

The UNIVERSITY OF CHICAGO
The Division of Biological Sciences • The University of Chicago Hospitals

CONSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: **15617B** Name of Subject: _____
Medical History Number: _____

STUDY TITLE: **Neonatal Diabetes Mellitus Registry: Web log (blog) discussion group**

Doctors Directing Research: **Louis Philipson, MD, PhD**
Graeme Bell, PhD; Siri Atma W. Greeley, MD, PhD; Rebecca Lipton, PhD; Julie Stoy, MD

Address: **University of Chicago**
5841 S. Maryland Ave.
MC 1027
Chicago, IL 60637

Telephone Number: **773-795-4454 or 312-342-7808**

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 overall purpose of this study is to learn more about the number of people who have neonatal diabetes mellitus (NDM), how and why it happens, and how best to treat it. As described in the separate consent form related to the overall NDM Registry protocol, recent advances in the understanding of NDM and its treatment highlight how important it will be to find and identify as many patients with NDM 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 NDM. The website through which patients and physicians will answer the research questions will also serve as a centralized resource for information on NDM for patients and families, physicians/diabetes providers treating NDM patients, and researchers trying to learn more about NDM. In particular, the website will host a moderated discussion web log (blog) through which patients/parents and physician/diabetes providers will be able to discuss various aspects of NDM including its treatment. Through this centralized forum for patients with this rare disease, we hope that valuable information and experience may be more easily shared to those living and dealing with NDM every day.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 3,000 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 blog discussion group.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Philipson and his research team will moderate discussion on the blog hosted on the website through which only participants in the overall NDM Registry study will have access. The moderators of the discussion will attempt to provide clarification of what is known or unknown regarding NDM and its treatment; however, it is extremely important to note that the discussion group is in no way meant to replace a physician or diabetes provider who should be overseeing your treatment. Any changes in your treatment program that you may consider implementing must be done only in consultation with your physician or diabetes provider. Participation in the discussion is purely voluntary, one 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 given access to the discussion group by providing a username and password. Your blog posts may be linked to the health information collected about you as part of the main Registry study, but only Registry staff will have access to that information. 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 NDM Registry study. Furthermore, if in the future Dr. Philipson and his research team publish findings related to the NDM Registry research, they may choose to quote from the discussion blog. 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 may make you identifiable to others.

Data Gathered for This Study:

The discussion blog is not designed to collect any specific information, but rather for potentially useful information to be freely shared among participants, which will include both patients or their parents/guardians, as well as their treating physicians or other diabetes providers (such as nurse practitioners). Inasmuch as such sharing of information may prove to be helpful to individuals coping with NDM, the physicians/diabetes providers who care for NDM patients and diabetes researchers may be interested to know about this study and the discussion blog. Thus, research publications may make reference to the discussion blog, 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. Only your name, medical history number and date of entry are collected as part of the blog portion of the study; however, as mentioned above, any information you choose to share in posting to the blog may be linked to the personal health information collected as part of the main Registry 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 individuals could know some of your personal medical information other than your doctor and other caregivers. Every effort will be made to prevent this from occurring.

By participating in the discussion group on the website, you may increase the risk of revealing such personal information, particularly if you choose to identify yourself. 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 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, if you choose to participate in the blog discussion group on our website, you will be likely to learn more about various aspects of living with NDM. Similarly, other individuals may benefit from any information you choose to share with them that you have gained from your experience with NDM.

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 care at the University of Chicago Hospitals 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 study staff will have access to this information. The records from the main NDM Registry study will be linked to the username under which you will participate in the blog discussion group, but this information will only be accessible by Registry staff. No specific information is meant to be collected as part of this blog discussion group, as it is meant primarily to benefit the participants, who will choose to share whatever information they wish. Only patient/parent or physician/diabetes provider participants who have consented to participate in the main NDM Registry study will have access to and be allowed to post on the blog discussion group. All records related to the main study as well as the blog 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.

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 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.

During your participation in this study, you will have access to your medical record. Dr. Louis 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. 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. 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 Hospitals, or whatever clinic/hospital at which you are currently 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 Hospitals, or whatever clinic/hospital at which you are currently 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. Louis Philipson in writing at the address on the first page. Dr. Louis 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.

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 Dr. Louis Philipson or Siri Greeley at 773-795-4454 or 312-342-7808.

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 of age 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 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

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)