

RESEARCH CONSENT FORM

Protocol Title: A Case-Finding Approach to Screening for Monogenic Diabetes
Family Member Testing

Study No.: HP-00053483

Principal Investigator: Toni Pollin, M.S., Ph.D., Phone: 410-706-1630

Sponsor: National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH)

We are asking you to take part in a research study. Joining the study is voluntary. Please read this information and ask any questions before you decide if you want to take part. If you are consenting for a child or someone unable to provide consent for themselves, the word “you” means that person.

BACKGROUND INFORMATION

Diabetes is a disease that causes high amounts of sugar in the blood. People get diabetes for many reasons. For example, type I diabetes occurs when a person’s immune system destroys the insulin-producing cells in the pancreas. Another reason is someone’s genes. Genes carry the instructions that tell our bodies how to work. Genes are passed down through families and can affect what diseases we develop. Most cases of diabetes are due to many genes and the environment working together. Some cases of diabetes, however, called monogenic diabetes, are caused by a change in a single gene. Individuals with “monogenic diabetes” sometimes do better if they take a pill instead of insulin to control their diabetes. It can be hard for doctors to know whose diabetes is caused by a single gene change and whose is caused by something else. Monogenic forms of diabetes can be identified using a blood test. These genetic tests are not usually done as standard practice. By studying the blood and health information of many people with diabetes, we hope to figure out a better way to identify people with monogenic diabetes.

A member of your family is in this study. Your family member has a single gene change that causes diabetes or high blood sugar. You are being asked to join the study because you may benefit by getting genetic testing to learn whether you have the same gene change.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to:

- develop a good way to screen for monogenic diabetes
- find single gene changes in people with diabetes and their family members
- provide people with monogenic diabetes the chance to get the treatment that will work best with their type of diabetes

We will enroll about 1500 patients in this study across three U.S. sites. Up to 500 patients will be enrolled at University of Maryland.



WHAT WILL HAPPEN IF I JOIN THE STUDY?

If you join you will be asked to complete 1 or 2 study visits. The **first visit** will take about 2 hours.

- We will ask you questions about your current and past health.
- A genetic counselor will make a chart of your family members to learn about any diseases in your family. The counselor will talk with you about genetic testing and answer any questions you have. This may be done in person or on the phone soon after the visit.
- You will fill out surveys about your health, your diabetes care, if you have diabetes and attitudes about genetic testing.
- We will collect up to 5 teaspoons of blood. If you are an adult who does not have diabetes, we will do a blood test and a finger stick to screen you for diabetes. If the results show that you have high blood sugar or diabetes, we will refer you to your doctor for further evaluation and treatment.
- We will review your medical records to collect information about your health history. If you are not a patient of the University of Maryland, we will ask you to sign a release form to obtain this information from your health care provider.
- If you have diabetes, pre-diabetes, high blood sugar or a condition related to the gene change your family member has, your blood will be sent for genetic testing to see if you have the same gene change.
 - If you do not have diabetes, pre-diabetes, high blood sugar or a condition related to the gene change your family member has, you will talk with a genetic counselor to discuss your options for genetic testing. After the counseling session you will choose whether you want to have genetic testing. If you decide not to have genetic testing your participation in this study will be finished.

For participants who have genetic testing, this will happen next:

- Your blood will be sent to a clinical lab for genetic testing. The lab will look only for the gene change found in your family member. The clinical lab will receive your name and date of birth with the sample.
- You will speak with a genetic counselor and sometimes a physician in person or by phone to discuss your genetic testing results and how you and your physician can use the information. This **second visit** will take around 30 minutes.
- We will add your genetic test result and recommendations for your doctor to your University of Maryland medical record if you have one. If you are not a patient of the University of Maryland, we will send the test result and recommendations to your doctor. We will also give you a copy.
- About 18 months after your first visit, we will mail you surveys similar to the ones you filled out on your first visit. We will ask you to complete them and send them back to us.
- We will review your medical record from before you join the study and for up to two years after your last study visit to record information about your health and health care. If you do not receive care from the University of Maryland we will ask you to sign a release form to obtain this information from your health care provider.
- Scientists' understanding about the relationship between genes and disease can change over time. New information may be discovered that is not known at the time you meet with the genetic

counselor to learn about your test results. If new information becomes known about your test results, we may contact you and ask if you want to learn about the information.

For all participants:

- We will share data collected from you with researchers at other institutions who are engaged in similar research. This is a policy of the National Institutes of Health (NIH), which funds this study. Information that might identify you personally will NOT be provided to the researchers.
- We will keep any remaining blood samples indefinitely for use in future research. We may use your blood and DNA (material that makes up the genes) in research to learn more about diabetes or other health problems. Your samples and your information from the study may be shared with other researchers. Information that might identify you personally will NOT be provided to the researchers. You will not be contacted in the future about research performed on remaining samples. The results from future research done with your samples will not be given to you or be placed in your health records.
 - Any future research using your blood samples will be reviewed and approved by an Institutional Review Board (IRB), which is a special Committee that oversees research studies to protect the rights and welfare of research participants.
 - If the research leads to the development of new tests, medicines, or other commercial products, you will not receive any money made from those products.
 - If at any time you wish to have your samples removed from the study and destroyed you may do so by contacting Dr. Pollin by telephone (410-706-1630) or mail (University of Maryland School of Medicine, 660 W. Redwood Street, HH, Rm. 445C, Baltimore, MD 21201).
- To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored indefinitely along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. Some of your genetic and health information may be placed into the Database of Genotypes and Phenotypes (dbGaP) or other appropriate database on the internet. The NIH maintains dbGaP. A researcher who wants to study the information must receive approval from an NIH Data Access Committee. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database.
- In the future, we may want to ask you if you want to be in other research studies. The choice to be in future studies is up to you. There will be a new consent process just for those studies. If you do not want to be contacted about future studies, it's okay too.
 - You can contact me to ask if I want to be in other research studies.

Please initial your choice: Yes _____ No _____



WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for:

- having a blood sample drawn and completing questionnaires
- talking with the genetic counselor before and after genetic testing
- following up with your doctor about your test results

ARE THERE ANY RISKS TO ME?

Blood Drawing

Blood drawing can cause pain, bruising, feeling faint or fainting, and rarely infection. To lower these risks, only trained staff will draw your blood. If you are pregnant, there are no further risks to you or your unborn child.

Genetic testing

The clinical laboratory will look only for the single gene change present in your family member. Still, you may receive unexpected information. For example, the gene change may put you at risk for health conditions unrelated to diabetes. Receiving genetic test results may cause some people to worry.

If the genetic test finds a gene change in you, there is a risk that your other family members could also have the same gene change. Genetic testing of the family member can tell us whether or not this is the case. In very rare cases, we may know your family member has the same gene change without even testing him/her.

There is a possible risk that misuse of genetic information could lead to discrimination. The chance of this happening is very small. There may be a risk that your genetic information could be used to try to make it harder for you to get or keep a job or insurance. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies and employers with 15 or more employees to discriminate against you based on your genetic information. GINA, however, does NOT protect against discrimination by companies that sell life, disability, or long-term care insurance.

Loss of Confidentiality

There is a risk that someone could see the genetic or health information we have stored about you. We believe that the chance this will happen is very small, but we cannot promise that this will not happen. We will do our best to protect your study information.

Data Sharing in Public Databases

There is a risk that someone could link the information in a scientific database back to you. Even without your name or other information, your genetic information is unique to you. We believe the chance that someone will figure out the sample is yours is small.

WILL BEING IN THIS STUDY HELP ME?

You may or may not benefit by taking part in this study. Diabetes screening may lead to early diagnosis and treatment which is likely to benefit your health. If we find you have monogenic



diabetes, your doctor may be better able to treat your diabetes. This may prevent diabetes-related health problems from developing. If you are or become pregnant, better sugar control benefits your pregnancy and your unborn child. If we find you have monogenic diabetes, this information may be useful to your family members' health as well. Your participation will help scientists understand how genes cause diabetes and may help us develop a better way to screen people for monogenic diabetes. If you are filling out this form for your child, you must decide if it is in your child's best interest to take part in this study.

WHAT ARE MY OPTIONS?

This is not a treatment study. You can choose to take part or not take part. If you take part, you can quit at any time. You can have testing for monogenic diabetes done outside of this study, but it is not always covered by insurance. No matter what you decide, it will not affect your care at University of Maryland.

WILL IT COST ME ANYTHING TO TAKE PART IN THIS STUDY?

There are no costs to you to take part in this research study.

WILL I GET PAID?

You will be paid \$25.00 for each study visit you complete at the University of Maryland. You will be mailed a check about 3 weeks after each visit. We will also provide parking vouchers (up to \$8.00 value) to participants that park at the University of Maryland Medical Center garage. If you complete and return the surveys we send you at 18 months, we will mail you a check for \$20 about 3 weeks after we get the surveys. Over the course of the study, you will be paid up to a total of \$70.

HOW WILL YOU KEEP MY INFORMATION SAFE?

We will try to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Results of your testing will be sent to your physician and placed into your University of Maryland medical record. This can be viewed in a password-protected system by only those who have access to this system and your chart. Otherwise information collected during this study will be kept private to the fullest extent allowed by law. Here are just a few of the steps we will take to protect your information:

- We will remove your name and other identifiers from your study information, and replace them with a code number. We will keep the list that links the code number to your name separate from your study information. Only a few of the project staff can see the list.
- We will store your information in locked cabinets and on password-protected computers.
- We will not give information that identifies you to anyone, unless required by law. In this case, information that is shared outside of the University of Maryland may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.
- Information that might identify you personally will NOT be given to researchers outside of University of Maryland when data is shared.
- The data from the study may be published. However, you will not be identified by name.



- Organizations that may see and copy information that identifies you by name include the Office of Human Research Protections (OHRP), the NIH, the Institutional Review Board (IRB) and other representatives of the University of Maryland, Baltimore. This is necessary to make sure the research findings are true. They also protect your safety and wellbeing.

The study has a **Certificate of Confidentiality** from the NIH. This means that we will not have to hand over any information that may identify you for use in a court case, even if they have a subpoena. The Certificate does not stop you or a member of your family from giving out information about your involvement in this research. For example, if you sign something that says your insurance company or employer can see your medical record or study information, we cannot use this Certificate to withhold the information. We have to give it to them. So this means you and your family need to make sure to protect your privacy too. You should understand that we must report to the authorities any sign of child abuse or neglect, or any information to prevent serious harm to yourself, your child, or others.

WHAT IF I NO LONGER WANT TO BE IN THE STUDY?

Your participation in this study is your choice. You do not have to take part in this research. If you choose to take part in the study, you can leave the study at any time. There are no negative consequences if you decide to leave the study. Just let us know and we will destroy any blood sample we have left. We will not collect any more information from your medical record. It will not be possible to remove your genetic test result from your medical record. Samples and data generated from your samples that have already been shared with other researchers or placed in public research databases may not be able to be removed.

You will be told if any significant findings develop during the study that may affect your choice to continue in the study. If you refuse to take part, or if you stop taking part in the study, you will not be punished or lose any benefits you are owed. It will not affect your current or future care at the University of Maryland Medical System, or your professional or academic standing at the University. Please contact Dr. Toni Pollin at 410-706-1630 if any of the following occur:

- You decide to quit the study.
- You have questions, concerns, or complaints.
- You need to report a medical injury related to the study.
- You have any problem at any time that you believe may be related to the testing.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the sponsor decides to end the research study early. The study team will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review



Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date: _____

Signature of Parent/Guardian
(When applicable)

Relationship: _____

Date: _____

Investigator or Designee Obtaining Consent
Signature

Date: _____

