Protocol Title: Celiac Disease Screening Among Type-1 Diabetic Patients and their Relatives

Principal Investigator: Alessio Fasano, MD

Site Principal Investigator:

Description of Subject Population: Individuals with type-1 Diabetes mellitus and their relatives

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research study to learn more about the link between type-1 diabetes and celiac disease. Celiac disease (CD) is a complex disease caused by eating gluten, a protein contained in the cereals wheat, rye, and barley. To develop CD you must eat gluten and have specific genes.

All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

Your immune system helps protect your body from disease and infection. Autoimmune diseases are diseases that result from your immune system attacking your own body. People with one autoimmune disease are likely to develop another in the future because of the many shared genes between diseases. An example of this is a person with type-1 diabetes who later develops CD. We are going to study the genes that are shared between CD and type-1 diabetes to learn more about how autoimmune diseases develop.

This is the sixth year of conducting this study. Up to 500 people can take part in this study at the Friends for Life conference in Orlando, FL per year.

The Center for Celiac Research and Treatment at Mass General Hospital *for* Children and Juvenile Diabetes Research Foundation (JDRF) are paying for this study to be done.

How long will I take part in this research study?

It will take you about 15 minutes to complete this research study. We may also contact you in approximately 6 months with some follow up questions.

What will happen in this research study?

If you choose to take part in this research study, we will ask you to sign this consent form before we do any study procedures.

We will draw your blood (just over 1 teaspoon) and test it for markers of celiac disease. We will send the results of your celiac testing to the address that you provide. It will take approximately 1-2 months to receive these results. We will also use your blood to perform genetic testing for genes related to celiac disease and type-1 diabetes. These genetic tests will be done for research purposes only. You will not receive the results of this genetic testing.

We will ask you to fill out a short questionnaire about your health. This includes questions about your symptoms and the diseases people in your family may have. When we contact you for follow-up in approximately 6 months, we will ask for updates to this information. We will also ask questions related to your results, such as if you received follow-up care based on the results that we gave you. You can choose not to answer these follow up questions if you do not wish to.

Donation of Extra Blood for Additional Research

If you are 14 years or older and agree to help us with additional studies about celiac disease and type-1 diabetes, you will be asked to give additional blood (just over 2 teaspoons). You will only be pricked by a needle once in this study, even if you agree to give more blood. This additional blood will be used to study the way your immune system works.

☐ I am 14 years or older and agree to provide additional blood (just over 2 teaspoons).

Initials: _____, Parent Initials: _____

Stool Sample Donation

We would like a sample of your stool (poop) to study the communities of micro-organisms that reside in your intestinal tract. Our gastrointestinal tract is home to many micro-organisms (such as bacteria) that help our body to carry out important functions. These include aiding in digestion or helping to create certain vitamins that our bodies need.

Recent scientific studies have shown that people with certain disease, such as type-1 diabetes, have a distinct pattern of micro-organisms residing in the gastrointestinal tract. We would like to study this idea further and compare the communities of micro-organisms in individuals with and without type-1 diabetes and/or celiac disease. If you agree to donate a stool sample as part of this research, additional instructions and materials will be given to you.

Please check one of the boxes below:

☐ I decline to provide a stool sample as part of the research.
☐ I will provide a stool sample while at the Friends for Life Conference.
☐ I would like to receive a collection kit in the mail (to my home address) to collect a stool sample at home after the conference has concluded.

Storing Samples and Health Information at MGH for Future Use

We would like to store some of your samples and health information for future research related to the immune system. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password protected computer.

Do you agree to let us store your samples and health information for future research related to the immune system?

Yes ☐ No ☐ Initials_____

If later you change your mind and want your samples destroyed, contact Dr. Alessio Fasano in writing at 114 16th Street (114-3503), Charlestown, MA 02129.

Which researchers can use my samples and what information about me can they have?

Your samples will be made available to researchers at MGH (Massachusetts General Hospital), BWH (Brigham and Women's Hospital), and other Partners institutions, as well as non-Partners academic institutions. Occasionally, your samples may be shared with for-profit companies that are working with MGH, BWH or other Partners researchers on a specific research project. Your samples will not be sold to anyone for profit. The study will usually provide samples with limited information that does not directly identify you.

- All of the samples stored from this study are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the study staff, and will be securely stored.

- Researchers at Partners institutions, whose studies have been approved by the hospital ethics board, may be allowed to review your medical record to collect more health information about you. The ethics board is a group that independently reviews and watches over all research studies involving people. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected.

- Researchers outside of MGH and BWH will not be given the key to the code that links your sample and medical information to your name or other direct identifiers.

What are the risks and possible discomforts from being in this research study?

Risks of Blood Draw
Blood draw has a small risk of infection and pain. You may have a bruise (a black and blue mark) where we take the blood samples. There is also a small risk of feeling lightheaded or fainting. Only licensed physicians, nurses, phlebotomists (person trained to draw blood), or other trained personnel will collect the blood samples. All members of the study team who draw blood will have adequate teaching, practice, and certification.

Risks of Genetic Testing

There is a risk that information about your taking part in a genetic study may influence insurance companies or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be shared with you and will not be placed in your medical record.

Risk of Privacy and Confidentiality
There is a potential risk of loss of confidentiality. To prevent this, the results of all tests will be kept private and files will be kept in a locked room. Only research staff will have access to computers or files with your information. Tubes for blood samples will be labeled with a number; your name will not be used.

What are the possible benefits from being in this research study?

If you are found to have signs of celiac disease in your blood sample, you may benefit from early diagnosis and treatment. Complications associated with celiac disease can be prevented if diagnosis is made early.

You might not benefit directly from being in this study, but you will help doctors to better understand the connection between celiac disease and type-1 diabetes. Individuals who are diagnosed with celiac disease in the future may benefit from what we learn from this study.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

There will be no costs to you as a result of participating in this study.

If you choose to collect a stool sample at home after the FFL conference concludes, we will provide you with all of the necessary materials, including pre-paid shipping materials. This will ensure that this process will be at no cost to you.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Alessio Fasano, MD is the person in charge of this research study. You can call him at 617-726-4166 (M-F 9-5). You can also call Tori Kenyon at 617-643-4366 (M-F 8-4) with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857 282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent _____ Date/Time _____

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject _____ Date/Time _____

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child Date/Time

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Child, Ages 14-17 Date/Time

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name Date Time (optional)

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