HALT-C Trial Q x Q

Baseline History

Form # 6 Version B: 08/20/2001

Purpose of Form #6: The purpose of the Baseline History form is to:

- Learn about the patient's exposure to the hepatitis C virus
- Record the investigator's assessment of the year that the patient was infected with hepatitis C
- Document prior treatments with interferon or interferon/ribavirin combination therapy

When to complete Form #6: This form should be completed at the Screening visit (S00) for all patients entering the HALT-C Trial.

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. The visit number, S00, is pre-printed on the form.

A4. Record the date of the baseline visit using the MM/DD/YYYY format.

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

SECTION B: HEPATITIS C RISK FACTORS

Section B asks about the patient's exposure to the hepatitis C Virus. For YES/NO questions, please circle 1 for YES or 2 for NO.

B1. Enter the date in MM/YYYY format when the patient first tested positive for hepatitis C.

B2a. – B2g. Circle 1 for YES or 2 for NO and continue to next question.

B2h. If NO, skip to B2j. If YES, continue to B2i.

B2i. Enter the date in MM/YYYY format when patient was first told s/he had non-A, non-B hepatitis.

B2j. If YES, circle 1 and specify reason on the line provided. 40 spaces are provided. If NO, circle 2 and continue to B3.

B3. If NO, skip to B4. If YES, record the number of times the patient received a blood transfusion and the year(s) (YYYY) received starting with the earliest year. If patient has received more than 4 transfusions, record the years of the four earliest transfusions.

B4. If NO, skip to B5. If YES, record the first and last year (YYYY) the patient had direct contact with human blood.

B5. If NO, skip to B6. If YES, record the number of times the patient received a needle stick and the years (YYYY) exposed, starting with the earliest year. If patient has received more than 4 needle sticks, record the years of the four earliest needle sticks.

B6. If NO, skip to B7. If YES, record the number of times tattooed and the years (YYYY) starting with the earliest year. If the patient has been tattooed more than 4 times, record the years of the four earliest tattoos.

B7. If NO, skip to B8. If YES, record the number of times of body piercing and the years (YYYY) starting with the earliest year. Note that ear piercing is not included. If the patient has received more than 4 body piercings, record the years of the four earliest piercings.

B8. If NO, skip to B9. If YES, record dates in years (YYYY) of first and last injection of recreational drugs. Record approximate number of times the patient reports injecting recreational drugs during her/his lifetime.

B9. If NO, skip to B10. If YES, record dates in years (YYYY) of first and last time the patient snorted cocaine. Circle the approximate range of times the patient reports snorting cocaine during her/his lifetime.

B10. Record in years (YYYY) the date that the patient thinks s/he was infected with hepatitis C.

After completion of the interview, the interviewer should sign the form at the end of Section B.

This is the last question of the patient interview.

SECTION C: INVESTIGATOR'S ASSESSMENT OF ACQUISITION OF HEPATITIS C

Section C records the investigator's assessment of the source and year that the patient was infected with hepatitis C. Information is gleaned from medical records and patient interview. The investigator should complete this section.

C1. If NO, circle 2 and skip to C3. Record whether the patient became infected with hepatitis C as a result of injections or procedures related to medical care. If YES, circle 1 and continue to C2.

C2. Record the investigator's confidence in relating the source of infection to medical procedures. Circle 1 for PROBABLE, 2 for POSSIBLE, or 3 for UNLIKELY.

C3. Record date in years (YYYY) of the earliest year the patient could have contracted hepatitis C.

C4. Circle the appropriate level of confidence regarding the estimate of the correct year.
- If PROBABLE, circle 1 and continue to C5.
- If POSSIBLE, circle 2 and continue to C5.
- If UNLIKELY, circle 3 and skip to Section D.

C5. If NO, circle 2 and skip to Section D. If YES, circle 1 and continue to C6.

C6. Record the range of dates in years (YYYY) when the patient most likely contracted hepatitis C.

C7. Record the investigator's confidence in the estimated range of years the patient could have contracted hepatitis C. Circle 1 for PROBABLE, 2 for POSSIBLE, or 3 for UNLIKELY.

The investigator should sign the form, where indicated, upon completion of section C.

SECTION D: PRIOR TREATMENT WITH INTERFERON (CHART ABSTRACTION)

General Instructions for Section D:
The patient's most recent course of treatment for hepatitis C prior to the HALT-C trial was recorded on the Trial ID Assignment form (#1). Section D is used to document all other courses of treatment prior to or after the most recent course of treatment. Answer these questions using chart review and/or patient interview.

D1. If the patient had more than one course of treatment prior to the HALT-C trial, circle 1 for YES and continue to D2.

If the patient had only one course of treatment prior to the HALT-C trial (the course of treatment documented on the Trial ID Assignment form #1), circle 2 for NO and skip the form is complete.

D2. Enter the number of courses of treatment that the patient had prior to or after the most recent treatment. Do not include the most recent treatment.

D3. Prior courses of treatment:

- For each prior treatment with interferon (not including the most recent one), record the appropriate type using the Medication Code List in column a.
- For each prior treatment with interferon (not including the most recent one), record the approximate duration of treatment. Treatment duration of "inadequate" length should also be recorded.
- The start date of interferon treatment should only be recorded for the very first course of treatment.
- Treat a change in type of medication as a subsequent course of treatment. For such a case, move to the next row and record the type and duration of treatment.