

Newborn Cohort Genetic Screening Summary

Purpose:

- A. To obtain a population-based sample of newborns which can be used to describe the prevalence of HLA markers in the general population.
- B. To identify newborns from the general population who are at increased risk of Type I diabetes for the purpose of recruitment into a follow-up study of the genetic and environmental factors associated with the development of diabetes autoantibodies.

Background and Significance:

Procedures:

A. Collection of cord blood samples

An attempt is made to obtain a cord blood sample for every infant born at St. Joseph's Hospital in Denver, Colorado. All obstetricians practicing at St. Joseph's are given instructions for cord blood collection, and supplies for blood collection are made available to them. The sample collected for genetic screening is obtained after the routine sample is collected as per the hospital's own protocol. The sample is labeled with the *mother's hospital ID number, the mother's last name, and the infant's date of birth.*

B. Recruitment

DAISY staff members go to St. Joseph's Hospital every morning to obtain consent from the newborns' mothers to participate in the genetic screening. Attempts are made to contact the mothers of all infants for whom a cord blood sample was obtained. Ideally this contact is made while the mother is still in the hospital, but if that fails then contact is attempted by telephone. If mothers consent to having their infant's cord blood screened for genetic markers then a brief interview is conducted (NEC Screen Interview, Appendix B). The purpose of the interview is to collect basic demographic data for the parents and the infant, to determine if the infant has any first-degree relatives with Type I diabetes, and to obtain contact information so that parents can be notified of the results of the testing. If consent is not given then staff members record the reason for refusal if a reason is given and the blood sample is discarded.

C. Cord blood processing, storage, and shipment

Cord blood samples for all infants for whom consent was obtained are transferred to the study laboratory in a personal-size cooler marked with a biohazard sticker. Whole blood samples are aliquoted for storage and for HLA typing. After the sample is spun, plasma is aliquoted into samples for storage and for antibody testing, and buffy coat is aliquoted into samples for storage.

D. Screening data entry

1. Information about the biologic samples are recorded in the NEC book.

2. NEC Screen Interview data is entered into the Recruit database.

E. Screening data management

Data from the St Joe's Log form and NEC Screen Interview are entered into the Access database on a shared drive at L:\Daisy\Recruit.mdb. New data entered into the recruit database is transferred to the St Joe backend (L:\dci\StJoeBe.mdb) of the main study database on a weekly basis.

F. Checklist for new Recruiter

Checklist for new recruiters, important phone numbers and general computer instructions.

APPENDIX

- A. NEC_Track (St Joe's Log)
- B. NEC Screen Interview
- C. Subject Consent to Genetic Screening
- D. Authorization for Release of Medical Information
- E. Script for St Joe's
- F. Cover letter for pendings