

Valid for Use Through:

Informed Assent for:

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

Principal Investigator: Joel Friedlander, DO MA-Bioethics

COMIRB No: 13-2721

Version Date: November 27, 2013

What is this study about?

The goal of this study is to see if looking through a very small tube put in my nose to look at my esophagus will be a better way to see how the treatment for my eosinophilic esophagitis is going.

Why are you asking me?

I am being asked to be in the study because you have eosinophilic esophagitis (EoE) and because you have been receiving treatment

What Do I Have to Do or What Will Happen to Me?

If I am in the study, I will:

- *Be given some medicine in my nose/mouth to make my nose and throat numb*
- *Have a small video camera the size of a piece of spaghetti put in my nose that will lead to my esophagus to see how the treatment is working*
- *Have small pieces no larger than the tip of a pen taken from the esophagus to look under the microscope to see how the treatment is working*
- Be asked to fill out a survey with my parents of what we thought of the procedure
- The procedure and the survey will take about 30 minutes.

Will this Hurt?

- When I have the camera put in my nose or the biopsies taken it may feel like a pinch or a gag. The medicine should help with this.
- I might cry if I don't like how it feels.

Can I ask Questions?

I asked any questions I have now about the study. All my questions were answered.

I know that if I have a question later, I can ask and get an answer. If I want to, I can call Dr. Joel Friedlander at 720-777-6669

Do I Have to Do This?

I know that I do not have to be in this study. No one will be mad at me if I say no.

I want to be in the study at this time. yes no

I will get a copy of this form to keep.

Child's Printed Name: _____

Child's

Signature: _____

Date: _____

Witness or

Mediator: _____

Date: _____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _____

Date: _____

Initials: _____