HALT-C Trial Q x Q

Randomization Checklist II

Form # 99 Version A: 06/15/2000

Purpose of Form #99: This form is to be completed only for Express and Breakthrough/Relapser patients that are willing and eligible for randomization, and assigns these patients to either the treatment or control arm of the trial. **Once randomization status is assigned for a patient, randomization may not be repeated or undone.**

When to complete Form #99: The Randomization Checklist II (Form #99) should be completed and data entered prior to the Randomization (R00) visit.

- For Express patients, Form #99 should be entered following completion and review of all screening visit results.
- For Breakthrough/Relapsers, Form #99 should be entered following receipt of a second positive HCV RNA result and review of all randomization eligibility requirements.

Results from the Central Pathology Biopsy Review (Form #51), HCV RNA results from the appropriate study visit (Form #31), ultrasound (Form #22) from the appropriate visit, CTP score (Form #15) from the appropriate study visits, and Local Lab and AFP results (Forms #30 and #34) are needed to complete the Randomization Checklist (Form #21).

Form #51 (Central Review of Pathology) from the Screening visit and Form #31 (Central Lab) from the appropriate visit must be data entered in the HALT-C Data Management System (DMS) prior to entering Form #99.

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 study visit at which this form will be entered. For Express patients this will be S00. For Breakthrough/Relapser patients the DMS will add Form 99 to the appropriate visit.

A4. Record the date this form is completed using MM/DD/YYYY format.

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

SECTION B: RANDOMIZATION CHECKLIST

B1. Circle the Ishak fibrosis score range reported from the central reading of the liver biopsy submitted for the Screening visit (S00). These results are sent in an email message from the DMS once they are data entered into the system. These results may also be reviewed in the DMS in Form #51, Central Pathology Biopsy Review.

- **Form #51 must be data entered in the DMS before entering Form #99. There is a cross check in the DMS to validate completeness and accuracy of the data.**

B2a. Enter the total CTP score (question B6 on Form #15) from Screen visit 1 (Express patients) or the appropriate W20 Responder visit (Breakthrough/Relapser patients).

B2b. Enter the total CTP score (question B6 on Form #15) from Screen visit 2 (Express patients) or the appropriate W20 Responder visit (Breakthrough/Relapser patients)

- If both CTP scores are >= 7, the patient is **not** eligible for randomization.
- If only one CTP score is >= 7, the patient **is** eligible for randomization.

B3. Circle the patient's HCV RNA status, based on the central virology lab HCV RNA results from S00 (Express patients) or the appropriate W20 responder visits (Breakthrough/Relapser patients). These results should arrive in an email message from the DMS once they are data entered by the Central Virology Lab. These results may also be reviewed in the DMS on Form #31, Central Lab – HCV RNA.

- Patients must be HCV RNA positive to be eligible for randomization. Breakthrough/Relapser patients need to have two positive HCV RNA results from two separate time points after W24 to be eligible for Randomization.

- **Form #31 must be data entered in the DMS before entering Form #99. There is a crosscheck in the DMS to validate completeness and accuracy of the data.**

B4. Enter the serum alpha-fetoprotein (AFP) level using the S00 visit (Express patients) or appropriate W20 responder visit (Breakthrough/Relapser patients) AFP results (Form #34).

- AFP level must be less than or equal to 1000 ng/mL to be eligible for randomization.

B5. Circle YES or NO based on information from the S00 visit (Express patients) or appropriate W20 Responder visit (Breakthrough/Relapser patients) ultrasound results (Form #22).

- For a patient to be eligible for randomization there must be no evidence of hepatocellular carcinoma (HCC) on ultrasound.

B6. Circle YES or NO based on the results of the S00 (Express patients) or appropriate W20 Responder visit (Breakthrough/Relapser patients) local lab values (Form #30).

B7. Circle YES or NO based on the answers to questions B1 through B6. In order for the Express/Breakthrough/Relapser patient to be eligible for randomization, all of the following must be true:

- One or both of the patient's CTP scores must be less than 7, and
- Central HCV RNA result(s) must be positive, and
- The AFP result must be less than or equal to 1000 ng/ml, and
- There must be no evidence of HCC on ultrasound.

- If the Express/Breakthrough/Relapser patient **is** eligible for randomization, circle 1 for YES and continue to question B8.

An Express/Breakthrough/Relapser patient is not eligible for randomization if any of the following is true:

- Both of the patient's CTP scores are 7 or higher, or
- Central HCV RNA result(s) is negative, or
- The AFP result is greater than 1000 ng/ml, or
- There is evidence of HCC on ultrasound.

- If the Express/Breakthrough/Relapser patient is **not** eligible for randomization, circle 2 for NO and the form is complete. DO NOT DATA ENTER THIS FORM IN THE DMS.

If an Express patient is found to be ineligible or unwilling to be randomized, do not data enter this form. Please complete Form 5-Trial Ineligibility.

If a Breakthrough/Relapser patient is found to be ineligible or are unwilling to be randomized, do not complete this form. The patient should continue to be followed according to the W20 Responder protocol.

B8. Circle 1 for YES if the Express/Breakthrough/Relapser patient is willing and appropriate for randomization. Continue to Question B9.

Circle 2 for NO if the Express/Breakthrough/Relapser patient is unwilling to be randomized or is inappropriate for randomization. The form is complete. DO NOT DATA ENTER THIS FORM IN THE DMS.

B9. When this form is data entered, Question B9 confirms that the patient should be randomized. If YES is data entered, the DMS will automatically randomize the patient to the "**Treatment Group**" or the "**Control Group**".

- Once the patient is randomized, visit windows will be set for the Randomization (R00) study visit. **The R00 visit must be held within 2 weeks of data entry of Form 99.**

- The randomization status will always be visible in this patient's record in the DMS. You will receive email notifying you of the patient's status. Print out the email and file it in the patient's research notebook.