QxQ updated: 09/21/2004

HALT-C Trial

Life Events Status Interview

Form # 45 QxQ Version B: 08/20/2001 (Rev. 05/28/2002)

<u>Purpose of Form #45:</u> This form collects data about the life events status of study participants, e.g., marital status, housing, working status, health insurance and education. Because Form #45 may be used as a source document, data collectors must sign the form.

<u>When to complete Form #45:</u> Sections A and B of Form #45 should be completed for all patients at the following study visits:

- Lead-in Phase patients: Baseline visit (W00).
- Express patients: Randomization Visit (R00).
- Responder Phase patients: Week 72 visit (W72).
- Randomization Phase patients: Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54) visits.

Section C of Form #45 should only be completed once at the following visit:

- Lead-in Phase patients: Baseline visit (W00).
- Express patients: Randomization Visit (R00).

The Life Events Status Interview should take approximately three minutes to complete.

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 using MM/DD/YYYY format.
- A5. Enter the initials of the person completing Section A of the form.

SECTION B: COMPLETING THE LIFE EVENTS STATUS INTERVIEW

Note: Section B should be completed at every visit that requires a Form #45. The HALT-C staff member who collects the data recorded in Section B and C must sign the form on page 3.

Using interview technique, read the introduction, questions, and all answers to the patient. Circle the number next to the patient's answer. If the patient gives two answers, probe using interview technique to elicit the answer that is closest to the current situation.

B1. Circle one number that corresponds to the patient's current marital status.

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- B2. Record the number of people the patient reports living in his/her household.
 - If the patient lives alone, record "1".
 - If the patient lives with one other person, record "2"; etc.
- B3. Circle one number that corresponds to the patient's current housing type.
 - If answers 1 6 do not apply, circle 7 for OTHER. Briefly record the housing type.
- B4. Circle one number that corresponds to the patient's current employment situation.
 - If you circle answers 1 5, skip to Question B6.
 - If you circle answer 6, continue to Question B5.
 - If answers 1 6 do not apply, circle 7 for OTHER. Briefly record employment situation.
- B5. Circle one number that corresponds to the unemployed patient's situation.
- B6. If the patient's work situation has changed because of reasons related to health, circle 1 for YES. Otherwise, circle 2 for NO.

B7a-e. Circle one number for each question corresponding to the patient's current health insurance.

- If the patient currently has the insurance listed in B7a-e, circle 1 for YES.
- If the patient does not have the insurance listed in B7a-e, circle 2 for NO.
- If the patient does not know about the insurance listed in B7a-e, circle 3 for DON'T KNOW.
- B7e. If the answer to B7e is YES, briefly record the kind of health insurance.

SECTION C: BASELINE DEMOGRAPHICS INTERVIEW

Note: Section C should be completed only at baseline (W00) for Lead-in Phase patients and Randomization Visit (R00) for Express patients. The HALT-C staff member who collects the data recorded in Section B and C must sign the form on page 3.

- C1. Circle one answer corresponding to highest grade or year of school completed. Do not read the answers aloud. Probe using interviewing technique as appropriate.
 - 1. Less than high school: Schooling ended before high school.
 - 2. Some high school: Attended high school, but did not graduate.
 - 3. Completed high school: Graduated from high school.
 - 4. GED: Received a GED diploma.
 - 5. Vocational or technical school: Graduated from a vocational or technical school.
 - 6. Some college: Attended college or took college classes, but did not graduate.
 - 7. Completed college: Graduated from college.
 - 8. Some graduate school: Took post-college courses, but did not receive a graduate degree.
 - 9. Graduate/Professional Degree: Completed post-college graduate or professional school degree.

After completion of the interview, the HALT-C staff interviewer should sign the form on page 3.