COMIRB
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Study Title: **A Multi-Center Study of the Prevalence of Known Congenita Sucrase-Isomaltase Deficiency (CSID) Genetic Variants and Functional Sucrase Activity by 13C-Sucrose Breath Test in Children with Chronic Diarrhea or Chronic Abdominal Pain.**

Principal Investigator: **Joel Friedlander, DO, MA-Bioethics**
COMIRB No: **13-1469**
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You (you = you or your child) are being asked to be in a research study. This form provides you with information about the study. The Principal Investigator (referred to as the researcher in this consent form) and 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 why some people cannot digest table sugar well. The researcher wants to use a breath test to see how changes in a gene are connected with Congenital Sucrase-Isomaltase Deficiency (CSID). The official name of this gene is sucrase-isomaltase (*SI*).

You are being asked to be in this research study because you have experienced chronic diarrhea or chronic abdominal pain.

Other people in this study

Up to 150 people from your area will participate in the study.

Up to 2000 people around the country will be in the study.

What happens if I join this study?

If you join the study, you could be in this study for up to 8 weeks. Your time in the study may be shorter than 8 weeks if certain specifics are not met by the next study visit. If you join the study, you will be asked to do the following:

Visit 1 (10-20 minutes of time)

1. 4 Cheek Swab Samples: A research staff member will swab the insides of both cheeks. Only the gene connected with digesting table sugar will be looked at for changes.

2. Survey: The survey will take less than 5 minutes to complete. This survey asks general questions about intestinal problems.

3-4 weeks after **Visit 1,** you will be asked to return for a second visit if your genetic samples are possibly connected with chronic diarrhea or chronic abdominal pain.

You may be chosen by chance as 1 of 30 participants controls if your genetic samples do **not** have a genetic connection with chronic diarrhea or chronic abdominal pain.

You will be finished with this study if your samples do not show a genetic connection with chronic diarrhea or chronic abdominal pain, and if you are not picked by random chance to stay in the study'.
If you are asked to continue in the study, neither you nor the research staff will be told if your genetic samples are connected with symptoms of abdominal pain or diarrhea. You will receive a phone call to let you know if you can take part in Study Visit #2.

Visit 2 (3-4 hours of time)

1. 4 Cheek Swab Samples: A research staff member will re-swab the insides of both cheeks. The entire gene connected with digesting types of sugar will be looked at for specific types of changes .
2. Breath Sample: You will return to a scheduled clinic visit. Before this visit, you will be asked to not eat or drink anything for at least 4 hours. You will be asked to provide 5 breath samples over a 3 hour time period while eating small amounts of sugar for the breath test.
3. Medical History: The research staff will ask for medical history information from your medical records.
4. Family History: The family medical history will take less than 10 minutes to complete. This form will ask about any intestinal problems biological parents have experienced throughout life. It will be completed in person between breath samples.
5. Questionnaire: A questionnaire will take about 15 minutes to fill out that asks more details about your digestive symptoms.
6. If you previously had a biopsy taken by your GI physician for poor absorption of sugar the results will also be given to the researcher.

2-3 weeks after **Visit 2**, if the breath test shows a low level of sugar being digested, you will be contacted for a third visit. If you have a normal level of sugar being digested, you will be informed of this result and you will be done participating in this study**.**

Visit 3 (20-40 minutes of time)

Study Closeout: 2-3 weeks after **Visit 2**, you will return for a third visit. The researcher at Children's Hospital Colorado will discuss the breath test's study test's results. The researcher will also answer any questions you may have about caring for chronic diarrhea or chronic abdominal pain. Decisions about how to re-test and look at the research findings from the breath test will be up to your primary GI physician. A treatment plan to address chronic diarrhea or abdominal pain will be up to your primary GI physician. The researcher at Children's Hospital Colorado will not suggest any treatment or make further testing recommendations

At the end of the study to better understand the findings, the Lead Researcher, not at Children's Hospital Colorado, will test all genetic samples for any possible changes in the *SI* gene or other genes related to sugar digestion. All genetic samples will be destroyed after the researcher finishes these tests. These results are blinded (de-identified) and are not available to the researcher or physicians at Children's Hospital of Colorado.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include very minor risks associated with a cheek swab and collecting breath samples. There may be a very minor discomfort when the cheek is swabbed, but this discomfort will pass immediately when the swab is removed.

The researcher or research staff may use a mask to help do the breath test in small children. This mask may cause a small child to cry. It will not hurt a small child and does not make it hard to breathe.

People in this study who have troubles digesting table sugar may experience diarrhea, gas, bloating, or abdominal pain.

Some of the questions asked as part of this study may make you feel uncomfortable.

You may stop answering any of the questions at any time during the study. You may also take a break or stop being in this study at any time.

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 a gene connected with Congenital Sucrase-Isomaltase Deficiency (CSID). The official name of this gene is sucrase-isomaltase (*SI*).

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Are there alternatives to participating in this study or treating your symptoms?

This study wants to learn more about why some people cannot digest table sugar well. It also wants to see how changes in a gene (sucrase-isomaltase (*SI*)) are connected with Congenital Sucrase-Isomaltase Deficiency (CSID).

There may be other ways of treating your chronic diarrhea or chronic abdominal pain. These other ways include changing your diet, taking nutritional supplements or medication, and learning skills to manage your symptoms.

You could also choose not to participate in this study. You do not have to participate in this study and you can stop participating at any time.

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

Who is paying for this study?

The sponsor, QOL Medical, LLC, will only pay for procedures not considered standard of care, as detailed below.
- Breath Test
- Cheek Swab

Will I be paid for being in the study?

You will be paid $30 to complete visit 1. If you receive a phone call to participate in Study Visit 2, you will be paid $50 for completing visit 2. If you are contacted for a third visit, you will be paid $25 for completing visit 3. This will add up to a total of $ 105 if you complete all of the visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study are taxable income. Children's Hospital Colorado uses a debit card payment system. Each time you complete the requirements for payment, the cash value will be loaded onto the card. In order to meet requirements of the Internal Revenue Service (IRS), we must report these payments as income. You will be asked to provide your social security or tax identification number to meet these IRS regulations. If by the third payment you have not provided this information, no further payments will be made for study participation.

Will I have to pay for anything?

It will not cost you anything to be in the study.

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 to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. These findings may not be known for several years.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researcher carrying out this study is Joel Friedlander, DO MA-Bioethics. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Joel Friedlander, DO, MA-Bioethics, 720-777-6669. 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, DO, MA-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 and the hospital(s) it works with 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 University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It 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 researcher, 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, DO, MA-Bioethics
13123 E. 16th Avenue B290
Aurora, CO 80045-7106

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) 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.
- QOL Medical, LLC who is the company paying for this research study.
- Officials at the institution where the research is being 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 researcher. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

The investigator (or staff acting on behalf of the investigator) will also make all or some of the following health information about you available to:

- LabCorp
- Baylor Texas Children's Hospital
- Clinical Inc: is the data capturing company for this protocol

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 my 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
- Other: sucrose breath test, buccal swabs

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

Scientists at Children's Hospital Colorado 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, or the tissue, or other specimens are given by you to the researcher for this research and so no longer belong to you.
- Both the researcher and any sponsor of this research may study your data and tissue, or other specimens collected from you.
- If data, tissue, or other specimens are in a form that identifies you, Children's Hospital Colorado may use them for future research only with your consent or 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

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

First Parent/Guardian Consent for Child's Participation:

I consent to have my child participate in this study.

Yes □ Initials _____ **No** □ Initials _____

_____ _____
1st Parent/Guardian Signature Date

Print Name: _____

Relationship to Participant: □ **Mother** □**Father** □**Guardian**

First Parent/Guardian Consent for his/her Participation:

I consent to have my demographic and history data collected for this study.

Yes □ Initials _____ **No** □ Initials _____

_____ _____
1st Parent/Guardian Signature Date

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

I consent to have my child participate in this study.

Yes □ Initials _____ **No** □ Initials _____

_____ _____

2nd Parent/Guardian Signature (optional) Date

Print Name: _____

Relationship to Participant: □ **Mother** □**Father** □**Guardian**

Second Parent/Guardian Consent for his/her Participation (if available):

I consent to have my demographic and history data collected for this study.

Yes □ Initials _____ **No** □ Initials _____

_____ _____

2nd Parent/Guardian Signature (optional) Date

Adult Participant (18 years of age or greater) Re-Consent for Self Participation:

I consent to continue to participate in this study

_____ _____

Adult Participant 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.

Consent and Authorization Form Approval

_____ _____
Signature Date

Title: ☐ Principal Investigator ☐ Sub Investigator ☐ Research Coordinator

Print Name: _____ _____
Time

Principle
Investigator: _____Date: _____
Investigator must sign within 30 days

_____ Date_____
Witness of Signature ❑

Witness of consent process ❑