HALT-C Trial

HVPG Measurement—Portal Hypertension AS

Form # 111 Q x Q Version A: 06/15/2000 (Rev. 12/09/2005)

Purpose of the form: This forms documents the results of the HVPG measurement performed for the Portal Hypertension Ancillary Study.

When to complete this form: This form is completed for all patients participating in the Portal Hypertension Ancillary Study at Month 48. Patients eligible to participate in this ancillary study include all patients at VCU and UCHSC in the control arm not receiving peginterferon maintenance therapy and those patients in the maintenance therapy arm of HALT-C who have remained on peginterferon for the past 6 months. This form is an addable form under the Month 48 visit in the DMS.

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.

A4. Record the date the form was completed.
- When entering this date, use the MM/DD/YYYY format.
- Enter the 2 digit number for the month in the first 2 spaces provided (i.e., January = "01", February = "02", etc.) enter 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.

A5. Enter the initials of the person completing the form.
- Enter the first initial in the first space provided; middle initial in the second space provided and the last initial in the third space provided.
- If the patient does not have a middle name, enter the first initial in the first space provided, leave the second space blank, and enter the last initial in the third space provided.
- If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the last space.

SECTION B: GENERAL INFORMATION

For more information on the performance of the HVPG measurement, see section K-5, Appendix 1, of the Manual of Operations.

This form should be completed by the person performing the HVPG procedure. Circle the number corresponding to the appropriate answer.

B1. Record the date the test was done.
- When entering this date, use the MM/DD/YYYY format.
- Enter the 2 digit number for the month in the first 2 spaces provided (i.e., January = "01", February = "02", etc.) enter 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.

B2. Indicate which type of conscious sedation was used. If other, please specify. Fifty characters (including punctuation and spaces) are provided.

B3. Answer YES if a medication was used to prevent dye allergy and go to question B3a.
Answer NO if there was no medication used to prevent dye allergy and go on to Section C.

B3a. Indicate the type of medication used to prevent dye allergy. If other, please specify. Fifty characters (including punctuation and spaces are provided).

SECTION C: STANDARDIZATION

Answer YES or NO for each question.

C1-C3.
- Answer YES for each measure of standardization set.
- Answer NO if the standardization was not set.

SECTION D: MEASUREMENTS

Record 3 measurements in mm/hg for each location.

D1. Pressure measurement in the inferior vena cava will be made at the level of the hepatic orifice.

D2. Free Hepatic Venous Pressure (FHVP) are then made with the catheter tip free in the hepatic vein (the FHVP should not differ from the inferior vena cava pressure by more than 1-2 mm Hg).

D3. For each Wedged Hepatic Venous Pressure (WHVP) measurements taken, the tracing must be 45-60 seconds long.

SECTION E: OTHER ABNORMALITIES

E1.
- Answer YES if other abnormalities were noted, or any problems or adverse events occurred during the procedure. If yes, describe in the space provided. 500 characters (including spaces and punctuation) are provided.
- Answer NO if there were no other abnormalities, and no problems or adverse events occurred. Go on to Section F.

SECTION F: SOURCE DOCUMENTATION

A source document is a part of the patient's medical record which serves to validate data collected on the data entry forms. The appropriate source documents should be attached to this form with all identifying patient information, such as patient name and medical record number blacked out. The HALT-C Trial requires the following source documents for each HVPG measurement:

F1. A written report of the HVPG measurement findings.

F2. A recording of the HVPG measurement.

F2a. The recording should show the establishment of the zero point.

F2b. The recording should show the calibration of the transducer and recording equipment.

Answer YES or NO for each source document provided.