

ENROLLMENT FAQ's_Scripts

A. Contacting Families

How do you know who to contact?

NEC/NOC

As HLA results from Roche for newborns screened at St. Joe's are imported into the DAISY database, letters are generated for families of newborns at low, moderate, and high risk. For moderate and high risk newborns, as well as NOCs, an enrollment follow-up sheet is also printed. The letters and follow-up sheets are copied.

What do you do with the NEC/NOC enrollment forms, results letters?

Moderate, high, and NOC letters and follow up sheets are given to the Enrollment Coordinator for mailing.

When do you send them out?

Generally, moderate, high, and NOC letters are mailed on Mondays, to ensure that the family receives the letter during the workweek when someone will be available to answer their questions when they call. Low risk, non-NOC letters can be mailed immediately. The follow-up sheets are filed alphabetically according to the child's last name in the NEC/NOC enrollment binder. It is noted on the follow-up sheet when the letter was mailed.

What do you tell families about the HLA result when you contact them?

When contacting families for enrollment, a general script is followed.

Hi, my name is _____ and I am calling from the DAISY diabetes study at the University of Colorado School of Medicine. When (baby's name) was born in (month) at St. Joe's hospital you agreed to have him/her screened for diabetes gene markers to find out genetic risk of developing type 1 diabetes. We have mailed you the results of this screening and I would like to speak with you about these results. Did you receive the letter? *If letter was not received, immediately confirm address.* Do you have any questions about the letter?

Basically, what the letter says is that (name) has 1(2) of the genetic markers. What that means is that (name) has an increased chance of developing diabetes in the future—it DOES NOT mean that (name) *will* develop diabetes.

Most kids have a 1 in 300 chance of developing diabetes. If a child has 1 marker, the risk is about 1 in 60, and with 2 markers, the risk is 1 in 15. Is there any diabetes in your family? What kind?

Our study is looking at type 1 diabetes, and I would like to just give you some basic information about diabetes. Normally, when you eat carbohydrates, your body

breaks them down into a type of sugar, glucose, that you use for energy. This sugar circulates into your blood, where it is then taken up into the cells for energy. Without this sugar, your cells would not have the energy to function. The way that the sugar gets into the cells is with a hormone called insulin. It's produced by the islet cells in the pancreas. Think of insulin as a key that unlocks a door.

There are 2 types of diabetes. Type 2, formerly known as adult-onset diabetes, is a problem with your body not being able to use insulin. The body still makes insulin, but can't use it or is resistant to it. It's like the key doesn't fit the lock.

Type 1 diabetes, formerly known as juvenile diabetes, is different, it is an autoimmune disease, meaning the body's immune system attacks the body's own cells. There are several autoimmune diseases, and in the case of type 1 diabetes, the body is attacking the insulin producing cells. Something, and we don't know what, triggers the immune system to see the insulin-producing cells as foreign, and the purpose of the immune system is to attack anything foreign. So the immune system begins to attack the islet cells. This is a process that takes a long time—many months to years. Finally, the body is no longer able to produce insulin on its own. If the body can't make insulin, then the sugar can't get into the cells to be used for energy, and the sugar just stays in the blood. This is when diabetes happens. Before this, you have no idea that this immune process is happening inside your body. People appear perfectly healthy, but they are developing diabetes, and just don't know it. There are no outward signs. However, sometimes, by looking at your blood, we can see this process happening.

Now, we know that part, but not all, of what causes diabetes is genetic, and it is widely believed by researchers that part is environmental—meaning that there is probably something in the environment, such as viruses, diet, stress, that either helps to trigger diabetes or prevent diabetes. Our study is trying to find out what that trigger might be.

In the past, other studies that have looked at this have studied kids that developed diabetes and asked parents about environmental exposures that happened in the past. This isn't the best way to do it, because most kids develop diabetes between the ages of 8 and 12. It's hard for parents of kids that age to remember back when their kids were babies to see what they might have been exposed to. What we want to do with our study is gather the information on all kids before diabetes happens. We gather the information the same way on all the kids in our study. Now, most of the kids in our study will never develop diabetes. But some will. Eventually we expect to see patterns of differences between the kids who go on to diabetes and the kids who don't. Generally, it takes about 10-15 years for patterns to show up. We're halfway there—our study has been going on 7 years, and we have funding for several more years.

The way that this follow up portion of our study works is, every 3 months we would call you on the phone to ask you questions about (name)—what he/she is eating, if he/she has been sick, stressful events, allergies, pets, all kinds of things that could potentially be triggers. This interview takes only about 10 minutes.

Then, when (name) is 9, 15, 24 months old and yearly after that, we want to get a blood sample to test for immunologic markers in the blood. These are things that would tell us if the immune system is beginning to attack the insulin-producing cells.

Specifically, we're looking for things called autoantibodies—signs that the immune system may be attacking the pancreas insulin-producing cells. This is a real blood test from a vein in the arm, it's not a finger poke. However, we have been drawing babies' blood for a long time, so we're really good at it! Also, we use a numbing cream on their skin, so they don't feel the poke. Now they might fuss a little, because babies don't like holding still for 45 seconds, and they don't like strangers touching them! But they'll be with you and sitting on your lap the whole time.

At this time, we also want to collect information on viruses that (name) might have been exposed to. We're interested in both respiratory and gastrointestinal viruses. We can get this in a couple of ways. For the respiratory viruses, we take a simple throat culture and we also collect some saliva—we give them a special sucker that makes them drool a lot and just get a little saliva. For gastrointestinal viruses—illnesses in their tummy or intestines, or diarrhea, things like that, we take a rectal swab, which is really quick and painless—just like a wipe from their bottom. If they come in with a poopy diaper, it just makes it that much easier. We'll also collect a little bit of urine, and this is done by placing a few cotton balls in their diaper before you come in. Usually by the end of the visit the cotton balls are wet. We'll also see how much (name) weighs, and when he/she is old enough, height, to check his/her growth.

The first time (name) comes in for a blood test, we also like to get a blood sample on you and (other parent's name) and any other children you have. Since this is a genetic study, we want to have genetic information on all family members, and we'll also test everyone's blood for the autoantibodies. Another thing that we will test all of you for is celiac disease, which is a gluten, or wheat, intolerance. Like diabetes, it is an autoimmune disease, in which the body attacks itself, and interferes with gluten digestion. Celiac disease is not life threatening, and many people don't even know they have it. We know that it is related to diabetes, because people with diabetes have an increased risk for celiac, but we don't know exactly how they are related.

Now being in the study will not change anything for (name). We are just observing. The nice thing about it is, with the blood test, we can see any changes to the insulin-producing cells in the blood. This kind of test is not available at your doctor's office, and it allows us to see any changes before any symptoms of diabetes develop. If kids do develop any of these changes, or autoantibodies, we like to follow them a little more often—every 3-6 months. Once these autoantibodies show up, there is no known way to slow or stop progression to diabetes, but because our study is connected with the Barbara Davis Center for Childhood Diabetes, we can provide you with more education about diabetes. *(Some kids may be eligible for DPT if a cousin or aunt/uncle has IDDM)*

Do you have any questions?

Parent/Family FAQ's:

- Sharing info with doctors—Because we offer every study subject confidentiality, we don't share any information with your doctor. But we encourage you to discuss it with them if you choose. If (name) did develop any of the autoantibodies, our study pediatrician would request permission

from you to contact your pediatrician, to let them know what steps to take in case we were unavailable—on a weekend or holiday for example.

- No family history: Even though you may not know of any family members with diabetes, insulin wasn't even discovered until the 1920's. Before that, people with diabetes just died. So it is possible that you might have had some ancestors who had diabetes.
- Other children who were screened previously: Look up before calling to see if they have any other kids who were screened, and these kids will keep their original ID. If they have a kid who was screened as having one marker but not recruited for enrollment, explain that it is because our study goes through different cycles. Sometimes we change who we are enrolling, just due to funding issues and study cycling. The actual risk markers are not any different. It (could be) the same genetic marker.
- Is there anything that can be done? At this point, we have no strong data showing a known relationship. Some things which were previously thought to contribute to diabetes (such as cow's milk) were later found to have no effect, and for some other things (such as viruses), we just don't have enough data yet to show any relationship. It takes about 10-15 years for trends to become apparent.
- How long will my child be followed? As long as you are comfortable with your child participating. Our goal is to follow kids through puberty. Looking at some of the older kids we have followed because they have a diabetic family member, we have found that puberty really does have an effect. But we definitely don't want the study to be a burden on you, so you only participate as long as you want to.

What do you do if you get an answering machine?

If you must leave a message, the following script is followed.

Hi, this is _____ with the DAISY diabetes study at the University of Colorado School of Medicine. When your baby _____ was born at St. Joe's hospital you consented to having his/her cord blood screened for diabetes genetic risk markers. We have mailed you the results of this screening and I would like to speak with you about these results. I will be attempting to contact you again but in the meantime please feel free to call me at 303-315-_____.

What do you do if you can't contact the family?

If the phone number is wrong, or you are unable to leave a message, but the letter has not been sent back to us due to an incorrect address, the unable to contact letter is sent.