

Valid for Use Through:

Informed Assent for:

Study Title: **A Multi-Center Study of the Prevalence of Known Congenital Sucrase-Isomaltase Deficiency (CSID) Genetic Variants and Functional Sucrase Activity by C-Sucrose Breath Test in Children with Chronic Diarrhea or Chronic Abdominal Pain.**

Principal Investigator: **Joel Friedlander, DO MA-Bioethics**

COMIRB No: **13-1469**

Version Date: **August 02, 2013**

What is this study about?

I am being asked to be in this research study. The goal of this study to better understand my stomach problems.

Why are you asking me?

I am being asked to be in the study because I have diarrhea or stomach pain.

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

If I am in the study, I will:

- *Visit 1:*
 - *Have my cheek swabbed.*
 - *Answer questions about how I feel.*
 - *The visit will last 10-20 minutes*
- *Visit 2:*
 - *Have my cheek swabbed.*
 - *Wear a mask and breath into a bag*
 - *Answer questions about how I feel.*
 - *The visit will last 3-4 hours*
- *Visit 3:*
 - *If Visit 1 or 2 has something that tests positive I will talk with the study doctor about my diarrhea and stomach pain.*
 - *The visit will last 30-40 minutes*

Will this Hurt?

- When I have my cheek swabbed it may be sore.
- I might cry when I wear a mask to breath into a bag

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: _____