

Recruitment: DAISY Newborn Genetic Screening

Recruitment

Recruitment at St. Joseph's Hospital is divided into 3 phases: pre-interview, interview, and post-interview.

Pre-Interview Procedure

1) A DAISY recruiter will arrive at the hospital around 7 a.m. six days a week. She will begin her day in the **scrub room located on the mother baby (Labor & Delivery) unit, 2nd floor of the hospital**, where cord blood samples are kept. **The recruiter must always remember to wear gloves when handling test tubes of blood.** The recruiter will fill out a screening interview form for each cord blood sample collected. On the screening interview form, the recruiter will write down the following:

- today's date,
- the mother's last and first name,
- mom's date of birth,
- hospital ID number,
- attending physician

2) Once all the names are collected, the recruiter will keep the blood samples in the scrub room and walk over to the **mother-baby unit (MBU) on the 2nd floor**. While in the MBU nurses' station, the recruiter will fill out the top half portion of the screening interview forms. By looking at the patient list white board the recruiter will determine the following:

- Room # for each of the mothers to be interviewed.
- Baby's DOB and gender

NOTE: If the mother is not listed on the patient white board (the mother may be on another floor, may not be transferred to her MBU room yet, etc.), the recruiter can print off a face sheet on the MBU computers (see Instructions for Hospital Computer) to determine the room number.

Instructions for Hospital Computer:

- 1) Minimize the Gateway Program window or any other windows open on the computer by clicking in the “_” in the upper right portion of the screen
- 2) Open the Med Tech Program by double clicking on the icon on the desktop screen
- 3) Type “daisyp” as the user name and press “Enter” (it will not show that you typed this until you hit “Enter” afterwards) (user name and password are case-sensitive, so Caps Lock should be off)
- 4) Type “recruit” for password and press “Enter” (note: the password alternates between “recruit” and “recruiter”)
- 5) Type option #16 and press “Enter”
- 6) Enter hospital ID # starting with “E000.....” and press “Enter”
- 7) The name of the patient should pop up
- 8) If this is the correct patient, type “y” and press “Enter” to bring up the patient's facesheet

- 9) Type S.P.2S1 and press “Enter” to print the facesheet
- 10) To look up another patient keep hitting “Enter” until the screen for Hospital ID entry is cleared and repeat steps 6-9
- 11) Exit out of the program by clicking on the “X” in the upper right portion of the screen

Recruiting Procedure for Twins!

- 1) Each twin needs to have its own separate NEC Screen Interview and separate signed consent form.
- 2) Make sure mom signs both consent forms.
- 3) If you know a mom had twins and but only one cord blood sample is identified, look at the tube to see if it was Baby A or Baby B if the tubes are not labeled then there is no way to distinguish which baby’s cord blood received therefore in the log enter it as “No” for blood and “No” for interview.

Interview Procedure

Mothers of newborns are given information about the genetic screening study and asked if they would like to participate. If they agree then the NEC Screen Interview is filled out completely. A typical interview format is as follows:

“Good morning/hello, my name is _____, and I work with Exempla Saint Joseph Hospital research department. We are conducting a research study in collaboration with a study at the University of Colorado, School of Medicine to learn more about the causes of childhood/type I diabetes and find ways to prevent it.

We are offering a free genetic screening to let you know whether your baby is at low, moderate or high risk of developing childhood diabetes in the future. We have already screened about 30,000 babies at this hospital and our goal is to screen 50,000. **When your baby was born, a sample of the umbilical cord blood was collected for routine testing, this sample is normally discarded after your baby is discharged from the hospital, the study is asking for permission to use a portion of that cord blood to do the screening for diabetes gene markers so there are no pokes to your baby.**

We expect that only 1 in 12 babies will be at moderate risk for developing diabetes and only 1 in 40 will be at high risk.

Would you be interested in doing this screening?

If no,

Thank you for your time and we will destroy the sample. (Record the refusal reason on the NEC screening form)

If yes,

I just need to collect some information from you and then have you sign a consent form.

Fill out all the information on the NEC screening form, WHEN OBTAINING ADDRESS AND PHONE NUMBER MAKE SURE THEY CAN STILL BE CONTACTED AT THE SAME ADDRESS AND PHONE IN 8 WEEKS AND THEY ARE NOT MOVING

It is important to let you know, too, that when we send your baby's cord blood to the lab for screening, his/her blood will be kept confidential and will only be identified by a number, never by his/her name. In addition, you'll be the only one to receive the results, and you'll get those results explaining your baby's risk in a letter in about 8 to 10 weeks.

Begin explaining the consent form

(Note: It is the responsibility of the recruiter to obtain informed consent. Obtaining informed consent is not simply the act of getting a signature on the consent form; it is a process that includes explaining the study to the subject in language that he/she can understand and allowing time for questions and answers about the study. It is important that you explain to the parents that we are testing for genetic markers that may indicate increased risk of getting Type I diabetes, but that these markers don't necessarily mean the child will definitely get diabetes.)

Now, I'll need you to sign our study consent form, and I'll go over it with you. There are four pages total and we are making 3 copies of each page; one copy will go to you, **one will be kept at St. Joe's research dept**, and the other will come back with me to the study. Please stop me if you need to read any part of it.

The first page is describing the purpose of our study, and I'll need you to initial at the bottom. The second page is describing the procedure that **the cord blood has been obtained and is in storage**, so the baby is not going to be touched.

There are **three additional parts** that you can consent to on the **second** page. First, we'd like to ask for your permission to store a portion of your baby's cord blood for future testing, this testing may include medical research projects on other medical conditions. If you give your consent to have your child's blood stored, the sample will be labeled only with a number, and will only be used by our study, never experimentally.

Do you consent to the storage of blood?

Wait for response and have the parent check the appropriate box and initial below

The second part is asking for your permission to store DNA from that blood sample for future testing

As we learn more about diabetes, we may discover other genes associated with risk of diabetes or other autoimmune diseases, and we may want to go back and use that stored DNA for a rescreen.

If we learn something new from a rescreen of the **stored DNA** that will be useful to you would you like us to inform you? (only if they marked "I do" **for DNA storage**)

Wait for response and have the parent check the appropriate box and initial below

The last page is describing the confidentiality of the results. Your participation is voluntary and you can withdraw your consent at any time. **On the last page**, I'll need you to do is write your child's first and last name on the line, sign below, and initial at the bottom of the page. On the back of your copy of the consent form is the phone number of Michelle Hoffman, our Study Coordinator (show the yellow 1/3 sheet). Please call Michelle if you have any questions or if at any time you change your mind and decide that you don't want to participate.

Next I have an authorization to use health information form also known as a HIPPA form that gives permission to the study to keep your personal health information such as name, age, demographics. The study will not share this information with anyone outside the study except for regulatory agencies (recruiter can point on the form the agencies listed). A copy is given to the patient, staple together the consent and HIPPA form and give it to patient.

Thank you for your help and congratulations!"

If you are unable to talk with the parents (mom was not available, etc.) then recruitment is handled according to the procedure for 'pending' interviews below.

Post Interview Procedure

Once all the interviews are completed. **The recruiter returns to scrub room and gathers all the cord blood samples with completed interviews and prepares them for transport to the DAISY lab by placing the tubes and paperwork (yellow copy of consent and NEC screen interview form) in the transport cooler**

If any mothers refused to have screening done, the recruiter can throw the cord blood samples away in the hospital's sharps container located in the scrub room, DO NOT THROW AWAY THE NEC FORM. Make sure to include the screening interview form with the other paperwork that will be transported to DAISY lab

The white copy of the consent form and the signed HIPPA forms will be turned in to the research dept and filed in the appropriate filing cabinet

Pendings

A pending occurs when a cord blood is collected and the recruiter could not contact mom that day because of one of the following reasons:

- Mom was sleeping and is not going to be discharged until the next day
- Mom wanted to think about the consent or discuss it with the father and will not be discharged the next day
- Recruiter could not visit with mom after making several attempts because of too many things going on and mom will not be discharged until the next day

The recruiter should leave cord blood sample(s) with the paperwork in a bag marked "Pendings" for interviews still pending for the next day in the scrub room

Make sure to mark the tube and paperwork as pending and the reason for pending, the recruiter working the next day will attempt to interview these moms.

Data Entry

Once a recruiter is back from the hospital, he/she should assign a DAISY ID number to all "Yes" interviews, enter the NEC tracking forms (log forms) in the access database L:/DAISY/Recruit under "St. Joe's Log", screening interview forms are entered in access under "NEC Screening form". Data entry is done daily. The number of blood samples obtained is also entered in the database see "lab Protocol 2000"

Information about Juvenile Diabetes and the DAISY Study

Sometimes parents want to know more about diabetes; here are a few useful explanations that you can use:

- A person with juvenile diabetes suffers from high blood sugar level, called hyperglycemia. There are two forms of diabetes Type I and Type II. Type I, also known as insulin-dependent diabetes or juvenile-onset diabetes most commonly occurs between the ages of 8 and 12. Type I is an autoimmune disease. In other words, the person's immune system (the body's defense system) makes antibodies that destroy the individual's insulin producing cells, which are called beta cells in the pancreas. Once all the beta cells are destroyed, the child becomes unable to produce insulin, so individuals with the Type 1 diabetes must take insulin daily as long as they live.
- This study's goal is to find out what triggers autoimmune process and the disease outcome.
- We are screening newborns at St. Joseph to determine how many newborns from this hospital are carrying genetic risk markers for Type I diabetes.

