QxQ updated: 05/17/2004

HALT-C Trial Q x Q

Baseline Visit Date

Form # 8 Version A: 06/15/2000

<u>Purpose of Form #8</u>: The Baseline Visit Date form records the date that a Lead-In patient received the initial supply of Trial medications. This is the date of the baseline visit (W00), and is the official date of entry into the Lead-In phase of the HALT-C Trial. All visit windows for the week 2 to week 24 visits (W02 – W24) will be set based on the Baseline Visit Date.

<u>When to complete Form #8</u>: The Baseline Visit Date form must be the first form data entered for the baseline visit (W00). Other baseline forms cannot be data entered until the Baseline Visit Date form is data entered.

Note: The baseline visit (W00) should occur within 8 weeks of the end of screening (the date that screening was completed, as recorded on form #4, Screening Checklist).

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 W00 is pre-printed on the form.
- A4. Record the date that the form was completed using the MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: OFFICIAL DATE OF ENTRY INTO THE HALT-C TRIAL

- B1. Record the date using the MM/DD/YYYY format that the patient received the initial supply of Trial peginterferon and ribavirin. This is the official date of the baseline (W00) visit, and is the date that sets visit windows for W02 W24 visits.
- B2. Circle 1 for YES or 2 for NO depending on whether the baseline visit was completed on the day that the patient received the initial supply of Trial medications.