Do GIPs Improve Practice (GIP) at Home? Effects of Home Gluten Immunogenic Peptide Testing on Children With Celiac Disease

Consent Form

NCT03462979
March 26, 2020

Boston Children's Hospital

RESEARCH CONSENT FORM

This section only to be edited by IRB office.

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title:
Do GIPs Improve Practice (GIP) at Home? Effects of home gluten immunogenic peptide testing on children with celiac disease
Principal Investigator:
Jocelyn Silvester, MD PhD

Please check one of the following:

_____ You are an adult participant in this study (18 years or older).

_____ You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child"

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Participation in this research study is voluntary. You are free to say yes or no and your decision will not impact the care you receive at Boston Children's Hospital. You can withdraw from the study at any time. This consent form contains a description of the study and its risks, potential benefits and other important information. Please read this consent form carefully and take your time making a decision. The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, friends, family, or other doctors) before you decide to participate in this research study.

How are individuals selected for this research study?

You are being asked to participate in this research study because you are a patient at Boston Children's Hospital who has confirmed celiac disease and is trying to follow a gluten-free diet. You have been identified either directly through your doctor or by review of the clinic and procedure schedule. We may have spoken with you about this before the visit.

Why is this research study being conducted?

Following a gluten-free diet is difficult. Eating small amounts of gluten may be relatively common and may not produce symptoms so there is not always a "feedback loop" to alert to accidental gluten exposure. These "silent" gluten exposures may interfere with recovery and healing of the tissue lining the small intestine.

The goal of this research study is to look in urine and stool for biomarkers of gluten exposure, nutrition and celiac disease activity. These will be compared to other measures, including antibody tests and your dietitian and/or doctor's assessment. If these tests are effective, biomarkers of gluten exposure could help patients and doctors to identify possible sources of gluten and help patients work to avoid gluten in the future. These tools may also provide reassurance for patients and families when used to confirm that a person with celiac disease has not been exposed to large amounts of gluten.

The test kit we are testing is marketed on line and sold as Gluten Detective. This is the same test that is mentioned in some of the celiac support groups and on line celiac sites.

Who is conducting this research study, and where is it being conducted?

This study is being done at the Celiac Disease Program at Boston Children's Hospital. Jocelyn Silvester, MD PhD (Research investigator), from the Division of Gastroenterology, will conduct the study. The research is funded by the Celiac Disease Program at Boston Children's Hospital and biomarker testing is being provided by Glutenostics.

Your health care provider may be a research investigator for this research and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate or not to allow your child to participate, your care at Boston Children's Hospital and/or with your health care provider will not be affected in any way.

How many people will participate in this research study?

Approximately 100 people will take part in this study at Boston Children's Hospital.

What do I have to do if I am in this research study?

If you decide to participate in this study, you will be in this research study for about 30 weeks, or about 8 months. As a participant, you will be asked to follow the timeline detailed below and summarized in the table.

- **Week 0: Recruitment Visit** in clinic at Boston Children's Hospital
    - Learn more about the study and give written consent to participate.
    - Provide urine and an optional stool sample (may be collected by the participant prior to appointment). The urine sample should be a first morning void, if possible.

- Provide a blood sample that will be stored and tested for biomarkers of nutrition, gluten-free diet adherence and celiac disease activity. The amount of blood that we ask for is about 1 to 2 extra tablespoons and it will usually be collected at the time of blood draw for tests your doctor ordered.
- Height and weight.
- A short survey about symptoms, the gluten-free diet, and quality of life. Parent(s) or guardians(s) may help you complete the survey and/or may complete a separate survey for some questions.
- Receive surveys and containers for home collection of urine.

- **Weeks 1 – 7: At Home**
  - 2 additional urine samples. You will be contacted by the study coordinator to let you know how and when to collect these samples and to fill out the survey. You will be given all the materials for this during the recruitment visit.
  - Keep a diary of possible gluten exposures.
- **Week 8: Study Visit** at Boston Children's Hospital
  - Bring the 2 urine samples and surveys completed at home.
  - Bring a stool sample collected up to 72 hours before visit
  - Randomization to "lab test" or "home test" group. Because no one knows whether this tool will be useful, you will be "randomized" into one of the two study groups. The "home test" group will be given kits to use the tool at home while the "lab test" group will not. Randomization means that you are put into a group by chance. It is like flipping a coin. You have an equal chance of being placed in either group. Neither you nor the research investigator can choose the group you will be in.
  - Height and weight.
  - Complete the survey(s).
  - Complete a dietician assessment with a Registered Dietitian, either in person or by telephone/video teleconference.
- **Weeks 8 – 30: At Home**
  - The study coordinator will call you at random once every 4 weeks to collect urine samples and complete the survey.
    - Home test group – use the kit to test your samples AND store and save samples.
    - Blinded group – store and save samples to bring to week 30 visit
  - Keep a diary of possible gluten exposures.
  - Home testing group may use stool kits provided during at times of their choosing. Sample date, results, and reason for use should be reported to the research team.
- **Week 30: Final Study Visit** at Boston Children's Hospital
  - Return stool and urine samples and surveys completed at home.
  - Provide an optional blood sample, height and weight.
  - Complete final survey(s).
  - Complete a dietician assessment, either in person or remotely.
  - Receive results of sample from week 8 study visit.
- All participants will be notified of results once the samples are processed.

- After your final visit, your medical record will be reviewed by the investigator or research assistant for dietary and celiac disease information.

Study Visit Timeline	Week 0: Before Recruitment Visit	Week 0: Recruitment Visit	Weeks 1-7 at Home	Week 8: Study Visit	Weeks 8 - 30 at Home	Week 30: Final Study Visit
Consent /Assent		X		X		X
Urine Sample	X	Bring Sample	2	Bring samples	6 x (Home Test group will test and store samples when contacted by study team)	Bring samples
Stool Sample	X (optional)	Bring stool Sample		Bring stool sample (collected up to 3 days before visit)	0 - 4 x (Home Test group will use stool testing kit at times of their choosing)	
Blood Draw		X				X (optional)
Height and Weight		X		X		X
Parent and Child Visit Questionnaires		X		X		X
Parent and Child Symptom Questionnaires			2x		6x	
Diary of suspected gluten exposures			X		X	
Dietician Assessment				X		X

What are the risks of this research study? What could go wrong?

Risks and discomfort associated with answering questions: Some of the information about you may be uncomfortable to answer. If you feel uncomfortable, these questions may be left blank or stopped at your request.

Risks and discomforts associated with blood collection: Risks associated with a blood draw may include minor discomfort, bruising, fainting, and infection. When possible, we will draw blood at the time of a clinically-indicated procedure to reduce the number of needle sticks. In order to reduce discomfort and anxiety surrounding the blood draws, BCH offers a numbing cream called LMX-4 at no cost to you. Participants who want to use this cream may do so by requesting it at the CVS located at BCH's Longwood location. Study staff will give you a card with information for acquiring this cream, and will answer any questions you have about obtaining this service.

Risks and discomforts associated with receiving test results about gluten exposure: We expect that some samples will contain gluten biomarkers. In other studies with this test, as many as 1 in 3 children have had gluten biomarkers in their stool. You may receive results that your samples have tested positive for gluten biomarkers. The gluten biomarker test is investigational and is only one way to find out if you have been exposed to gluten. If you are distressed by your results, then you may contact the study staff. If you are in the home testing group, then you will receive the results when you take the test. If you are in the sample collection only group, then you will receive your results all at once after they have been processed in the lab.

What are the benefits of this research?

Being in this research may not help you right now. When we finish the research, we hope that we will know more about whether the tools we are testing are helpful to manage the gluten-free diet. This may help other people with celiac disease in the future.

Are there costs associated with this research? Will I receive any payments?

You will be given a parking voucher at each of the three visits. You will also be given a $30 ClinCard at each of the two study visits (week 8 and week 30) as a token of our appreciation for you participation. The ClinCard can be used for in-store purchases as a Credit or Debit card), online purchases, ATM withdrawals or cash advances. Participants in the blinded arm will also be given 4 testing kits at their week 30 visit as a token of appreciation for completing the study.

Are there other things I should know about?

You can buy this test, online, without being in the study. The company is not saying that the results of this test help with clinical care.

At the completion of this research, we would like to store any remaining sample(s) for possible future use. The remaining samples may be stored indefinitely and may be used for future research of relevance to celiac disease and other gastrointestinal and autoimmune diseases. Your sample will not be stored with identifiers, such as your name or medical record number. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified.

If you have questions about storing samples or would like to request that samples be removed from storage, please let us know. It is not always possible to remove samples from storage or to retrieve samples that have already been sent to other investigators.

I agree to allow my samples and information to be stored and used for future research as described above:
(please check and initial one to indicate your choice)

_____ ☐ YES _____ ☐ NO

It is possible that the samples we collect or what we learn or create from the samples, may be made available to other hospitals, universities, and businesses for further research or to create commercial products, research tools, or inventions that have value. If this were to occur, Boston Children's Hospital and/or the research investigator might receive financial benefits. As in all research studies, the hospital has taken steps designed to ensure that this potential for financial gain does not endanger research participants, or undercut the validity and integrity of the information learned by this research. Further, Boston Children's Hospital believes that devoting payments we receive to research and health care is the best way to benefit patients as whole, so we do not transfer those payments to research participants.

Why would I be taken off the study early?

The research investigator may take you out of this study at any time. This would happen if:

- *The research is stopped.*
- *You fail to follow the research requirements.*

If this happens, the research investigator will tell you.

Other information that may help you:

Boston Children's Hospital has developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

Who may see, use or share your health information?

A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children's Hospital, one will be created for you.

The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

The clinical information, protected by the unique code and both the standard and new laboratory tests will be shared with Glutenostics the sponsor of the study. Only the research team here at Boston Children's will have your name and personal identifying information.

The sponsor (Glutenostics) is not currently seeking approval for this test from the FDA. Should they decide in the future to seek approval, the FDA may want to see the specific information from this study

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

Contact for Future Studies: Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying celiac disease or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children's Hospital.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies.

What should you know about HIPAA and confidentiality?

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research;
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;
- And/or your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigator: **Dr. Jocelyn Silvester**	Phone: **617-355-6058** Pager: 617-355-7243 **Pager #4689**	▪ General questions about the research ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Research Assistant	Phone: **617-355-8881** Pager: 617-355-7243 **Pager #3635**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Institutional Review Board	Phone: **617-355-7052**	▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints.

- If investigator/research contact cannot be reached.
- If I want to speak with someone other than the Investigator, Research Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.
- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

Child Assent

■ _____ _____

Date (MM/DD/YEAR) Signature of **Child/Adolescent Participant**

■ If child/adolescent's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Adult Participant (if applicable)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Participant (***18+ years)*

Research Investigator /or Associate's Statement & Signature

- I have fully explained the research escribed above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).

■ _____ _____

Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness