Protocol Title: Imaging of Type 1 Diabetes Progression

Principal Investigator: Jason Gaglia, M.D.

Site Principal Investigator:

Description of Subject Population: Individuals age 18 or older in diabetes trial

Screening Consent Form

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.

If you decide to take part, you will be asked to sign another consent with more information about the remainder of the study once the screening process is completed.

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.

Why is this research study being done?

The pancreas is an organ located in the abdomen (belly) close to the liver and stomach. The pancreas helps control sugar levels in the body by making insulin. Type 1 (autoimmune) diabetes (formerly called juvenile diabetes) results from destruction of the insulin producing cells in the pancreas. This research study is being done to see if changes in the pancreas that occur with the

development of type 1 diabetes can be seen with magnetic resonance imaging (MRI). We would like to track these changes over time.

MRI uses strong magnets to take pictures of the body. MRI is routinely used to aid in medical diagnoses. This technique is very sensitive in detecting iron.

Ferumoxytol (Feraheme®) is a drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of iron deficiency anemia in persons with chronic kidney disease. Although ferumoxytol is FDA-approved, its use in imaging (taking pictures) is experimental.

Since ferumoxytol contains iron, we are able to detect it on MRI. We would like to find out if ferumoxytol and MRI are able to detect changes in the pancreas that occur with the development of diabetes and/or its treatment with various drugs.

We are asking you to take part in this study because you are already involved in diabetes research or to serve as a control.

We will enroll about 65 people in this research study at Massachusetts General Hospital (MGH).

Funding for this study comes from a National Institutes of Health (NIH) and JDRF.

How long will I take part in this research study?

The screening process typically takes 1-2 weeks. If you qualify, you will be asked to be in this study for the next year.

What will happen in this research study?

This consent form tells you what will be done to see if you qualify to be in this study. If the results of the screening tests show that you can be in this study, you will be asked if you would like to join the study. You will be given a separate consent form that explains the study in more detail.

Signing this screening consent form does not mean you have to be in the study, it only means that you agree to have the tests done to see if you can be in the study.

During screening you will be asked questions to see if there are any reasons that you should not have an MRI or participate in this study. You will be asked questions about the diabetes study that you are participating in and asked to provide permission for us to contact the investigators in

that study to confirm your participation and share information. If not already available, you will have blood collected for safety labs including iron saturation and creatinine. If you are a woman of childbearing potential, pregnancy testing may also be performed. About 15 mL (1 tablespoon) of blood may be drawn.

Details on what may occur in the remainder of the study once the screening process is completed is available in a separate consent document.

Study Information Included in Your Electronic Medical Record
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

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

Blood drawing
During screening you may have a blood sample taken from a vein in your arm. You may have a bruise or pain from where the blood sample is taken. There is also a small risk of feeling lightheaded, fainting, or infection.

Participation in the study
If you continue to participate in the study after screening, you will have MRIs performed. As part of the MRIs you will be given ferumoxtyol to better visualize the changes in the pancreas associated with type 1 diabetes. Ferumoxytol is FDA approved as an iron replacement product for the treatment of iron deficiency anemia in adults with chronic kidney disease. As with any drug, there are potential risks. Most side effects to ferumoxytol are of a mild to severe allergic type reaction. Life-threatening and even fatal reactions have been reported. Ferumoxytol carries a boxed warning — the FDA's strongest warning. Persons known allergic to ferumoxytol or any intravenous (IV) iron-replacement product may not participate in this study. Further details on risks associated with participation are available in the separate consent document covering that portion of the study.

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

You will not benefit from taking part in this study. Others with diabetes or who are at risk for developing diabetes may benefit in the future from what we learn in 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.

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

Will I be paid to take part in this research study?

Compensation is not provided for the screening portion of this study. If you take part in the rest of the study, compensation will be provided as described in the separate consent document.

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

Study funds will pay for any screening laboratories that are needed. If you continue participating in the study beyond screening, study funds will also pay for the ferumoxytol, MRI examinations, and all the tests or procedures that are done only for the research.

Charges for any ongoing or routine medical care you receive will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

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.

The study sponsors have no plans to offer you any other payments or other type of compensation

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.

Jason Gaglia, M.D. is the person in charge of this research study. You can call him at 617-830-2604, available 24 hours a day/7 days a week. You can also call Mukesh Harisinghani, M.D. at 617-726-0679, available M-F 9-5 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 617-424-4100.

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: AMAG Pharmaceuticals (the manufacturer of ferumoxytol)

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your

permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and 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 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

Signature of Study Doctor or Person Obtaining Consent:

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

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

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter Date

OR

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

Consent Form Version: v4.0 (06/19/2015), Screening