit from surgical intervention to treat LM.

Who should I contact with medical questions?

- If you have any medical questions, you may contact the ENT department at Children's Hospital at 412-692-5460 and select option #4 to speak with a nurse. For all medical emergencies, call 911.
- If you think 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. You do not, however, waive any legal rights by signing this form.

VOLUNTARY CONSENT

The above information 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 part of this research study at any time. I understand that I may contact the University of Pittsburgh Human Subjects Protection Advocate of the IRB office (866-212-2668) to discuss problems, concerns, and questions.

By signing this form, I agree to participate in this research study by having my child be randomized into a treatment group. I authorize the research team to look at my child's medical records. A copy of this consent form will be given to me.

PARENTAL CERTIFICATION

_____	_____
Printed Name of Your Child	Your Relationship to Participant (Child)

I understand that, as a minor, the above-named child is not permitted to participate in this study without my consent; therefore, by signing this form, I give my consent for his/her participation in this research study.

_____	_____	_____
Parent's Signature	Parent's Name (Print)	Date

INVESTIGATOR CERTIFICATION

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

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date and Time