HALT-C Trial Q x Q

Clinical Center Biopsy

Form # 52 Q x Q Version A: 06/15/2000 (Rev. 07/20/2004)

Purpose of Form #52: The Clinical Center Biopsy form is used by the local pathologist to record whether a randomized phase liver biopsy is adequate for central review.

When to complete Form #52: Liver biopsies are requested at the Month 24 (M24) and the Month 48 (M48) study visits. Form #52 should be completed for every patient or set to missing in the following manner:

- This form should be completed when the patient has a liver biopsy done.
- If at M24 or M48, the biopsy is not done, but is scheduled for a later date, leave this form as expected in the DMS and complete the paper copy when the biopsy is done.
- If you know for certain that the biopsy will never be done, record on the paper copy of the form why the biopsy will never be done. "Not Done" is not an acceptable explanation. "Not Done because patient has had liver transplant " is an example of an acceptable explanation. Write a note on the form for the Data Manager to set the form to missing.
- Set this form to missing in the DMS and copy the explanation written by the coordinator on Form # 52 into the textbox "Enter Missing Form Reason."
- Mark on the paper form that the form has been set to missing in the DMS and place the form in the patient notebook under the M24 and/or M48 visit(s).
- This form was revised in order to comply with HIPAA regulations. The hospital accession # for the biopsy should be recorded in the medical records, but not on form # 52 or the DMS.

In the HALT-C Data Management System (DMS), Form # 14: Specimen Collection and Form # 52: Clinical Center Biopsy are set to be expected even if the patient misses the M24 or M48 visit. You will be reminded when you run an Outstanding Forms Report that you must complete these two forms as outlined above. This report will allow you to enter the forms when the patient is willing to have the biopsy after a missed M24 or M48 visit.

Note on dates:

- All dates on this form should be entering using MM/DD/YYYY format.
- In this format, Enter the 2-digit number for the month in the first 2 spaces provided (i.e., January = "01", February ="02", etc.), the 2-digit number for the day of the month in the second 2 spaces provided, and the 4-digit number for the year in the final 4 spaces provided.

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. Record the visit for which this biopsy is being reviewed. It can only be M24 or M48.

A4. Record the date Sections A and B of this form were completed using MM/DD/YYYY format.

A5. Enter the initials of the person completing Sections A and B of this form.

SECTION B: TO BE COMPLETED BY STUDY COORDINATOR

B1. Record the date that this biopsy was performed using MM/DD/YYYY format.

B2. See the box below regarding Hospital Accession #.

Per HALT-C Communication #43 dated 09/30/2003:
Changes have been made in the way local biopsy forms (Forms 50 and 52) are data entered. These changes were made in order to comply with the new HIPAA regulations.

From now on, you will not be able to data enter the hospital accession ID recorded on Form 50, Screening Biopsy, and Form 52, Clinical Center Biopsy. You will get an error message stating -9 is the only acceptable value for any question that asks for the accession ID. Data enter -9 in place of the accession ID.

Do not write the Hospital Accession # of the biopsy (B4 on Form # 50, B2 on Form # 52). Mark it with a -9. The Hospital Accession # should be available on the source documentation of the pathology report.

In addition, all accession IDs previously entered in the DMS have been blanked out, and will appear as "-9" if you open a completed form to look at the data.

SECTION C: TO BE COMPLETED BY THE LOCAL PATHOLOGIST

C1. Enter the initials of the HALT-C pathologist who reviewed the liver biopsy and is completing this section of the form.

C2. Record the date that this liver biopsy was read using MM/DD/YYYY format.

C3. Record whether or not the biopsy is adequate for grading and staging. If the answer is YES, circle 1. If the answer is NO, circle 2.

The criteria for scoring can be found in: Ishak KG, et al.: Histological grading and staging of chronic hepatitis. J Hepatol 1995; 22:696-699.

C4. Record the number of unstained slides available for shipment to AFIP.

- **Ten unstained slides should be sent to the DCC for blinding.**
- Slide boxes will be supplied to Study Coordinators for shipment of slides to the DCC.
- The DCC will blind the unstained slides and forward them to AFIP.
- AFIP will stain the slides in preparation for review by the Central Pathology Committee.

C5. Record the total number of slides that will remain at your center following shipment of the 10 unstained slides to the DCC.

- If there is a problem with the shipment of the unstained slides (i.e.: shipment lost or slides broken), we may request that these slides be sent to the AFIP to allow for central review.

C6. Record if the block is available at your center. If the answer is YES, circle 1. If the answer is NO, circle 2.

Return the completed Form #52 and 10 unstained slides to the Study Coordinator.