

The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/ASSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: 09-408-B Name of Subject: _____
Medical History Number: _____

STUDY TITLE: **Monogenic Diabetes Registry**

Doctors Directing Research: **Louis Philipson, MD, PhD; Rochelle Naylor, MD; Graeme Bell, PhD;
Siri Atma W. Greeley, MD, PhD**

Address: **University of Chicago
5841 South Maryland Avenue
MC 1027, N 235
Chicago, IL 60637**

Telephone Number: **(773) 834-5207**

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form. Throughout this consent form, “you” will refer to you or your child, as appropriate.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify people who have monogenic diabetes. Monogenic diabetes is diabetes resulting from errors in a single gene. A gene is the basic unit of heredity in individuals. Genes are made up of DNA and contain information to pass genetic traits from parents to their children. All humans have two sets or copies of each gene; one copy from each parent. Each gene corresponds to a different trait, including traits we see such as eye color, and traits we cannot see such as blood type. Some genes change a person’s risk of developing a certain type of disease but do not by themselves cause the disease. However, other genes can cause a disease if they have a mutation, or an error, in the way they are made. These types of diseases are known as monogenic diseases and include cystic fibrosis and sickle cell disease and also certain types of diabetes mellitus.

The term diabetes mellitus or diabetes can refer to many different diseases that all cause high blood sugars. The most common types of diabetes are Type 1 diabetes and Type 2 diabetes. Both of these types of diabetes are polygenic disorders where many genes as well as other factors such as diet and weight act together to cause the disease. In some other cases, diabetes can be monogenic. This means that there is a mutation in a single gene and this mutation is sufficient by itself to cause disease. Monogenic causes of diabetes are rare compared to other forms and so many people with monogenic diabetes are misdiagnosed as having type 1 diabetes or type 2 diabetes. However, the most appropriate treatment and the way the disease affects people over time can be different for monogenic forms of diabetes. This research is being done so that we can identify people who have monogenic forms of diabetes. We will follow such

people over time to learn more about the different types of monogenic diabetes including how they present, what other problems or diseases they are associated with, and what is the best treatment. We also hope to discover new gene mutations that cause monogenic diabetes.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect about 3000 people throughout the United States will take part in this study. As this study does not involve site visits to the University of Chicago Medical Center, verbal consent will be obtained by telephone. Subjects will then be sent hard copies of consent forms for their signature. Once signed consent forms are returned, they will be reviewed and signed by study investigators, completing the enrollment process. After enrollment into the study, subjects will receive a copy of the signed consent form.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Philipson and his research team will collect information about you for the purposes of this research. Individuals who wish to participate in this study will access our web-based registry via the internet. The website will allow individuals to review study inclusion criteria. Individuals who do not meet the inclusion criteria for this study will not be included in the Registry. Individuals who do meet the study inclusion criteria will be able to review the consent form, which will be available for download as a pdf file on the website. You will be asked to register on the website by typing in your first and last name, gender, date of birth, and contact information (telephone number(s), address, and e-mail address). Registration information will be sent to the study investigators in an encrypted e-mail. We will use special software in order to view this e-mail with your contact information. One of the Registry staff will contact you and will review the consent form with you in detail to ensure that you understand why this study is being done and what is involved if you decide to participate. As a part of the consent form, you will also be asked to provide the name, address, and telephone number of the doctor/provider who cares for your diabetes, if you wish to have them contacted by the study team for participation in this study. You will be required to download and sign the consent form and send the signed consent form to us in order to be enrolled in this study. The form should be sent to the address on the first page of this document.

After your consent form is received, you will be sent an e-mail with a link to a survey to complete. Arrangements can be made to complete the survey by phone if preferred. You will also receive a unique identification number to include in the survey. The survey will ask you questions about how you were diagnosed with diabetes, whether you have a known genetic mutation causing your diabetes, what medications you are on, and how well your diabetes is controlled. It will also ask questions about your overall health and your family's medical history. This information will be used to better understand each type of monogenic diabetes and to determine which medications best control each type of monogenic diabetes.

We will also ask you to provide the name and contact information of your physician/ diabetes care provider so that they can participate in our study as well. We will ask your health care provider to provide us with your medical information relevant to your diabetes management in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Information relevant to your diabetes may include: episodes of diabetic ketoacidosis, antibody testing, c-peptide level, glycosylated hemoglobin, measures of kidney function, blood pressure, body mass index or any other information about your diabetes that your doctor may have.

You may be contacted as frequently as every 3 months and you will be contacted at least

annually to provide updates on your diabetes control and treatment.

I give permission for the study team to contact my diabetes care doctor/provider and have included their name and contact information below:

Initials: _____ Date: _____
 Doctor/Provider’s Name (first and last): _____
 Phone Number: () - _____
 Address: _____

 City: _____ State: _____ Zip code: _____

I do **not** give permission for the study team to contact my diabetes care doctor/provider.

Initials: _____ Date: _____

Data Collected for this Study:

Registration information and survey responses will be kept in secured password-protected databases that can only be accessed by the research team. Once information is submitted to the database, study participants will not be able to make changes. However, corrections can be made by contacting the Registry Staff.

In order to answer new research questions, you could be asked to participate in new research studies about monogenic diabetes or the data from this study may be used in combination with data about you from other studies that you agree to, or have already agreed to participate in at the University of Chicago. Additionally, the information in the database may be used for future research studies. For any future studies that involve intervention or are greater than minimal risk, you would be contacted and asked if you would like to participate in the study. A new consent form would be reviewed and completed for that study. In addition, we are asking your permission to use the information in the database for any future studies that do not involve any intervention and are of minimal risk. If the Institutional Review Board, a committee that reviews all research studies conducted at the University of Chicago Medical Center, approves a “waiver of consent” for such future studies, we would not re-contact you to ask your permission to use your registry data for that research study. Again, these types of studies would be of minimal risk. Only data from the registry would be used and would be limited to the minimum amount of information needed for the proposed research. All appropriate measures would be taken to maintain your confidentiality in these future studies.

Data from Other Studies in Which You May be Participating or May Wish to Participate:

If you have agreed to participate in Dr. Bell’s study #6858, *Genetic Studies of Diabetes Mellitus*, we would like your permission to use the data collected for Dr. Bell’s study in conjunction with the data collected under this study for future research.

The data collected as part of this study could be used in future research studies that examine the progression, treatment, and prevention of monogenic diabetes. To do this, your data from study #6858 would be combined with any data collected under this protocol, *Monogenic Diabetes*

Registry.

Data collected as part of Dr. Bell’s study #6858 will be controlled by Dr. Bell. However, Dr. Bell could decide to share your data with other doctors for future research studies.

Please indicate whether or not you give your permission to use your study data from study #6858, *Genetic Studies Diabetes Mellitus*, in conjunction with the data collected under this study, *Monogenic Diabetes Registry*.

Yes, you may combine my study data in this manner

Signature: _____ Date: _____

No, you may not combine my study data in this manner

Signature: _____ Date: _____

Please indicate whether or not you give your permission to be contacted in the future by other researchers who wish to do new studies about monogenic diabetes. By agreeing below, you are under no obligation to participate in any other study, only to be contacted and given the opportunity to do so:

Yes, you may contact me in the future about other studies related to monogenic diabetes

Signature: _____ Date: _____

No, you may not contact me in the future about other studies related to monogenic diabetes

Signature: _____ Date: _____

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for as long as you choose to participate. Unless you withdraw the use of your information, any information you have previously entered will be kept in the study’s Monogenic Diabetes Registry database indefinitely. Although we plan to maintain the database indefinitely, you should know that unforeseen circumstances, such as a lack of the necessary funding, could cause us to be unable to continue the study at some point in the future. You would also be removed from the study if it was no longer in your best interest to participate as judged by the study investigators or your diabetes care provider.

WHAT ARE THE RISKS OF THE STUDY?

The risks of participating in this study include the minimal risk of possible loss of confidentiality. Appropriate measures are in place to protect your personal and medical information.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be direct medical benefit to you. However, we hope the information learned from this study will benefit all individuals with monogenic diabetes as we learn how to best treat each genetic cause of monogenic diabetes.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate. The decision you make regarding whether or not to participate in this study will not affect any care that you receive at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Only the research team will have access to this information. Information collected about you will be stored electronically on secured databases in encrypted format. Information in the database can only be accessed on password-protected computers with installed decryption software. The servers are protected by a firewall and virus protection software and are backed up regularly. Any paper-based study records will be secured in locked offices at the University of Chicago.

The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Philipson is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Philipson in writing at the address on the first page. Dr. Philipson may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to _____ about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Philipson at (773)702-9653.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5751 S. Woodlawn Ave., McGiffert Hall, Chicago, Illinois 60637.

CONSENT

SUBJECT (18 years old or older)

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ **Time:** _____ **AM/PM (Circle)**

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject (and family, if the subject is a minor).

Signature of Person Obtaining Consent: _____
Date: _____ **Time:** _____ **AM/PM (Circle)**

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____
Date: _____ **Time:** _____ **AM/PM (Circle)**

PARENT/GUARDIAN/ OR LEGALLY AUTHORIZED REPRESENTATIVE:

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Signature of Parent/Guardian/ or Legally Authorized Representative:

Date: _____ **Time:** _____ **AM/PM (Circle)**

ASSENT

SUBJECT (12-17 years old; parent/guardian/legally authorized representative must also give consent for participation by signing above)

The research project and the procedures have been explained to me. I will receive a signed copy of this assent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ **Time:** _____ **AM/PM (Circle)**