

## **Enrollment Into Follow-Up Summary**

### **A. Contacting families**

Call sheets for families to be contacted are printed each time that new HLA results are imported. Families must be provided information about the genetic results and be invited to enroll in the follow-up portion of the study.

### **B. Decline Enrollment in Follow-up**

If the family declines follow-up try to find out why and find out whether or not they would object to hearing from us on an annual basis.

### **C. Agree to Enrollment in Follow-up**

If families accept enrollment into follow-up then there are a number of enrollment forms to fill out and a packet of information is sent to the family.

### **D. Lab Requests – Roche QC**

A QC sample is sent to Roche for all NECs and NOCs who enroll in the study. This is to verify their HLA status.

### **E. Lab Requests – Cord blood antibodies**

The purpose of the cord blood antibody testing is to see if there are any diabetes antibodies present at the time of birth.

### **F. Enrollment data entry**

Data from the Family Structure for DAISY/CEDAR Enrollment form are entered into the database after verifying that the data are complete. A series of macros are run from the Enrollment Menu of the database in order to create records in the Protocol, Form Track, Call Track and Clinic Track tables. Face sheets are printed and a chart is prepared for each child enrolled in the study.

### **G. Enrollment of Siblings with the 3/4 HLA type**

We are interested in enrolling the siblings of our study participants if we find out that they have the 3/4 HLA type.

### **H. Disenrollment**

Children can be disenrolled either upon the request of the family, because we are unable to contact the family, or because of persistent failure to show up for clinic visits. Efforts are made to contact families before declaring them to be 'lost to follow-up' and to accommodate families that are having trouble keeping their appointments. If these efforts fail, or if the family requests to be disenrolled then a disenrollment form is filled out and the appropriate information is entered into the database. The disenrollment form is filed in the child's chart.

### **I. Re-enrollment**

Sometimes a family that has requested disenrollment or that has been ‘lost to follow-up’ is re-enrolled in the study. The child’s chart is moved back to the active file cabinets, the enrollment status is updated in the database, and new Call and Clinic tracking records are created. The re-enrollment form is filed in the child’s chart.

### **J. Disenrollment/Re-enrollment data entry**

Changes in enrollment status are entered into the database using *frmDeDisenroll* which can be accessed from the Disenrollment button on the Enrollment Menu. When the enrollment status is changed macros are invoked which change the values of other related fields and delete tracking records as appropriate.

## **APPENDIX**

- A. Consent to Prospective Follow-up
- B. Family Structure for DAISY/CEDAR Enrollment
- C. NEC Individual
- D. SOC Individual
- E. Pregnancy FFQ and Instructions
- F. Informational Packet
  - 1. What is Diabetes?
  - 2. The Enemy Within
  - 3. Getting to the Root of Type I Diabetes
  - 4. Screening at Birth
  - 5. Before It Starts
  - 6. What’s Your Problem?
- G. Disenrollment form
- H. Re-enrollment form