HALT-C Trial Q x Q

Analgesics Medications History – Risk Factors AS

Form # 141 Version B: 12/03/2001

Purpose of Form #141: The Analgesics Medications History Form #141records the patient's historic use of analgesic medications using a self-administered questionnaire.

When to complete Form #141: This form should be completed for all patients at the following study visits. Form #141 will be data entered at each clinical site.

- Lead-in patients: Baseline (W00).
- Express patients: Baseline (R00).

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 of the visit in MM/DD/YYYY format.

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

SECTION B: PRESCRIPTION ANALGESICS

- The patient should complete Section B by following the directions written on Form #141.

- If the patient is not able to complete Form #141 by her/himself, the interviewer may read the questions and answers to the patient and record the answers given by the patient on the form. If the interviewer completes the form in this manner, please note so in the margins of the form by writing "form completed by interviewer" with the initials of the interviewer.

- It is important that the patient complete all of the items on Form #141.
  - Review the form for any missing items.
  - Make sure that each item has only a single answer selected.
  - Please ask the patient to complete any missing or doubly marked items.

B1. The patient should circle one answer. If the patient answers NO (code of 2), then the form is complete, and the patient may stop here and return the form. If the patient answers YES (code of 1), then s/he should complete the rest of the form.

B2. For each prescription medicine medicine listed under B2, the patient should consider whether s/he has taken that medicine at least once a week over the last twelve months. For each medicine that s/he has taken at least once a week over the last twelve months, the patient should circle that medicine and circle the number to the right that best describes how often s/he has taken it. The patient does not need to make any marks for medicines that s/he has not taken at least once a week over the last twelve months (the patient may skip those medicines).

B3. For each non-prescription medicine listed under B3, the patient should consider whether s/he has taken that medicine at least once a week over the last twelve months. For each medicine that s/he has taken at least once a week over the last twelve months, the patient should circle that medicine and circle the number to the right that best describes how often s/he has taken it. The patient does not need to make any marks for medicines that s/he has not taken at least once a week over the last twelve months (the patient may skip those medicines).

Additional instructions for data entry:

Data entry personnel should note that there is an additional question in the electronic version of Form #141 in the Data Management System that does not appear on the paper copy of the form. For each medicine listed in Section B of the paper form, an additional question appears in the DMS asking the data enterer to record whether the patient replied that s/he has taken that medicine. For each medicine, the question is "B2x1" or "B3x1" (where x is replaced by the letter corresponding to the listed medicine). The options for this question are YES (code of 1) and NO (code of 2).

- If the patient has recorded how often they took the medicine, then answer YES (code of 1) in question B2x1 or B3x1, to indicate that the patient has taken this medicine.

- If the patient has circled or otherwise marked a medicine to indicate that s/he has taken it, then answer YES (code of 1) in question B2x1 or B3x1. If, in addition to marking that medicine, the patient did not record how often s/he took the medicine, then record the frequency (question B2x2 or B3x2) as "Missing" (code of –9).

- If the patient has not recorded a frequency and has not otherwise marked a medicine, then answer NO (code of 2) in question B2x1 or B3x1, to indicate that the patient did not take this medicine.

B4. For each medicine that the patient selected in Section B2 and B3, s/he should answer additional questions about in Section B4. The patient should fill in the name of the medicine in the space provided. Then s/he should select one of the four options listed. The answer should best describe how the amount the patient took of the medicine over the last twelve months compares to what s/he typically took over the last ten years.

    - The patient may report on up to four medicines.

    - For the first question that has **not** been answered (the patient has not written anything in the blank or circled one of the four answers), the data enterer should enter –1, for Not Applicable.