

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

ASSENT TO PARTICIPATE IN RESEARCH
Neonatal Diabetes Mellitus Registry

1. My name is _____ (Staff obtaining assent)
2. We are asking you to help us with a research study. The study involves your parents answering questions on our website about your health and medical history. The purpose of this study is to help kids like you who have neonatal diabetes by learning more about who has it and how best to treat it.
3. If you agree to be in this study, your parents will login to our website and answer a series of questions about your diabetes when it first happened, what medicines you have needed to take since then and any other medical information that may be related. The first series of questions is longer and may take them about an hour to finish. After this we will ask them to update us anytime you change the medicines you are taking. This should be at least once a year, if not much changes, or no more than once a month, if things change a lot.
4. You should continue doing everything your doctor tells you to do to help control your diabetes. If this study makes you think of any questions about your diabetes, you may ask us at any time, but you should also talk with your doctor.
5. If you agree to participate, we will also ask your doctor to login to the website to answer a series of questions about how he/she is taking care of your diabetes. Also, we will ask your parents to sign a consent for us to get your old medical records about how they found out you had diabetes and how they decided which medicines to give you.
6. There is a risk that people will find out you participated in this study and the results of your tests. It is important to us that this does not happen, we will not let anyone else see any of the information we get about you and will keep it in a secure website or locked room.
7. You may or may not benefit from this study. You or your parents or your doctor may learn more about neonatal diabetes and you may decide to take care of it differently. We will make it so you or your parents can see all the information we collect about you any time you log in to our website.
8. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.
9. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you, and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.

- 10. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you or your parents can call Drs. Philipson or Greeley at (773) 795-4454 or (312) 342-7808.
- 11. Signing your name at the bottom means that you agree to be in this study. You or your parents will be given a copy of this form after you have signed it.

SUBJECT

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)

PERSON OBTAINING 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 assent form to the subject and his or her family.

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

INVESTIGATOR

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