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

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

COLLECTION OF A SALIVA SAMPLE FOR GENETIC STUDIES

Protocol Number: 6858 Name of Subject: _____

Date of Birth / Medical History Number: _____

STUDY TITLE: Genetic Studies of Diabetes Mellitus

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You are being asked to participate in a research study. 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 or not to participate. 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" refers to you or your child, as appropriate.

WHY IS THIS STUDY BEING DONE?

Diabetes is a disease that is characterized by high levels of sugar in the blood and urine. The research study in which you are being asked to participate is aimed at identifying the genes that contribute to the development of diabetes. This study will be of no direct benefit to you. However, it could provide information about the genetic causes of diabetes that may lead to better diagnosis and treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 2,500 people are expected to take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

You will be asked to send a small tube of saliva (about one teaspoon) to the University of Chicago using a special container. We will also send you a piece of filter paper (similar to the paper used in newborn screening in most states) upon which we will ask you to put four (4) drops of blood. The blood spots would be collected just like when you check your blood sugar. These will be used to do tests related to Type 1 Diabetes to help clarify the type of diabetes in your family.

DNA, the genetic material in your saliva, will be prepared for analysis of genes that might increase your risk for diabetes or other conditions that you may have, such as high blood pressure. As part of this study, your DNA sample will be stored for an indefinite length of time. Your sample will be used to search for genetic alterations associated with diabetes. This includes genetic testing for mutations in genes known to cause diabetes and other conditions. The doctors directing this study will receive the results of these tests and use this information for the purposes of research only.

Because we are a research laboratory and not a clinical laboratory with certified procedures for reporting results, we cannot directly release results from this study to you. If we obtain information that we think might be significant to you or your family (e.g., identification of a mutation that has caused the disease, disorder or condition we are studying), we may suggest to your physician that these results be confirmed by a CLIA-certified laboratory. A CLIA-certified laboratory is a laboratory that is authorized to release results from patient tests for clinical and diagnostic purposes. Most CLIA laboratories will ask for a fresh blood sample in order to ensure the accuracy of the results. Please indicate below if you wish us to inform your physician if we believe confirmatory testing should be performed.

☐ Please contact my health care provider if results become available in the future:

Physician's Name: _____

Phone: _____

Address: _____

Your DNA sample will be given a number. Information about your name and this number will be kept in a locked drawer in a locked laboratory. Only Dr. Graeme Bell and his research staff will have access to this information. Although reasonable efforts will be made to keep your information confidential, there always exists a very slight risk that your information will be disclosed. Your coded DNA sample(s) will be stored indefinitely in Dr. Bell's laboratory. If you wish to have your sample(s) destroyed at any time, you may do so by calling Dr. Bell at (773) 702-9116.

Retrieval of Dried Blood Spot Card Samples from Newborn Screening Laboratories

When you were born, drops of your blood were collected on a filter paper card and used by newborn screening programs to test for rare conditions that can go unnoticed but eventually cause illness in babies. In some instances, these blood spot samples may still be stored in a repository in the state or country where you were born. If any of your blood spot samples are still available, we may request that they be sent to us for research testing, such as measuring the blood sugar level in your blood soon after you were born.

You will be asked to sign a separate medical release so that study staff can obtain access to your blood spot card.

During this study, Dr. Bell or his research team may collect information about you for the purposes of this research, including your name, age, date of birth, height, weight and the results of tests performed as part of this study. Your medical history may also be collected from your medical records.

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

Please indicate whether or not you give your permission to be contacted in the future by other researchers who wish to do studies about 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 diabetes

Initials: _____ Date: _____

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

Initials: _____ Date: _____

HOW LONG WILL I BE IN THE STUDY?

You will be involved in a long-term study of the genetics of diabetes. The preparation of the saliva sample and collection of information about you will take about one hour. However, the identification of the genes that contribute to the development of diabetes could take many years.

WHAT ARE THE RISKS OF THE STUDY?

There is no risk associated with providing a saliva sample. There is no additional risk associated with collecting drops of blood in the same way as checking blood sugar.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may not be direct medical benefit to you. However, we hope the information learned from this study will benefit other individuals with diabetes in the future.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate in this study. Your participation is entirely voluntary. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?
Your participation in this study will not result in any cost to you or your insurance company. 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 receive payment for participating in this study.

WHAT ABOUT CONFIDENTIALITY?
Study records that identify you will be kept confidential. The data collected in this study will be used solely for the purposes described herein. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information (PHI). 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. This consent form document will be kept by the research team for at least six years.

On occasion, certain specialized tests might be required to clarify whether a certain genetic problem was the cause of diabetes or any related problems in your family. If this requires that any test be done in another laboratory not at the University of Chicago, we will not share any information that would identify you, and will instead give a part of your sample that will be coded only with a unique number but not your name. Such laboratories might include a commercial laboratory, the laboratory of Deborah Mackay at the University of Southampton, UK (a specialist in transient neonatal diabetes), the laboratories of Craig Hanis or Eric Boerwinkle at the University of Texas, Houston, or the lab of Jay Heinecke at University of Washington, Seattle

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research, including the Food and Drug Administration (FDA) and 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 this study is audited by Federal Investigators, they are not required to follow the same laws regarding Protected Health Information as the University of Chicago.

The results from tests and/or procedures performed as part of this study may become part of your medical record.

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

The study results will be kept in your research record and be used by the research team indefinitely. When the study is terminated, either the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results. Any research information in your medical record will be kept 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. Bell in writing at the address on the first page. Dr. Bell may still use your information that was collected prior to your written notice.

This consent form document does not have an expiration date.

You will be given a signed copy of this document.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to _____ about this study and you have 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. Bell at (773) 702-9116, our main number at 773-702-0829, or email us at: monogenicdiabetes@uchicago.edu.

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, 2nd Floor, 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/ASSENT

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 or the family.

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 to participate in the above described research project.

Signature of Parent/Guardian/Legally Authorized Representative: _____

Date: _____ Time: _____AM/PM (Circle)

ASSENT OF MINOR

SUBJECT (12-17 years old)

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)