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 [Physician]

Doctors Directing Research: Siri Atma W. Greeley, MD, PhD
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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.

WHY IS THIS STUDY BEING DONE?

The overall purpose of this study is to learn more about the number of people who have monogenic diabetes mellitus (MDM), how and why it happens, and how best to treat it. Recent advances in the understanding of MDM and its treatment highlight how important it will be to find and identify as many patients with MDM as possible, to determine whether they have been found to have identifiable genetic differences, and to figure out which treatments have been most effective in controlling their blood sugar levels.

In addition, we hope that the patients/parents and physicians/diabetes providers who chose to participate in this Registry will themselves learn more about MDM. The website through which patients and physicians will answer the research questions will also serve as a centralized resource for information on MDM for patients and families, physicians/diabetes providers treating MDM patients, and researchers trying to learn more about MDM. Separately, researchers will facilitate a moderated web-based discussion group on which patients/parents and physician/diabetes providers will be able to discuss various aspects of MDM, including its treatment. Through these forums for patients with this rare disease, we hope that valuable information and experience may be more easily shared to those living and dealing with MDM every day.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 5,000 people are expected to take part in the overall Registry study through participation on the website (or over the telephone if preferred), regardless of where they live. Somewhat fewer would be expected to participate in the web-based discussion group.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Greeley and his research team will moderate exchanges on a web-based discussion group, which is currently hosted through Facebook and only open by invitation to participants in the MDM Registry study. The moderators of the discussion group will attempt to provide clarification of what is known or unknown regarding MDM and its treatment; however, it is extremely important to note that the discussion group is in no way meant to replace the physician and/or diabetes provider who should be overseeing the treatment of MDM patients, with any changes in their treatment program implemented only in consultation with said provider(s). Participation in the discussion is purely voluntary; you may choose to post only a few times or never, even if you complete this consent process. Once you complete the consent, you will be instructed on how to access the discussion group. You may share as much or as little information as you like, but any information you do share will be readable by all other participants who have also consented to this part of the MDM Registry study. Furthermore, if in the future Dr. Greeley and his research team publish findings related to the MDM Registry research, they may choose to quote from the discussion group. In such instances, every effort will be made to protect the confidentiality of participants; however, certain information that you choose to reveal to other participants might make you identifiable to others.

Data Gathered for This Study:

The discussion group is not designed to collect any specific information, but rather to facilitate the sharing of potentially useful information among participants, which will include patients, their parents/guardians, treating physicians, and/or other diabetes providers (such as nurse practitioners). Inasmuch as such sharing of information may prove to be helpful to individuals coping with MDM, the physicians/diabetes providers who care for MDM patients and diabetes researchers may be interested to know about this study and the discussion group. Thus, research publications may make reference to the discussion group, including quoting illustrative examples of the helpful sharing of information among participants. Reporting the potential success of the discussion group in this way may promote similar discussion groups and research in the future. Participation in the group does not require that you "friend" any of the participants, unless you so choose. By modifying your privacy settings, you are in total control of what information, other than your user name and profile picture, you share with the discussion group participants. We will collect your contact information and date of entry into the study and keep it confidential. No other protected health information will be collected from physician participants in the discussion group portion of the study.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for as long as you choose to participate. We plan to maintain the discussion group indefinitely; however, it may be discontinued at any time in the future due to unforeseen circumstances, such as a lack of funding.

WHAT ARE THE RISKS OF THE STUDY?

There is some risk that your patient's confidential personal medical information could be revealed. Every effort will be made to prevent this from occurring. By participating in the discussion group, you may increase the risk of revealing such personal information; you should consider the ramifications of such discussion on your professional responsibility to maintain patient confidentiality as stipulated by regulations such as the Health Information Portability and Accountability Act (HIPAA) of 1996. If any studies are published in the future that use any text from discussions that have taken place, every effort will be made to maintain confidentiality by removing any identifying features. There are no additional physical risks.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you choose to participate in the web-based discussion group, you are likely to learn more about various aspects of treating MDM. Similarly, other individuals may benefit from any information you choose to share with them that you have gained from your experience with MDM.

WHAT OTHER OPTIONS ARE THERE?

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 employment status at the University of Chicago Medical Center, or wherever you practice.

WHAT ARE THE COSTS?

The will be no costs to you resulting from your participation in this research study.

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 study staff will have access to this information. The records from the main MDM Registry study related to your patients, about whom you entered information into the database, will be linked to the web-based discussion group, but this information will only be accessible by Registry staff. No specific information is meant to be collected as part of this web-based discussion group, as it is meant primarily to benefit the participants, who will choose to share whatever information they wish. As a physician/diabetes provider, you will be allowed to post on and/or have access to the web-based discussion group only if your MDM patient(s)/parent(s) have already consented to participate in the main MDM Registry study to which you have also contributed data. All records related to the main study as well as the web-based discussion group will be secured in locked offices. Neither your name nor other personally identifying information will be used in any publication resulting from the research study. You are reminded to respect your patient's privacy according to the Health Information Portability and Accountability Act of 1996 (HIPAA). In all posts and exchanges on the web-based discussion group you should make every effort not to disclose identifying information. 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.

The data collected in this study will be used solely for the purposes described in the form. 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.

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.

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 employment status at the University of Chicago/University of Chicago Medical Center, or wherever you practice, will not be affected. You may choose not to participate at any time during the study.

If you choose to no longer be in the study and you do not want any of your 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 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.

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CONSENT

SUBJECT

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)

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 or the family.

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

REGISTRY INVESTIGATOR/PHYSICIAN:

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

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