COMIRB
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Study Title: Use of Unsedated Nasal Esophagoscopy Using Ultrathin Pediatric Endoscopy for Monitoring Therapy in Eosinophilic Esophagitis

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You and your child are being asked to be in a research study. You in this form refers to you or your child. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the possibility of using endoscopy through the nose without the risk of sedation to follow up the health of the esophagus in a child with eosinophilic esophagitis.

The study team would like to see if the use of an ultrathin flexible tube and camera is safer and less expensive than undergoing a typical endoscopy with anesthesia and sedation.

We will also be looking to see if this procedure results in lower hospital charges and less of a chance of having pneumonia related to receiving anesthesia.

Your child is being asked to be in this research study because your child's primary gastroenterologist has recommended him or her to have a follow-up endoscopy with biopsies of his or her esophagus.

Other people in this study

Up to *90* people from your area will participate in the study.

What happens if I join this study?

If you join the study, your child will have endoscopy through the nose (insertion of a thin tube with a 3-4mm flexible camera attached to the end) that will look at your child's esophagus/feeding tube.

This is different from the endoscopy your child had done before because this will be done without sedation (your child was made sleepy) but your child will be given numbing medication to the nose and throat. A pulmonologist (lung doctor) or ENT physician (nose doctor) will assist with placing the scope in the nose while the GI

physician (stomach and esophagus doctor) will perform the evaluation and biopsy of the esophagus.

The esophagus/feeding tube will then be looked at and 3 pieces of tissues from two different areas will be taken. These pieces are about the size of a pinhead. After the pieces are taken, they will be analyzed for ongoing allergy by the pathologist at Children's Hospital Colorado. The study doctor will also look at the tissues taken from your child for quality and adequacy.

Your child's primary gastroenterologist will tell the results to you.

This procedure will take about 30 minutes.

After the procedure you and your child will be asked to fill out your satisfaction with the procedure, the ease of scheduling your procedure, and your satisfaction with the services provided. This is a 9-question multiple-choice survey. This will take about 2-5 minutes.

Approximately 2-6 weeks after your child's endoscopy you will be called and asked to fill out an electronic survey regarding your thoughts about the nasal endoscopy procedure.

The time that this procedure takes to occur will be collected and compared, if available, to the previous endoscopy.

The total cost of nasal endoscopy/esophagoscopy as your insurance company charges will also be collected. This will be compared to your previous scope test.

Your child's medical record number will be collected to help with gathering this information.

After you complete the survey, you and your child's participation in the study is complete.

What are the possible discomforts or risks?

Discomforts your child may experience while in this study include nose pain, sore nasal passages, a bloody nose, a sore throat, gagging, or nausea. There also may be some anxiety/nervousness experienced as a result of undergoing the endoscopy or filling out the survey.

Other possible risks include sore throat, bloody nose, sore nasal passages, nausea, vomiting, bleeding, bruising, infection, and rare risk of hole in the throat, nose, esophagus and the rare need for surgery, infection, or ICU admission. These risks are also associated with standard nose endoscopy or oral (mouth) sedated endoscopy. The risk of serious complication is generally thought to be less than 1 in 10,000 endoscopies.

The risks of the nasal numbing medication (lidocaine) may include an allergic reaction, bloody nose, nose swelling, numbing of the nose, fast heart rate, fatigue, itching, lightheadedness, redness of the nose, weakness, or a rare blood condition called Methemoglobinemia that can be serious and usually treated.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the use of nasal endoscopy without sedation in pediatrics (children) to evaluate eosinophilic esophagitis.

Are there alternative treatments/evaluations?

There may be other ways of evaluating your child's eosinophliic esophagitis. These other ways include standard upper endoscopy utilizing anesthesia and sedation, other research methods, or surgery. You could also choose to get no treatment at all.

You should talk to your child's doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. Your child may leave this study and still have these other choices available to him or her.

Who is paying for this study?
The study is being sponsored by the Digestive Health Institute, The Breathing Institute, and the Division on Otolaryngology at Children's Hospital of Colorado

Will I be paid for being in the study?
You will not be paid to be in the study.

Will I have to pay for anything?
You will need to pay your insurance's standard charge for esophagoscopy with biopsies.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose for your child to take part, you and your child has the right to stop at any time. If you or your child refuse or decide to withdraw later, your child will not lose any benefits or rights to which you are entitled.

If your child leaves this study, he or she will still receive his or her normal medical care. The only medical care that he or she will lose is the medical care he or she is getting as

part of this study. He or she might be able to get that same kind of medical care outside of the study. Ask his or her study doctor.

If there are any new findings during the study that may affect whether you want your child to continue to take part, you will be told about them by your child's primary gastroenterologist

Can I be removed from this study?

The study doctor may decide to stop you and your child's participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Joel Friedlander D.O., M.A.-Bioethics and your primary gastroenterologist immediately. His phone number is 720-777-4725 or 720-777-6669.

Who do I call if I have questions?

The researcher carrying out this study is Joel Friedlander D.O., M.A-Bioethics. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Joel Friedlander D.O., M.A-Bioethics at 720-777-4725. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Joel Friedlander D.O., M.A-Bioethics with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- Children's Hospital Colorado

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Joel Friedlander D.O., M.A-Bioethics
13123 E 16th Avenue, B290
Aurora, CO 80045

Others who have a legal right to see that information, such as may look at both the research records that identify you and the consent form signed by you:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data, Tissue, and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, or other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, or other specimens collected from you.
- If data, tissue, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Child's Name: _____ _____

First Middle Initial Last Date of birth

First Parent/Guardian Consent for Child's Participation:

I consent to allow my child to participate in this study.

_____ _____

1st Parent/Guardian Signature Date

Print Name: _____ _____

Relationship to Participant: ☐ **Mother** ☐**Father** ☐**Guardian** Time

Second Parent/Guardian Consent for Child's Participation: (if available)

I consent to allow my child to participate in this study.

_____ _____
2nd Parent/Guardian Signature Date

Print Name: _____ _____
Relationship to Participant: ☐ **Mother** ☐**Father** ☐**Guardian** Time

Child Participant Ages 13-17 Who Can Read This Consent:

I consent to participate in this study

_____ _____
Child Participant (Age 13-17) Signature Date

Print Name: _____ _____
Time

Consent form explained by

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

_____ _____
Signature Date

Title: ☐ Principal Investigator ☐ Sub Investigator ☐ Research Coordinator

Print Name: _____ _____
Time

Principle Investigator:

Investigator must sign within 30 days

_____ _____
Signature Date