

NAME
STREET ADDRESS
CITY, STATE, ZIP CODE
ID #####

Dear Parents,

When your baby, NAME, was born on DATE, you consented to participate in a screening study for 'diabetes gene markers' conducted by the University of Colorado School of Medicine. At that time, a sample of your baby's blood was obtained from the umbilical cord and then screened, as was explained to you in the hospital.

About 1 in every 300 children will develop diabetes by the age of 20. This risk increases to 1 in 25 for children who have a parent or sibling with type 1 diabetes. The risk for children who have a parent or sibling with type 1 diabetes and who also have high risk genetic markers may be as high as 1 in 4.

This letter is to inform you that we were unable to test your baby's blood due to technical difficulties. In order to do this testing we will need to draw a blood sample. Because of this, we are unable to estimate your baby's risk of developing type 1 diabetes. However, because your baby has a parent or sibling with diabetes, your baby continues to have a greater risk of developing diabetes than the average child. This does NOT mean your baby will definitely develop diabetes. Type 1 diabetes is caused by the immune system damaging the insulin-producing cells in the pancreas. It is believed that genetic and environmental factors are necessary to trigger the body to destroy its own insulin-producing cells. This process is called autoimmunity and it occurs prior to the development of diabetes.

In order to learn which environmental factors are important in the development of autoimmunity and diabetes, the University of Colorado School of Medicine is conducting a study of children who have one or more 'diabetes gene markers' and/or a parent or sibling with diabetes. We would like to ask you to participate in this study. Participation would include telephone interviews every 3 months to gather information on your baby's diet and illnesses. You would also be asked to bring your baby in for clinic visits at 9, 15, 24 months of age and then annually after that. During the clinic visits, your baby's growth would be measured, blood drawn from a vein in the arm or hand, viral cultures taken by simple throat and rectal swabs, and saliva obtained for the study. This will tell the research team about your child's health and if your child is beginning to develop autoimmunity. Participation in this study is voluntary; you can withdraw at any time. All information obtained will be treated professionally and is confidential. Because your baby is at a greater risk of developing diabetes than the average child, we strongly encourage you to participate in this study.

Our study nurse will be calling you to answer any questions you may have and, if you are interested, to enroll you in our study group. If she has not yet contacted you, please call her at (303) 315-7852.

Thank you for your participation in the screening phase of this study.

Sincerely,

Marian Rewers, MD, PhD

Jill M. Norris, PhD