HALT-C Trial Q x Q

Cognitive Effects AS Withdrawal Form

Form #155 Version A: 06/15/2000 (Rev. 07/03/2002)

Purpose of Form #155: The Cognitive Effects Withdrawal form documents that patients have withdrawn from the Cognitive Effects Ancillary Study and the reason(s) for patient withdrawal. Data entry of this form removes the expectancy of study forms from future visits in the Data Management System (DMS).

When to complete Form #155: This form should be completed upon withdrawal of a patient from the Cognitive Effects Ancillary Study. Form #155 can be added to any study visit by clicking on the "Additional Forms" button on the study visit screen. This form should be completed when a patient withdraws consent, is no longer at Site 17 (University of Southern California) or Site 18(University of Michigan), or if other problems are encountered during data or sample collection.

If all of the required samples for the study are collected at the first few visits (S00 and W00), the patient is eligible for the Cognitive Effects Ancillary Study. Patients may decide at a later date to withdraw from this Ancillary Study. However, if samples are missed at initial visits, they are ineligible and require a Form #155.

Express patients were not eligible for the Cognitive Effects Ancillary Study and do not require Form #155.

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit or the most recent study visit.

A4. Record the date the form was completed in MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: WITHDRAWAL INFORMATION

B1. Record the date that the patient withdrew from the Cognitive Effects Ancillary Study in MM/DD/YYYY format. If you do not know the exact date that the patient withdrew from the study, then record the date the patient was last seen or the date you last had telephone contact with the patient.

B2. Circle the one primary reason why the patient withdrew from the Cognitive Effects Ancillary Study. If the reason is not listed, circle "Other" and specify a reason is (sixty characters including spaces and punctuation are available).

B3. Please enter any additional information regarding the patient's withdrawal from this study (four hundred characters including spaces and punctuation are available).

Data entry note: If there is no additional information recorded in B3, data enter -1. The form is complete.