

## DAISY PENDING Cord Blood PROTOCOL

DAISY has defined a certain category of individuals in the study as “pending”. Pending individuals are people who have given birth at St. Joseph Hospital and cord blood samples were collected but were not interviewed by a DAISY recruiter. This is an outline of the necessary steps to resolve “pendings”

### 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.

#### I. Contacting a pending individual

- A) In order to contact a pending individual(s) it is important to have the appropriate information. This would include the mother’s name, address, phone number, baby’s date of birth and hospital identification number. All of this information can be obtained from the patient’s medical chart or computer tracking system at St. Joseph Hospital. After the information has been collected it is brought back to DAISY clinic along with the umbilical cord blood sample.
- B) The recruiter will attempt to call a pending individual over a duration of 2 weeks from the baby’s date of birth. Within that time period **No less than two contacts** should be made. A contact would include leaving a message.
- C) When a pending individual gives consent by telephone it is important that the consent process is witnessed by another individual. The witnessing is done by a signature. When witnessing a person is confirming that the pending individual agreed to have their child screened for diabetes gene markers, and the participant was fully informed and understands all aspects of the study.
- D) The cord blood samples collected from St. Joe’s are stored in the DAISY lab in an Igloo cooler at room temperature. For tracking purposes a log is kept with the cooler which records the mother’s name, hospital identification number, whether or not the parents agreed or refused, and recruiter’s initials.

#### II. Pending Outcomes

- A) “pending” individual agrees to participate (gives consent to screen for diabetes-related Genetic markers). The recruiter should assign a DAISY ID #, fill out the NEC Screening Interview with the mother over the phone obtaining all necessary information, and also

fill out the consent form, writing that consent was given over the phone in the space where the mother's signature should go. The recruiter should sign the consent form with her own name, print her name and add the date. A witness needs to sign the form also to verify that consent was given. A copy of the consent form and a copy of a cover letter (found in the recruiting desk) stating that they will receive the results of the genetic screening in 8-10 weeks and that the enclosed copy of the consent is for their records only should be mailed to the mother. The cord blood sample is processed in the same manner as if they had given consent at the hospital (SEE St. Joseph Hospital lab protocol).

B) If a "pending" individual refuses to participate

If a "pending" individual refuses the screening of the cord blood, the recruiter must ask for reason for refusal and enter the reason in the database under St. Joe's log, and discard the cord blood sample. **NO DAISY ID #** is assigned for that individual.

C) Unable to contact the "pending" individual

If a pending mother is not home when the call is made, a detailed message should be left. The recruiter should follow up with another call at another time, again leaving a message. If two or more messages are left and the mother has not called DAISY, she is considered to have refused to participate and the blood sample is destroyed. If the phone number is disconnected, she is also considered as a "no" and the sample should be destroyed.

III. Updating the database

A) Once a consent is given or not given, the status of the pending should be Changed in the St. Joe's log form on the computer.

1. If the individual was interviewed then the log is changed from "pending" to "interviewed-yes" and a DAISY ID # is assigned.
2. If the individual was not interviewed then the log is changed from "pending" to "interview-no" and an explanation is recorded to why the person refused.

B) A NEC screening interview is entered in the computer for every person who was interviewed and assigned a DAISY ID number.

IV. Cord Blood Processing

A) Cord Bloods need to be processed in a timely fashion. Samples can only be left for a maximum of three days before processing, with the exception of unresolved "pendings" which can be left for a maximum of two weeks. If the blood remains unprocessed for longer than 2 weeks, the sample becomes hemolyzed and the samples do not retain their integrity.