BENAROYA RESEARCH INSTITUTE
Virginia Mason

IR#10024
REC'D AUG 12 2016

Diabetes Translational Research Project

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

IR Number: IR#10024

PRINCIPAL INVESTIGATOR

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APPROVED
JUL 25 2016
BRI IRB

SUPPORTED BY

Benaroya Research Institute at Virginia Mason

PARTICIPANT'S NAME: _____

This is a research study. You may take your time and ask questions about the study or anything in this consent form. When all of your questions have been answered, you can decide whether or not to participate. You will receive a copy of this consent form for your records.

You are being asked to take part in this study because you or a family member has an autoimmune or immune mediated disease, specifically type 1 diabetes. You may also be asked to participate because you have another type of diabetes. There are more than 80 known immune mediated diseases. The normal job of the immune system is to fight off infections from pathogens, such as bacteria or viruses. The immune system works by identifying these pathogens as foreign - or not part of your own body. However, sometimes the immune system makes mistakes and fights your own body or causes excessive inflammation. This can result in immune mediated disease. In type 1 diabetes, the immune system attacks the insulin-producing cells in the body.

WHY IS THIS STUDY BEING DONE?

We are inviting you to participate in a research study to help us improve our understanding of diabetes and immune mediated diseases. The study consists of a computer registry where we store your contact, research, and health information and a sample repository where we keep blood and other biologic samples for current and future use in our research. The samples and information will be used for many different studies.

An important part of this study is to allow the sharing of information between researchers studying different immune mediated diseases. Therefore, the samples and information obtained in this study are part of the Benaroya Research Institute's Immune Mediated Diseases Registry and Repository.

The purpose of the registry and repository is to:

- Collect ongoing information about health and disease history from people with and without diabetes and other immune mediated diseases, and their family members.
- Create a repository of biological samples from people with diabetes and other immune mediated diseases and their family members.
- Identify and keep a list of people with diabetes and other immune mediated diseases, who might be interested in participating in future research studies related to diabetes.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

This study will be open indefinitely. We expect hundreds of people will take part in the study.

WHAT IS INVOLVED IN THE STUDY?

Study Visits and Data Collection

- You will be asked to come in for one or more study visits. Most of the time, the study visits will take place at the BRI Clinical Research Center. Each visit will last about 30-60 minutes, but may take longer in some cases. Sometimes, we may be able to arrange a visit at another location that is convenient for you.
- We will ask you for information about you and your health. This may be obtained by interview, physical examinations, and questionnaires, and may also be gathered from your medical record.
- Blood sample(s) will generally be collected from you by inserting a needle into your arm, but some studies may collect blood from your finger.
    - We will tell you what samples we need and how much blood we expect to draw.
    - We will never take more blood than is safe for your age and weight.
    - The exact amount we take will depend on your age, weight, and what test is being done. This may be as little as a few teaspoons (5-15 ml) to as much as 2 cups (500 ml; a "unit" of blood) every eight weeks.
    - It is possible you will need to fast overnight prior to the blood draw.
- We may conduct an Oral Glucose Tolerance Test (OGTT) or Mixed Meal Tolerance Test (MMTT). You will need to be fasting when you arrive for these tests. Before each OGTT or MMTT, you will get special instructions about diet and insulin dosing. To make the blood sampling easier, an intravenous needle and plastic tube (IV) will

be placed in your vein. The IV will be kept in place during the test. Two blood samples taken ten minutes apart (one teaspoon of blood for each sample) will be taken through the IV. You will then drink either a sweet liquid that contains glucose for the OGTT (Glucola), or a drink called Boost which has glucose as well as fats and proteins for the MMTT. Blood samples will be drawn through the IV at regular intervals for 2 hours. All together, the studies will require about 2 tablespoons of blood in adults. Each visit will take 2-3 hours.

- We may collect a buccal sample, which is a way to collect a genetic sample without drawing your blood. A buccal sample is collected by swabbing the inside of your cheek and gums with a sterile swab.
- We may collect a urine sample from you. These samples allow us to study how diabetes affects kidneys.
- We may contact you to see if you will come in for additional study visits or to update your health and contact information. We will always tell you what we need and let you decide if you are able to help us at that time. We may also contact you to let you know that you may be eligible for other studies.

What happens to the information and biologic samples after the study visit?

- The samples and the information about you will be part of the BRI Immune Mediated Diseases Registry and Repository.
- We will treat the information we collect about you as confidential.
    - This means that we keep your identity, research information and samples in a protected environment with limited access.
    - We do not use your name to store your samples or research information. Instead, we assign them a unique random code number. We create a link between your code number and your identity, and we carefully limit access to this link.
- Researchers studying diabetes and immune mediated disease will use your information and samples. These may include researchers from Benaroya Research Institute, as well as non-profit, academic, and for-profit groups such as pharmaceutical companies. Researchers may pay a fee for use of the samples and information to help cover the costs of obtaining, processing, storing, and testing the samples and information.
    - The samples will only be used for research related to diabetes or immune mediated diseases.
    - The research tests may include studies of genes and how genes function and studies of the immune system.
    - We may also do routine clinical tests on your sample. These may include an HbA1c measurement and a complete blood count (CBC).

What results will be available from this study?

- You can find out what we are learning from these studies by asking your research team or checking the BRI website www.benaroyaresearch.org.
- In addition, we will give you your HbA1c test result and notify you if there are any results on routine clinical blood tests that are important for your health.
- However, we will not routinely release your personally identifiable research information, including genetic information, to you, make it available to your doctor, or make it part of your medical record.
- Results from using your information and samples may lead to development of commercial products. There are no plans to pay you should this occur.

HOW LONG WILL I BE IN THE STUDY?

You will be a part of this study indefinitely. However, each time you are contacted for additional visits, you can say no. You may choose to withdraw from the study at any time.

If you leave the study for any reason, the information that has already been collected will remain in the study database, but no further information will be collected for the study. You may also request to have your samples still remaining in the BRI Immune Mediated Registry and Repository destroyed. However, results obtained from samples prior to your leaving the study will remain in the database. Also, we will not be able to destroy any samples distributed to other researchers prior to your leaving the study.

WHAT ARE THE RISKS OF THE STUDY?

The risks of having blood drawn are minimal. The risks of blood draws include: fainting, the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur.

Some people may not like the taste of the Glucola or Boost and occasionally people feel nauseous when they have the OGTT.

The MMTT requires that you drink a product called BOOST® which contains milk and soy ingredients. People with severe allergies to these could have a reaction. If you have a known allergy to either of these ingredients, please let us know. It is possible we may need to advise you to avoid MMTTs.

There is an unlikely risk that your information is viewed by someone outside the research team who is not authorized to see your health information. However, we will make special efforts to keep your information (including genetic information) private.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will be no direct benefit to you. We hope the information learned from this study will benefit other people with immune mediated disease and diabetes in the future.

WHO IS PAYING FOR THIS STUDY?

Funding for this research may come from various sources, including voluntary donations to Benaroya Research Institute, granting organizations or institutions, such as the JDRF, the National Institutes of Health, or from collaborating researchers at academic, non-profit, and for-profit organizations, such as biotech and pharmaceutical companies. You can ask your research team about our BRI research partners.

WHAT ARE THE COSTS?

Taking part in this study is not expected to lead to added costs to you or your insurance company.

You will be paid $50 for an initial blood draw, and $50 for each additional visit including visits that involve MMTT or OGTT studies.

We may also give you a parking voucher if needed.

WHAT IF YOU GET INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

It is important you tell your study team if you feel you have been injured because of taking part in this study. You can tell us in person or call 206-342-6931.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary, and you may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled outside of this research. Participation in this study will generally not limit your ability to take part in other research studies.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

- For questions about study appointments, procedures, study costs, or to report a study-related injury, call 206-342-6931.

- For questions about your rights as a research participant, contact the BRI Institutional Review Board (IRB) Manager at 206-342-6916. The IRB Administrator manages the IRB, which is a group of people who review this research to protect your rights and welfare.

WHERE CAN I GET MORE INFORMATION?

You will get a copy of this consent form. You may also receive a research volunteer handbook. You can also check the BRI website (www.benaroyaresearch.org).

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We are required by special federal and state privacy laws to protect the privacy of your health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Researchers (investigators) would like to use your health information for research. This section describes what researchers will do with information about you. To learn more about your individual privacy rights, you may ask your provider for a Notice of Privacy Practices.

WHAT IS PROTECTED HEALTH INFORMATION (PHI)?

For this study, Protected Health Information (PHI) is information that:

- Is received or created by a researcher.
- Directly identifies you or can be reasonably expected to identify you.
- Relates to your past, present or future health.

PHI includes information about you collected or created during this research study, for example: demographic information, personal information such as your name and birth date, answers to questionnaires and forms you fill out, medical information found in your medical record (such as test results, medications and symptoms), results of research tests performed on your blood.

If we remove all links to your personal identity from the information before using it, it is no longer PHI.

WHO MAY USE, SHARE OR SEE MY PHI?

The researchers listed above and their staff may use and share your personal health information. In addition, the researchers may get information from your health care providers and medical records.

WHAT MAY THE RESEARCHERS DO WITH MY PHI?

The researchers will use your personal health information to conduct the research.
As part of the research they may share your identifiable information with certain people and groups. These may include:

- The Institutional Review Board (IRB) that approved this research, Benaroya Research Institute (BRI) IRB. The IRB reviews, audits, and monitors studies to protect the rights and safety of research participants.
- BRI Regulatory Compliance and Education Department will conduct routine internal quality reviews, audits and monitor visits of the study and patient records.

- Government and public health agencies, their representatives, and others as required by law.

HOW WILL MY HEALTH INFORMATION BE KEPT PRIVATE?

All efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Researchers generally remove your name (and other information that could identify you) from your health information before sharing it. Once your PHI is given to a third party, that party may share it with someone else and the federal privacy law may no longer protect it; however, other privacy protections may still apply.

If research findings are published from this study, they will not identify you unless you allow it in writing.

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION?

You may change your mind at any time and withdraw this authorization. This request must be made in writing to the investigator, Carla Greenbaum at the address listed on the first page of this form. Beginning on the date you withdraw, no new identifiable health information will be used for research. However, the researchers may continue to use and share the information that was provided before you withdrew your permission. If you withdraw your authorization, you will not be allowed to continue in this research study.

HOW LONG WILL THIS AUTHORIZATION LAST?

If you agree by signing this form, the researchers can use and share your identifiable health information indefinitely. The authorization will not expire unless you withdraw your permission as directed above.

PARTICIPANT'S AUTHORIZATION

I have read this consent form and have been given a chance to ask questions about this consent form and HIPAA authorization, and I agree to take part in this study. I understand that I will be given a copy of this consent form and HIPAA authorization for my records.

SIGNATURE OF PARTICIPANT
AGE 18 YEARS AND OLDER

PRINT PARTICIPANT'S NAME

_____/_____/_____
DATE

ASSENT OF PARTICIPANT 12-17 YEARS OLD (If age<12, participant signs separate Assent Form)

SIGNATURE OF PARTICIPANT AGE 12-17 YEARS OLD

PRINT CHILD'S NAME

_____/_____/_____]
DATE

SIGNATURE OF PARENT/GUARDIAN

SIGNATURE OF PARENT/GUARDIAN

PRINT PARENT/GUARDIAN'S NAME

_____/_____/_____
DATE

RELATIONSHIP TO CHILD

CERTIFICATE OF PERSON OBTAINING CONSENT

I have provided an explanation of the above research study, and have encouraged the subject to ask questions and request additional information regarding the study and possible alternatives. A copy of this consent form has been given to the subject.

SIGNATURE OF PERSON OBTAINING CONSENT

PRINT NAME OF PERSON OBTAINING CONSENT

_____/_____/_____
DATE

BRI 206 342-6931
CONTACT INFORMATION of person obtaining consent

cc: Participant and Investigator's File