

## HALT-C Trial Q x Q

**Screening Medical History Interview**

Form # 3 Version B: 12/03/2001 (Revised 02/14/2002)

**Purpose of Form #3:** The Screening Medical History Interview form is part of the HALT-C Trial screening process. Form #3 records general medical history information and asks specific questions based on the HALT-C Trial eligibility criteria. Information is gathered by patient interview and reading the medical record.

The date in section A is the date used as the beginning of the HALT-C screening process. Baseline (W00) must begin within 14 weeks of this date.

**When to complete Form #3:** This form should be completed during the first Screening Phase study visit (S01).

**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. Data entry of this value is not required.
- A4. Record the date of the first screening visit using the MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.
- A6. Enter the initials of the person who conducted the interview.

**SECTION B: SCREENING MEDICAL HISTORY****General Instructions for Section B:**

- For each question, circle 1 for YES, 2 for NO, or -8 for DON'T KNOW. Follow skip patterns as indicated on the form.
  - Forty characters (including punctuation and spaces) are allowed in each specify field.
  - Question numbers that are **BOLD and circled** indicate exclusion criteria.
    - If any of the exclusion criteria questions are answered YES or DON'T KNOW, an explanation is required on question F3 of this form.
    - Please refer to Section F for questions related to the patient's eligibility for enrollment into the HALT-C trial.
- B1. This question is an exclusion criterion. Patients with any of these liver diseases are not eligible. Answer YES, NO, or DON'T KNOW and continue to B1a.
  - Note: On Version A of Form #3, Gilbert's syndrome must be recorded on Question B1.

- B1a. Patients with Gilbert's syndrome may have elevated bilirubin levels. Different scoring may be required when calculating the CTP score (Form # 15). Answer YES, NO, or DON'T KNOW and continue to B2.
- B2. This question is an exclusion criterion. Patients with any history of bleeding from esophageal varices are not eligible. Answer YES, NO, or DON'T KNOW and continue to B3.
- B3. This question is an exclusion criterion. Patients with any history of bleeding from gastric varices are not eligible. Answer YES, NO, or DON'T KNOW and continue to B4.
- B4. If the answer is YES, complete the specify field with the name of the specific intestinal disease or abnormality and continue to B5. If the answer is NO or DON'T KNOW, continue to B5.
- B5. Patients with diabetes are eligible for the HALT-C Trial. Any Lead-in Group patient with diabetes should have a glycosolated hemoglobin test done (Form # 121). If the answer is YES, continue to B5a. If the answer is NO or DON'T KNOW, skip to B6.
- B5a. This question is an exclusion criterion. Patients with uncontrolled diabetes are not eligible. Answer YES, NO, or DON'T KNOW and continue to B6.
- B6. This question is an exclusion criterion. Patients with hemophilia are not eligible. Answer YES, NO, or DON'T KNOW and continue to B7.
- B7. This question is an exclusion criterion. Patients with blood diseases or abnormalities are not eligible. If the answer is YES, complete the specify field and continue to B8. If the answer is NO or DON'T KNOW, continue to B8.
- B8. If the answer is YES, complete the specify field and continue to B8a. If the answer is NO or DON'T KNOW, skip to B9.
- B8a. This question is an exclusion criterion. Patients with active rheumatoid arthritis or systemic lupus are not eligible. The site PI determines "Active." Answer YES, NO, or DON'T KNOW and continue to B9.
- B9. If the answer is YES, complete the specify field and continue to B10. If the answer is NO or DON'T KNOW, continue to B10.
- B10. This question is an exclusion criterion. Patients with a malignancy diagnosed or treated within the last 5 years, other than local squamous or basal cell carcinoma treated with excision are not eligible. If the answer is YES, complete the specify field and continue to B10a. If the answer is NO or DON'T KNOW, skip to B11.
- B10a. Patients are eligible if the only cancer diagnosis was local squamous or basal cell carcinoma treated with excision. If the answer is YES, skip to B11. If the answer is NO or DON'T KNOW, continue to B10b.
- B10b. Patients are eligible if the only cancer diagnosis was local squamous or basal cell carcinoma that has been adequately treated and have excellent chance for cancer free survival. Answer YES, NO, or DON'T KNOW and continue to B10c.
- B10c. Enter the date that the malignancy was diagnosed using the MM/YYYY format. Date must be greater than 5 years from the date of this interview. Continue to B10d.

- B10d. Enter the date the treatment for the malignancy was completed using the MM/YYYY format. Date must be greater than 5 years from the date of this interview. Continue to B11.
- B11. This question is an exclusion criterion. Patients with severe heart, cerebrovascular, or lung disease are not eligible. If the answer is YES, complete the specify field and continue to B12. If the answer is NO or DON'T KNOW, continue to B12.
- B12. If the answer is YES, complete the specify field and continue to B12a. If the answer is NO or DON'T KNOW, continue to B12a.
- B12a. Significant and stable heart disease including hypertension has specific guidelines for patients taking ribavirin. If the answer is YES, complete the specify field and continue to B13. If the answer is NO or DON'T KNOW, continue to B13.
- B13. If the answer is YES, complete the specify field and continue to B14. If the answer is NO or DON'T KNOW, continue to B14.
- B14. If the answer is YES, continue to B14a. If the answer is NO or DON'T KNOW, skip to B15.
- B14a. This question is an exclusion criterion. Patients with periods of uncontrolled seizures within the past two years are not eligible. Answer YES, NO, or DON'T KNOW and continue to B15.
- B15. If the answer is YES, complete the specify field and continue to B16. If the answer is NO or DON'T KNOW, continue to B16.
- B16. If the answer is YES, complete the specify field and continue to B17. If the answer is NO or DON'T KNOW, continue to B17.
- B17. Hormonal abnormalities include diseases such as Addison's Disease and Cushing Syndrome. Menopausal symptoms are not included. If the answer is YES, complete the specify field and continue to B18. If the answer is NO or DON'T KNOW, continue to B18.
- B18. If the answer is YES, complete the specify field and continue to B19. If the answer is NO or DON'T KNOW, continue to B19.
- B19. If the answer is YES, complete the specify field and continue to B20. If the answer is NO or DON'T KNOW, continue to B20.
- B20. If the answer is YES, complete the specify field and continue to B21. If the answer is NO or DON'T KNOW, continue to B21.
- B21. If the answer is YES, complete the specify field and continue to B22. If the answer is NO or DON'T KNOW, continue to B22.
- B22. If the answer is YES, complete the specify field and continue to B23. If the answer is NO or DON'T KNOW, continue to B23.
- B23. If the answer is YES, complete the specify field and continue to B23a. If the answer is NO or DON'T KNOW, skip to B24.
- B23a. Answer YES, NO or DON'T KNOW and continue to B24.
- B24. Answer YES, NO or DON'T KNOW and continue to B25

- B25. This question is an exclusion criterion. Patients who use coumadin or immunosuppressive drugs are not eligible. Answer is YES, NO or DON'T KNOW and continue to B26.
- B26. This question is an exclusion criterion. Patients who have had organ, limb, or bone marrow transplants are not eligible. Answer is YES, NO or DON'T KNOW and continue to B27.
- B27. This question is an exclusion criterion. Pregnant patients or male patients with pregnant partner(s) are not eligible.
- Based on gender, ask the patient the appropriate question. Answer YES, NO or DON'T KNOW and continue to B28.
- B28. This question is an exclusion criterion. Female patients or male patients with partner(s) who are breastfeeding are not eligible.
- Based on gender, ask the patient the appropriate question. Answer YES, NO or DON'T KNOW and continue to B29.
- B29. The patient should include all current partners when answering this question. If the answer is YES, skip to B31. If the answer is NO or DON'T KNOW, continue to B30.
- B30. An answer of NO to this question is an exclusion criterion. If the answer is YES, the patient is eligible. Patients must be willing to use contraception according to the protocol guidelines.
- Based on gender, ask the patient the appropriate question. Answer YES or NO and continue to B31.
- B31. This question is an exclusion criterion. Patients participating in other clinical trials are not eligible. Answer YES or NO and continue to B32.
- B32. This question is an exclusion criterion. Patients who have used the illicit drugs specified within the past two years are not eligible. Answer YES or NO and continue to B33.
- B33. Major depression in and of itself is not an exclusion criterion. Interferon can increase depressive symptoms. If the answer is YES, continue to B33a. If the answer is NO or DON'T KNOW, skip to B34.
- B33a. If the answer is YES, continue to B33b. If the answer is NO or DON'T KNOW, skip to B34.
- B33b. This question is an exclusion criterion. Patients who have been hospitalized for depression in the last five years are not eligible. Answer YES, NO or DON'T KNOW and continue to B34.
- B34. If the answer is YES, complete the specify field and continue to B34a. If the answer is NO or DON'T KNOW skip to B35.
- B34a. This question is an exclusion criterion. Patients with any current (within the last six months) severe or poorly controlled psychiatric disorder are not eligible. If the answer is YES, skip to B35. If the answer is NO or DON'T KNOW, continue to B34b.
- B34b. Patients with a poorly controlled psychiatric disorder more than 6 months but less than 5 years ago must be assessed by a mental health professional (see B37). Answer YES, NO or DON'T KNOW and continue to B35.
- B35. If the answer is YES, complete the specify field with type of illness and name of medication and continue to B36. If the answer is NO or DON'T KNOW, continue to B36.

- B36. If the answer is YES, continue to B36a. If the answer is NO, skip to B37.
- B36a. This question is an exclusion criterion. Patients who have attempted suicide in the last 5 years are not eligible. Answer YES or NO and continue to B37.
- B37. Patients who have had a suicide attempt and/or hospitalization for depression more than 5 years ago OR patients who have had a severe or poorly-controlled psychiatric disorder more than 6 months ago but less than 5 years ago, **MUST BE WILLING** to be assessed and followed (if recommended) by a psychiatrist or other mental health professional. If they are not willing to be assessed and followed, they are not eligible.
- Answer YES, if the patient is **UNWILLING** to be assessed and followed.
  - Answer NO, if the patient is willing to be assessed and followed.
  - Answer NOT APPLICABLE (-1) if the question does not apply to this particular patient.

**This is the last question of the patient interview.**

**If appropriate, have the patient sign a medical release form.**

### **SECTION C: CONTRACEPTIVE USE**

#### General Instructions for Section C:

Review method(s) of contraception the patient and/or the patient's partner(s) will be using.

- C1. Record each method of contraception in the boxes provided. If the patient or patient's partner(s) are not of childbearing potential, i.e., sterilized, hysterectomy, post-menopausal, record 6 as an answer.

### **SECTION D: OTHER CONDITIONS**

#### General Instructions for Section D:

Record any significant condition not listed above that the patient currently has or had in the past that you became aware of by chart review or by discussion with the patient's health care provider. For example, if the patient is noted to have migraine headaches, record here. It may be helpful to fill out a Pre-Existing Conditions Form so that you will be able to differentiate symptoms and conditions that a patient experienced pre-treatment, with the usual severity and frequency and treatment (see Pre-existing Condition Form in Section L of MOO). Conditions such as Gilbert's syndrome and hypertension should be recorded under specific questions pertaining to those conditions (B1a, B12a).

- D1. If the answer is YES, complete the specify field. 100 characters (including punctuation and spaces) are provided. If the answer is NO, continue to E1.

If you become aware of conditions during the course of the study, return to this form and edit it to include them.

### **SECTION E: EXPRESS VERSUS LEAD-IN ENROLLMENT**

- E1. Circle 1 if this patient will be an Express patient. Circle 2 if this patient will enter the Lead-in Phase of the HALT-C Trial.

**SECTION F: FOR STUDY COORDINATOR OR PRINCIPAL INVESTIGATOR USE****General Instructions for Section F:**

In some situations, the Study Coordinator or Principal Investigator may think that a patient is eligible for enrollment into the HALT-C Trial, even though the patient answered YES or DON'T KNOW to one or more of the exclusion criteria questions in Section B. For example, the condition reported may be minor or adequately treated with medication or there may be no evidence of the condition in the patient's medical chart. You may request an exemption by completing and Exemption Request Form.

- F1. Circle 1 if any of the identified exclusion criteria were answered YES or DON'T KNOW and continue to F2. Circle 2 if all of the identified exclusion criteria were answered NO and Form #3 is complete.
- F2. Circle 1 for YES if the patient should be eligible to enroll in the HALT-C Trial in spite of a possible ineligibility and continue to F3. Circle 2 for NO if the patient is not eligible to enter the HALT-C Trial and Form #3 is complete.
- If you circled 2, please complete Form # 5: Trial Ineligibility.
- F3. Column 1: Record the exclusion question number (exclusion questions are bolded and circled) to which YES or DON'T KNOW was answered.

Column 2: Explain why the patient should be eligible, despite the exclusion criterion (i.e., the condition is minor, the condition is being adequately treated, there is no evidence of the condition in the medical chart, etc).

Column 3: Record if an exemption is requested.

- Record YES if an exemption is requested and submit an Exemption Request Form to the DCC.
- Record NO if an exemption is not necessary. For example, the patient states that she has uncontrollable diabetes but there is no record of her having diabetes in her chart and all blood tests are within normal limits.
- Record N/A for any other reason.

Signature of HALT-C staff completing Sections B, C, D, and E.

The signature of the person interviewing and obtaining information from the medical record must be recorded here. Your signature verifies that you have obtained the data asked for and this form becomes a source document.