

ENROLLMENT

H. Disenrollment

Children can be disenrolled 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.

Refused follow-up

This occurs if a family states that they do not want to continue to participate in the studies. Generally the family will either tell clinic staff, the clinic scheduler or the telephone interviewers. If the family clearly states that they want to stop participation then they are disenrolled. A disenrollment form is filled out and should clearly state that the family *refused follow-up* and give the reason why (if the family gave a reason).

In the database Enrollment.mdb located L:\DAISY DATABASES click the disenrollment button:

- a. Look subject up
- b. Enrollment status changed to 'Enrolled, then refused follow-up'
- c. Reason for disenrollment entered
- d. Date of disenrollment entered – this is automatically copied to the 'End date' in the Protocol table.
- e. Click Remove Track Records -Clinic Track records are removed and Call Track records for calls that have not been completed are removed.

The disenrollment form is filed in the subject's chart and the chart is marked as disenrolled. Send a C letter to the parents located at L:\DAISY MOO>Contact Problems\Appendix DAISYLtr_C.doc. If questionnaire data needs to be entered the questionnaires are pulled from the chart and given to the staff member in charge of data entry. The file is placed in the cabinet for disenrolled subjects.

Lost to follow-up

Unable to contact for a telephone interview – *wrong number or phone disconnected.*

If we are unable to contact because the phone has been disconnected then the following attempts are made to get an up-to-date phone number:

1. Call information
2. Try alternate contacts
3. Try BDC clinic-email Lisa Ide or Kim to look in Pink Panther database

If attempts to get an up-to-date phone number fail, then a letter is sent notifying the family that interviews will be done at the next clinic visit. The questionnaire form is prepared and placed in the clinic chart.

This is not cause for disenrollment!

Unable to contact for a telephone interview – *won't return calls or too busy to do interview:*

A letter should be sent notifying the family that interviews will be done at their next clinic visit and the interview should be prepared and put in the clinic chart.

This is not cause for disenrollment!

Unable to contact to schedule a clinic appointment – *wrong number or phone disconnected:*

If we are unable to contact because the phone has been disconnected or is a wrong number then the following attempts are made to get an up-to-date phone number:

1. Call information
2. Try alternate contacts
3. Try BDC clinic-email Lisa Ide or Kim to look in Pink Panther database

If attempts to get an up-to-date phone number fail then a letter should be sent notifying of intent to disenroll unless we hear from them within the next 2 weeks

If after 2 weeks we have not heard from this family then a disenrollment form is filled out and the subject is disenrolled in the database. The form should clearly state that this family was *lost-to-follow-up*.

In the database Enrollment.mdb located L:\DAISY DATABASES click the disenrollment button:

- a. Look subject up
- b. Enrollment status changed to 'Enrolled, then lost to follow-up'
- c. Date of disenrollment entered – this is automatically copied to the 'End date' in the Protocol table.
- d. Click Remove Track Records -Clinic Track records are removed and Call Track records for calls that have not been completed are removed.

Unable to contact to schedule a clinic appointment – *won't return calls:*

A letter should be sent notifying the family of intent to disenroll unless we hear from them within the next 2 weeks.

If after 2 weeks we have not heard from this family then the situation should be discussed with the study coordinator (either DAISY or CEDAR) and a decision should be made whether or not to disenroll. If the family is to be disenrolled then a disenrollment form is filled out and the subject is disenrolled in the database. The form should clearly state that

this family was *lost to follow-up – won't return calls* and that the disenrollment was approved by the study coordinator.

- a. Look subject up
 - b. Enrollment status changed to 'Enrolled, then refused follow-up'
 - c. Reason for *Passive Refusal*
 - d. Date of disenrollment entered – this is automatically copied to the 'End date' in the Protocol table.
 - e. Click Remove Track Records -Clinic Track records are removed and Call Track records for calls that have not been completed are removed.

The disenrollment form is filed in the subject's chart and the chart is marked as disenrolled. Send a C letter to the parents located at L:\DAISY MOO>Contact Problems\Appendix DAISYLtr_C.doc. If questionnaire data needs to be entered the questionnaires are pulled from the chart and given to the staff member in charge of data entry. The file is placed in the cabinet for disenrolled subjects.

Consistent no-shows for clinic visit:

Families will be given 3 chances to reschedule. In the case of high-risk kids more effort will be expended and this will be extended up to 6 chances.

Once the limit of reschedules has been reached the case will be discussed with the study coordinator (either DAISY or CEDAR) and a decision will be made regarding how to proceed. If the decision is to disenroll then the family should be notified by phone, a disenrollment form is filled out, and the subject is disenrolled in the database. The notification should clearly state that this family was *lost to follow-up - consistent no-show* and that the disenrollment was approved by the study coordinator.

- a. Look subject up
 - b. Enrollment status changed to 'Enrolled, then refused follow-up'
 - c. Reason for disenrollment *consistent no-show*
 - d. Date of disenrollment entered – this is automatically copied to the 'End date' in the Protocol table.
 - e. Click Remove Track Records -Clinic Track records are removed and Call Track records for calls that have not been completed are removed.

The disenrollment form is filed in the subject's chart and the chart is marked as disenrolled. Send a C letter to the parents located at L:\DAISY MOO>Contact Problems\Appendix DAISYLtr_C.doc. If questionnaire data needs to be entered the questionnaires are pulled from the chart and given to the staff member in charge of data entry. The file is placed in the cabinet for disenrolled subjects.