

ENROLLMENT

C. Agree to enrollment in follow-up

What happens if the family agrees to enrollment?

Confirm address, including 4 extra zipcode numbers if they know it, and home phone #. Get work numbers or any other alternate phones, just in case we lose contact with them.

Confirm name (including middle initial and spelling), DOB, race, diabetes and celiac status of child and biological parents. Get the same information for all siblings of child. Be sure to confirm if they are full or half siblings.

“Is mom currently pregnant?”

Are there any 2nd or 3rd degree relatives with diabetes or celiac disease?

We are also looking for links between diabetes and other autoimmune diseases, so I have a list of about 35 diseases, and I want to know if you or other kids (baby’s immediate family) have any of these diseases. If you’ve never heard of them, you don’t have them.” (make note of any other diseases they mention, or 2nd or 3rd degree relatives)

This information is all filled out on the purple enrollment form. As the form is filled out, ID’s are assigned. The family ID is the 5 digit ID that the child was assigned when recruited at St. Joes. The member ID’s are –0 (study subject), -1, (mom), -2 (dad), -3 (sib) etc. etc. The exception is if an older sibling is already enrolled in DAISY. In this case, the family ID remains the 5 digit ID of the oldest sibling, the parent ID’s remain the same as originally, and the newborn newly enrolled keeps the 5 digit ID he was assigned when recruited.

Packet mailed? What’s included in the packet?

The packet includes a cover letter, DAISY flyer and magnet, return envelope, NEC_Indiv or SOC_Indiv form, pregnancy FFQ and instructions, 2 copies of consent (1 for us, 1 for them), and the 6 informational articles about diabetes and celiac. It is important to make sure the name and ID# of the subject are written on consents, individual form, and FFQ.

Script:

“I’m going to send you some information and things to fill out in the mail. There are a couple of questionnaires—the first asks a few things about your baby—his first weeks of life, etc. The second asks about your diet during your pregnancy with (name). I will also send you some consent forms, both to sign and return and one to keep for your records. This form looks really similar to the one you signed at the hospital, but it is a consent to follow up and is a little different. There is also a medical records release for you to sign, which is just to get info on immunization records. That’s all we want from the medical record. There will also be some informational articles about diabetes for you to read and keep. And when (name) is about 3 months, a study nurse will call you to do the first interview. The first one is really easy, because they aren’t doing much yet. But what you will want to do to make the interviews a little easier, is make a note on your calendar when you introduce new food groups, and when (name) is sick. Those are really the only time-

dependent things that we ask. If you have any questions at all in the future, please don't hesitate to call at any time." (give names and numbers).

Chart made or requested to be made?

The child's recruit status is entered into the recruitment table in the database. The information from the purple enrollment form is entered into the database, and a new chart is made for this new subject. The enrollment form and the NEC/NOC follow-up sheet are placed in the chart. If the subject is less than 3 months old, the chart is filed, but if they are due or past due for the 3 month interview, the chart is given to the telephone interviewer so it can be caught up as soon as possible.