The UNIVERSITY OF CHICAGO

The Division of Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: 15617B Name of Subject: _____

Date of Birth / Medical History Number: _____

STUDY TITLE: Monogenic Diabetes Mellitus Registry
(Formerly: Neonatal Diabetes Mellitus Registry AND Monogenic Diabetes Registry for MODY 09-408B)

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

Address: The University of Chicago; 5841 S. Maryland Ave.; N235 / MC 1027; Chicago, IL 60637

Telephone Number: (773) 702-0829

Email Address: monogenicdiabetes@uchicago.edu

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 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" will refer to you or your child, as appropriate.

WHY IS THIS STUDY BEING DONE?

The overall purpose of this study is to learn more about monogenic diabetes mellitus (MDM), which includes a number of diverse forms of diabetes caused by single gene mutations, or changes in DNA (the genetic information or "code" that is present in all the cells of our body). Therefore, our focus is on anyone with diabetes that is more likely to have a monogenic cause, whether a specific genetic mutation has been found yet or not. This includes anyone with **neonatal diabetes** (diagnosed under one year of age) as well as others who might fit the description of **MODY** (maturity onset diabetes of the young), typically having diabetes diagnosed under 25 years of age, often running in families, but frequently lacking one or more features of the more common type 1 or type 2 diabetes. By collecting information on as many individuals and families as possible over a long period of time, we hope to answer questions such as the number of people who have these forms of diabetes, how and why it happens, and how best to treat it. Previous studies have suggested that genetic laboratory testing will reveal a mutation in as many as 50% of people with neonatal diabetes or MODY. Often these results will suggest that a certain type of medical treatment will work better, such as sulfonylurea pills instead of insulin in some cases. Still, many uncertainties remain even about those with known genetic types, such as how their medical treatment may change over time, since most studies describing such patients have followed them for only a few months. It is therefore important to find and identify as many patients with MDM as possible, to determine whether they have been found to have such genetic differences, and to figure out which treatments might be most effective in controlling their blood sugar levels.

Some people with monogenic diabetes are at risk for later difficulties with development, behavior and possibly sleep. As such, we may also ask you to participate in a telephone-based assessment for these kinds of difficulties.

Patients who choose to participate in this Registry will enter their contact information primarily through a website (or over the telephone if preferred). This website will serve as a centralized resource for information on MDM for patients and families, physicians treating MDM patients, and researchers

trying to learn more about MDM. Any researcher who wishes to analyze the data we will be collecting will not have access to any information that could identify you. If, on the other hand, a researcher wishes to do a new study to learn more about MDM, you may agree to be contacted in the future to be asked if you would like to participate in such a study. This study will therefore allow for our knowledge about MDM to be greatly enhanced over time.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 5,000 people are expected to take part in this study through participation on the website or by telephone, regardless of where they live.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Siri Atma Greeley and his research team will collect information about you for the purposes of this research. First, you will be asked to register on the website, which will generate an entry into a secure database. Then, someone from the team will contact you to verify that you qualify for the study. Next, you will be asked a series of survey questions, which you may complete through secure link, which is stored securely in a database. Arrangements can be made to complete the survey by phone. The first series of questions you will be asked will be more extensive, and will include your name and date of birth, ethnicity, questions about the original onset of your diabetes (e.g., symptoms, tests that were done, treatments you received), about your past medical history (e.g., birth history including birth weight, any other medical problems that you have, medicines that you take), about how your quality of life is affected by your diabetes, about any genetic tests that you may have had related to your diabetes, and about current and past treatments of your diabetes. We expect this series of questions to take no more than 1 hour to complete. We will then ask you to provide us with brief updates every 1-12 months through a less extensive series of questions focused on your current treatment regimen, any changes in your medical history, and questions about how your diabetes is affecting your quality of life. We expect these update questions to take no more than 30 minutes to complete. We will contact you first by email, and then by telephone if necessary. If you have indicated that your treatment regimen is soon going to change or has recently been changed, then we will ask for more frequent updates, but no more than once a month. If you anticipate a change to your treatment regimen, you will be given the option of submitting an update before being requested to do so. If you have been on a stable treatment regimen with no expected changes, then we will ask for updates less frequently, but at least once per year. We may also periodically send you emails or mailings about events taking place or with information about monogenic diabetes, such as newsletters or voluntary surveys asking you about what kinds of information you would like to learn more about.

After you have begun the study, we will also ask your doctor or diabetes provider to access the website or contact us directly to provide further details about your medical history, including your presenting signs and symptoms, growth records, laboratory values and physical exam findings. Finally, we will request copies of your past medical records from which we will enter relevant information into the database. This will include such information as specific laboratory values from the time you were first diagnosed with diabetes, and any other exact medical details that you or your doctor may not remember precisely.

Additional surveys related to behavior, development and sleep:

Some people with certain forms of monogenic diabetes (especially those diagnosed as babies) seem to be at higher risk of having a variety of problems with their development, behavior and sleep. In order to determine whether these problems are related to your diabetes, your genetics, or any combination of these and other factors, it would be ideal to collect detailed information at multiple ages during development. If you agree to participate in this part of the study, someone may contact you to go through a series of questions over the phone, or complete questionnaires through the mail or online. This may take 1-2 hours, but will be scheduled at your convenience. These questions are taken from validated surveys used to identify potential problems with developmental progress, functional abilities, behavior,

sleep, and family caregiver coping/support. Repeat assessments would take place more frequently at younger ages. Your participation will always be voluntary.

Please indicate below whether or not you agree to be contacted regarding telephone-based screening surveys of development, behavior, and sleep:

☐ Yes, you may contact me regarding these surveys

Initial: _____ Date: _____

☐ No, you may not contact me regarding these surveys

Initial: _____ Date: _____

Data Gathered for This Study:
This information will be kept in a computer database that can only be accessed by the research team. You will not be able to make changes once you submit your survey, but you can contact the team and we will make changes on your behalf. Also, a member of the team will review your answers and contact you to make clarifications that may modify the information that is kept in the database.

In order to answer new research questions, data from this study may also 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, or you could be asked to participate in new research studies about MDM. The information in the database may be used for future research studies. For any studies that would involve intervention or are of greater than minimal risk, we would contact you and ask if you wanted to participate in the study. You will have the opportunity, at that time, to decide whether or not to participate in any study for which you may qualify. You would also be asked to consider a separate consent document.

In addition, for any studies that involve minimal risk and do not involve any interventions, we are asking your permission to use the data in your registry for these types of studies. 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" we would not contact you at that point to ask your permission to use your registry data for that research study. Again, these are only studies that are of minimal risk and only data from the registry would be used. We will use the minimum necessary amount of information for these studies. We will ensure that your confidentiality will be maintained in these studies. We are asking your permission at this time to use your data for those 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 Screening of Families with Diabetes Mellitus*, we will 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 MDM. To do this, your data from study #6858 would be combined with any data collected under this protocol, *Monogenic Diabetes Mellitus 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 be contacted in the future by other researchers who wish to do new studies about MDM. 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 MDM

Initial: _____ Date: _____

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

Initial: _____ 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 MDM 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 force us to be unable to continue the study at some point in the future.

WHAT ARE THE RISKS OF THE STUDY?

There is some risk that individuals, other than your doctor and other caregivers, could learn some of your personal medical information. Every effort will be made to prevent this from occurring. There are no additional physical risks.

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, since the study involves no medical tests or treatments. However, we anticipate that the process of reviewing your history and treatment with you and your doctor may give you a better understanding of MDM. In addition, through the links on our website, you will have easier access to additional information. Also, if you choose to participate in the web-based discussion group (which is currently hosted through Facebook and only open by invitation to our participants - see separate consent form), you will be likely to learn more about MDM. We hope the information learned from this study will benefit other individuals with MDM in the future by providing data on MDM patients that may be analyzed to further our understanding of MDM. Additionally, if you agree to be contacted in the future by investigators who wish to do new studies on MDM patients, these studies would also be of potential benefit.

WHAT OTHER OPTIONS DO I HAVE?

Instead of being in this study, you may choose not to participate.

The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center or the clinic/hospital at which you are being treated.

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.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Only the research team will have access to this information. Your study records will contain your name, medical history number, date of birth, race, name of your physician or diabetes provider, and information about your diabetes diagnosis, and will be available to the study doctors and data coordinators. Your study records will be secured in locked offices and the data collected through our website or the REDCap survey will be kept on secure servers protected by a firewall, virus protection software, and backed up regularly. Neither your name nor other personally identifying information will be used in any publication resulting from the research study. Data may also be shared with our collaborators. All of the data that is released to our collaborators will be coded. Our collaborators include: Mark Anderson, MD, PhD and Mike German, MD of University of California, San Francisco; Jorge Ferrer, MD of Imperial College London; Daniel MacArthur of the Broad Institute; Jagiellonian University Medical College in Krakow, Poland. If you have consented to participate in the RADIANT (Rare and Atypical Diabetes Network) study, all of your research records from this study can be shared with the RADIANT researchers in an identified manner, including your name, date of birth, dates of tests and results of all tests performed as part of this research and any records collected as part of this research.

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 to access 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. If you are not a patient at the University of Chicago, we will ask for release of your medical records after you have signed a separate release of medical records form. In addition, we will ask for the participation of your physician/diabetes provider, if possible, to enter similar PHI into a separate survey regarding your current medical care and history. 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 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 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. Greeley 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. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from 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. In addition, it may be used in applications for grant funding or in reports to agencies that have previously provided funding to support this research. 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.

To help us protect your privacy, the National Institutes of Health (NIH) has issued a Certificate of Confidentiality for this research. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project, and we will do so if we have evidence of suspected child abuse, elder abuse or harm to self or others.

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, or the clinic/hospital at which you are being treated, 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, or the clinic/hospital at which you are being treated.

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. Greeley in writing at the address on the first page. Dr. Greeley 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.

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 the monogenic diabetes line at (773) 702-0829.

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, 5841 S. Maryland Ave., MC7132, I-625, 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/ or 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)