

## ENROLLMENT

### G. Enrollment of 3/4 siblings

We are interested in enrolling the siblings of our study participants if we find out that they have the 3/4 HLA type. The following steps are taken to enroll these siblings:

- Family members are screened for HLA markers at study subject's clinic visit.
- When HLA results are imported from Roche a '3/4 Sib Recruitment' report will be generated for any non-diabetic sibling who has the 3/4 HLA type (see section on HLA Typing). The parents of these children are contacted and asked to enroll the child in the follow-up portion of the study.
- The recruitment report is used to indicate whether the family agreed to enrollment or not. Their response is entered into the database using the 'Family Enrollment' data entry form.

#### Agree to follow-up

- The *Enrolled* field in the 'Family Enrollment' data entry form is entered as "Enrolled" and the CURRENT DATE is entered as the enrollment date. It is important that the current date is entered as the enrollment date because the queries that assign newly enrolled children to the appropriate protocols are based on the child being enrolled on the current date.
- A SOC-Individual form is mailed to the family and they are asked to complete it for the 3/4 sibling.
- After entering this data in the Family Enrollment form, the 'Assign New Enroll to Protocol' button on the Enrollment Menu is pressed which adds an appropriate record to *tblProtocol*. In the case of 3/4 siblings *qryAddNewEnrollToProtocol2* adds a record to *tblProtocol* assigning the sibling to the Normal DAISY protocol. The child's clinic and call protocols are changed to 'SOC'.
- The 'Assign New Enroll to Form Track' button is pressed and a form track record is created if one does not already exist. In the past form tracking records were created for siblings and CEDAR Individual forms were filled out for them. A SOC Individual form is sent to the family whether or not a CEDAR form has been completed. When the SOC Individual form is returned the record in *tblFormTrack* is changed to show that this form has been received.
- Clinic Track and Call Track records are not created at this time (and won't be created even if the buttons on the Enrollment Menu are pressed). Now that the child is enrolled, new clinic track records will be added the month prior to the child's next due date.
- The child is not eligible for IVY unless they become antibody positive.
- A chart is created for this child now that he/she is a study subject.

#### Decline follow-up

- If the family declines follow-up then the *Enrolled* field is entered as "Refused enrollment".

[We need to find out if FFQ's should also be collected on these kids – if so then an FFQ tracking record needs to be added.]