The PROMISE Study

‘PRenatal and Obstetric Maternal Exposures and ISlet Autoantibodies in Early Life: The PROMISE Study.’

The purpose of this study is to find out more about how health and exposures during pregnancy, such as having an infection, diet and growth may impact later risk of islet autoimmunity in the child. We are also interested in finding out more about why having a father or sibling with type 1 diabetes increases risk of autoimmunity in the child than having a mother with type 1 diabetes.

We are enrolling women who are pregnant and either have type 1 diabetes or (if the pregnant woman doesn’t have type 1 diabetes) where another first degree relative (father or full sibling) of the baby has type 1 diabetes. Pregnant women will be asked to complete a visit once per trimester (3 visits) during pregnancy and at 4-6 weeks after delivery. The father is also invited to enroll in a single visit. We also plan to screen the baby for genetic risk for type 1 diabetes, using a bloodspot collection at birth. Families will be asked to complete questionnaires about growth health and diet at 6, 12, 18 and 24 months of age and between 5-6 years of age, and to complete blood testing for islet autoantibodies at 24 months and between 5-6 years of age. For those children with a high genetic risk score, we will also collect blood for islet autoantibody testing at 6, 12, and 18 months.

You may be eligible to participate if you are a pregnant woman who:

- Is between 8-24 weeks gestation with a singleton pregnancy
- Has type 1 diabetes for at least 12 months, or if you don’t have type 1 diabetes, the father or a full sibling of the baby has type 1 diabetes.
- Is 18 years of age or older
- Is willing to have blood, vaginal swabs and stool samples collected and to complete questionnaires about prenatal exposures once per trimester during pregnancy (up to 3 visits) and at 4-6 weeks after delivery
- Is willing to have your baby screened for genetic risk for type 1 diabetes, to complete online questionnaires and to have the child followed for measurement of islet autoimmunity according to the determined risk for type 1 diabetes, through 5-6 years of age.
  - If low risk, two screenings: at 2 years and again between 5-6 years of age
  - If high risk, five screenings: every 6 months through 2 years, and again at 5-6 years
- The father is also asked to complete one visit during the pregnancy, but this is not mandatory

If you are interested in finding out more about the study and whether you are eligible, please call or email Ankita Gyawali at 303-724-4080, Ankita.Gyawali@cuanschutz.edu or Kelly Valdez at 303-724-0308, Kelly.Valdez@cuanschutz.edu.