Consent Form Approval

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Allan Prochazka, MD/Stephen Bartlett, R.Ph., Co-Chairs, COMIRB
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Adam Rosenberg, MD/David Lawellin, Ph.D.,Co-Chairs, COMIRB

Date: **Valid Through:_____**

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

Title: Diabetes Autoimmunity Study in the Young (DAISY) (COMIRB Protocol 92-080)

Principal Investigator: Marian Rewers, MD, PhD
SUBJECT CONSENT TO GENETIC SCREENING
June 25, 2001

INFORMED PATIENT CONSENT
Diabetes Autoimmunity Study in the Young (DAISY) (COMIRB Protocol 92-080)

Patient/Subject Name:_____
Attending Physician:_____
Sponsor: University Of Colorado School of Medicine

Date of Consent:_____ Date copy to Patient/Subject:_____

Dr. Bob McDuffie, or his designee has advised me that they are conducting a research study at the Exempla Saint Joseph Hospital in collaboration with the University of Colorado School of Medicine . I have been offered the opportunity to take part in a research study because I have delivered a baby at this hospital.

Dr. Bob McDuffie or his designee has explained that Federal law requires that I consent in writing to the treatment or procedure before it is performed on my infant; and that by signing this document, I will be giving that consent. I also understand that Federal law requires my consent be an "informed consent," which means that I must understand the meaning of each and every part of this document before signing it. **I also understand that if there is something in this document I do not understand, that it is in my own interest, and that of the doctor or their designee to ask that the item which is unclear be clarified.** I also understand that I have the right to change my mind about participating in the research study, and that I may revoke this consent even after I have given it.
In giving my consent, I understand that:
If I agree to participate, my child will be among approximately 50,000 children taking part in this study. The purpose of this study is to understand the causes of childhood diabetes by studying children who may be at risk for developing diabetes. In order to find these children we are screening babies born in this hospital for diabetes gene markers. Babies with these diabetes gene markers will then be followed over time to see whether certain viruses or types of food cause diabetes and how to prevent it.
We expect to find that 1 in 12 children will have one diabetes gene marker. We also expect to find about 1 in 40 children will have two diabetes gene markers. If at least one of these diabetes gene markers is detected in your child, we will let you know these results within two months of your child's birth. We will explain what having these gene markers means in terms of the risk of getting diabetes and we will be available for any questions you might have. At that time we may ask you to participate in a second part of this study, which will include periodic examinations to detect antibodies to the cells that make insulin. These antibodies appear several years before the onset of diabetes and show that the cells that make insulin are being

destroyed.
Diseases other than diabetes, for example, celiac disease (an intestinal disorder caused by wheat), IgA deficiency (a defect in production of antibodies that protect against infections), rheumatoid arthritis (inflammation of the joints), diseases of thyroid and adrenal glands, and certain infections are also associated with the same gene markers that we are testing. Some of these diseases can be detected early in people with these high-risk genetic markers. Your child may be eligible for additional studies and treatment for these diseases. We are asking permission to contact you at a later date, should such a study become available.

Signing this consent form means that you agree to the screening of the cord blood and newborn screening sample. It also means that you agree to be contacted by mail or telephone once a year to ask if your child or anyone else in your family has developed diabetes. It does not obligate you to participate in the second part of this study that includes follow-up visits. We will explain the second part of this study fully when the results of the testing are available and you can then decide if you want your child to participate further.

The cord blood collected will be used for obtaining a sample of your child's DNA, the genetic material of our bodies. We would like to use this DNA sample to search for genes that may change a person's risk for developing diabetes. At the present time, none of the genetic analyses that we will do have clinical use, that is, they will not help your child's doctor in any way with any treatment. These analyses cannot also establish or rule out paternity or maternity of the child. We will use a study ID code instead of your child's name on the DNA sample that we store. Your child will not be identified by his/her name when the sample is analyzed.

Procedures

A sample of blood was routinely collected from the umbilical cord at the time of delivery of your baby. This blood sample is now in storage. If you agree, we will test the cord blood sample to see whether your child carries certain diabetes gene markers that increase your child's risk of childhood diabetes. If you decline participation, the sample will be destroyed. The blood sample will be identified only by a number, not a name, and will be sent to a laboratory in California where screening for the diabetes gene markers will be done. The laboratory will send the screening results back to the research study and we will inform you, and only you, of the results and the meaning of these results in terms of diabetes risk. In addition, the same testing may be done on the newborn screening sample that is routinely collected from your baby's heel by the hospital shortly after birth. This will help us to see if, in the future, the newborn screening sample can be used instead of the cord blood sample.

Please initial the statements below to indicate which conditions of the study you agree to participate in. You may withdraw your consent at any time in the future by checking the "consent withdrawn" box and initialing next to it.

☐ *I **DO** consent to the use of my child's DNA by the Diabetes Autoimmunity Study in the Young as described above. My child's name or other information that could identify him/her will not be released.*
Initials:_____

☐ *I hereby withdraw the above consent to the use of my child's DNA by the Diabetes Autoimmunity Study in the Young.* Consent withdrawn Date_____
Initials:_____

☐ *I **DO NOT** consent to the use of my child's DNA by Diabetes Autoimmunity Study in the Young as described above.* **Initials:_____**

☐ *I **DO** consent to the storage of my child's blood indefinitely by Diabetes Autoimmunity Study in the Young for future investigations that may include medical research projects on other medical conditions. My child's name or other information that could identify him/her will not be released.*

Initials:_____

☐ *I hereby withdraw the above consent to the storage of my blood indefinitely by Diabetes Autoimmunity Study in theYoung.* Initials:_____ Consent withdrawn Date_____

☐ *I **DO NOT** consent to the storage of my blood by the Diabetes Autoimmunity Study in the Young for future investigations that may include medical research projects on other medical conditions.*

Initials:_____

In the very unlikely event that a DNA analysis we conduct might become useful to me, I wish that you...

☐ ***DO** inform me of the results of the test, and its meaning.*
Initials:_____

☐ ***DO NOT** inform me of the results of the test, or its meaning.*
Initials:_____

Foreseeable Risks/Discomforts

Since the cord blood is routinely drawn and is now in storage, there is no risk of injury resulting from your participation as neither you nor your baby have been touched to obtain this blood sample. Some stress may occur from the information that your child has a higher than average risk of diabetes. It is our highest priority to preserve the confidentiality of this test. There is a small possibility that health, disability, and life insurance companies may interpret these screening results incorrectly and may affect your child's ability to get medical or life insurance in the future. However, the only way insurance companies would know of these screening results is if you told them directly or if the results were in the child's medical record. It is your choice as to whether or not to inform your child's pediatrician and place the results in the medical records.

Benefits

You will receive no health benefit from participating in this research study and there are risks as mentioned in the Risk section.

Source of Funding

All funding for this study will be provided by grants R01 DK32493 and DK49654 from the National Institutes of Health (NIH)

Compensation for Injury

There is no risk of injury because neither you nor your baby will be touched to obtain this blood sample. You or your child will not be paid for any lost wages, pain or suffering that may be caused by the results of the screening test. Further information may be obtained by calling Dr. Marian Rewers at (303) 315-7553.

Confidentiality
Your physician/investigator will treat your identity with professional standards of confidentiality. However, the U.S. Department of Health and Human Services, the NIH, the Western Institutional Review Board, and the Colorado Multiple Institutional Review Board have the right to inspect all of your medical records relating to this research for the purpose of verifying data. The information obtained in this study may be published in medical journals, but your child's identity will not be revealed. All records will be kept under lock and key. All computerized data files are password protected and your child will be identified only by a code number. All DNA samples will be labeled with a code number only, and any analysis that is done using your child's DNA will identify him/her only by the code. The code cannot be traced back to his/her name or other identifying information except by authorized study staff and investigators.

Cost to Subject
The genetic screening will be done and reported at no cost to you. You will not be paid for your child's participation in this study.

Questions about Research or Subject's Rights
You will receive a copy of this consent form. Please ask questions about this researcher consent either now or in the future. You may direct your questions to Dr. Marian Rewers at (303) 315-7553 or to Dr. Bob McDuffie at (303) 861-3115. If you have questions regarding your rights as a research subject, please call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055, or you may speak with the St. Joseph Hospital Patient Representative at 303-837-7850.

Participation
Your child's participation is voluntary. You may choose not to enter the study or withdraw at any time without affecting the care your child will receive or the benefits to which he/she is entitled. The investigator may also choose to withdraw your child from the study at any time if he feels that it would be harmful to his/her health.

New Findings
Significant new findings that relate to your child's participation in this study will be discussed with you.

AUTHORIZATION
I have read this paper about the study or it was read to me. I know what will happen, both the possible good and bad (benefits and risks). I choose to have my child in this study. I know I can stop being in the study and my child will still get the usual medical care. I will get a copy of this consent form (please initial the first two pages of the consent form).

Child's Name: _____

Parent or Guardian: _____/_____Date:_____
Signature Print name

Consent form explained by: _____/ _____Date: _____
Signature Print name

Investigator: _____/ Marian Rewers, MD, PhD_____ Date: _____
Signature