

NOTIFICATION OF RESULTS AND ENROLLMENT OF NEC/NOC COHORT

PURPOSE:

- A. To obtain a population-based sample of newborns from the general population, who are at an increased risk of Type I diabetes.
- B. To notify families of the results of the HLA screening, the significance of the results. To inform them about diabetes and follow up available.
- C. To enroll these children into a follow-up study, of the genetic and environmental factors associated with the development of diabetes autoantibodies.

BACKGROUND AND SIGNIFICANCE:

PROCEDURES:

- A. Once results of HLA screening results have been printed out in letter form, these are copied. The copy is kept under lock and key, the original of all low risk letters is mailed to the family by the administrative assistant. The data manager supplies the nurse with a calling record. These letters are then mailed on a Monday or Tuesday by the admin asst.. This assures the family will be able contact the study during the work week (if the family has not been contacted by the study nurse previously).
- B. Once results are know, the study nurse begins attempting to contact the family by telephone even before they have received the results letter.
- C. Each child will have a call sheet generated by the data manager to document notification attempts. On the call sheet the date, time, and result of the call are documented as well as family attempts to contact the study. Notes can be written in the comments section of each call attempt ie. No message machine, left message with day care provider, message left.
 1. If unable to contact the family.
 - a. Double check the phone number with the written NEC/SCREEN INTERVIEW form.
 - b. Attempt to contact alternate contacts if given. "My name is ----- with the DAISY diabetes study with the University of Colorado Health Science Center. I am attempting to contact (parents name) and they have given us your name and number in the event we cannot contact them. Could you give them the message that I am attempting to contact them or do you have another number I could reach them at?" Remind them you have written permission to obtain the new contact information.
 - c. Check with "Information" for a new listing.
 - d. For individuals who have Kaiser as insurance, the data manager can contact Kaiser for updated telephone and address information.
 - e. If the original results letter is returned indicating wrong address. Indicate on the call sheet "unable to contact" give to data manager for filing and storage.
 - f. If the original results letter is not returned, wait for 14 days for the family to contact the study. In no contact made, mail letter "Unable to contact". In no response from this letter, indicate on the call sheet "unable to contact" and give to data manager for filing and storage.
- D. Message left consists of: "Hi, this is _____ of the DAISY diabetes study with the University of Colorado Health Sciences Center. When your baby was born at St. Joseph's Hospital you consented to having your baby's umbilical cord blood screened for diabetes gene 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 303-315-7852."
- E. Attempts to contact the family should be made at various times of the day, morning, afternoon, evening.
- F. 6 attempts to contact the family should be made with a message left with each call. If a message is left with an individual, indicate who the message was left with in the comments section. Make sure the individual who is taking the message, writes down the information.

- G. Last message.
If after 6 messages have been left a final message is left. “Hi, this is _____ with the DAISY diabetes study with the University of Colorado Health Sciences Center. I have been attempting to contact you since (date of first call) to discuss with you the results of the umbilical cord blood screening for your baby _____. I have left several messages and would like to speak with you. Even if you are not interested in participating in the follow up phase of the study, I would like to answer any questions you may have about diabetes. Please call me at 303-315-7852. If I do not hear from you by (date in 7 days) I will assume you do not have any questions and are not interested in participating in the study and will no longer attempt to contact you by phone. In order to document any changes which may occur in your family we will mail a short questionnaire to you yearly. Thank you.”
- H. If no response, indicate on the call record, “unable to reach, not interested” and give to the data manager.
- I.