# HALT-C Trial Q x Q

## Early Termination of  Peginterferon alfa-2a Treatment

Form # 19  Version A: 06/15/2000

**Purpose of Form #19:**  This form records the date and reason Peginterferon alfa-2a treatment was terminated earlier than expected by the HALT-C Trial protocol.

**When to complete Form #19:** Complete Form #19 when HALT-C Peginterferon alfa-2a treatment was terminated **prematurely and permanently** only for the following types of patients:

- Lead-In Phase patients who permanently terminated HALT-C Peginterferon treatment after their first study dose and prior to the Week 24 (W24) study visit.
- Responder Phase patients who permanently terminated HALT-C Peginterferon treatment prior to their Week 48 (W48) study visit.
- Randomized patients in the treatment group who permanently terminated HALT-C Peginterferon treatment prior to their Month 48 (M48) study visit.

If the patient is also withdrawing from the HALT-C trial, Form #25 Early Termination from Trial should also be completed.

**Where to add Form #19:** Form #19 is an addable form in the Data Management System.  Add this form to the study visit closest in time to termination of Peginterferon treatment. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#19: Early Termination of Peginterferon alfa-2a Treatment" from the pull down menu, and then click the "OK" button. To see where this form has been added, click on the "More" link in the upper right hand corner of the screen.

### 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 this form is completed using MM/DD/YYYY format.

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

## SECTION B:   EARLY TERMINATION OF PEGINTERFERON ALFA-2A

B1.    Record the date in MM/DD/YYYY format that the last dose of HALT-C Peginterferon alfa-2a was administered.

- If the exact date is unknown, record the last date that Peginterferon alfa-2a was dispensed to the patient.

B2.    Record the code number of the primary reason for early termination of HALT-C Peginterferon alfa-2a treatment.  Choose one Reason Code from the list below.

If the Reason Code is recorded as 1, 2, or 3, the form is complete. These types of events also require a Form #63 Clinical Outcome to be completed and data entered.

If the Reason Code is recorded as 4, 5, or 6, continue to Question B3. These types of events also require a Form #63 Clinical Outcome to be completed and data entered.

If the Reason Code is recorded as 7, continue to Question B3. These types of events also require a Form #60 Adverse Event to be completed and data entered. Also complete a Form #61 Serious Adverse Event as appropriate.

If the Reason Code is recorded as 8 – 13, continue to Question B3.

If Reason Codes 1 – 13 do not apply, record 99, and continue to Question B3.

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### Reason Codes

| | |
|---|---|
| * 1.  Liver transplant | 8.  Patient request |
| * 2.  Hepatocellular cancer | 9.  Patient withdrew consent |
| * 3.  Meets 1999 criteria for UNOS transplant status 2b | 10. Non-compliance with protocol - dosing |
| | 11. Non-compliance with protocol – visits |
| * 4.  Ascites | 12. Other non-compliance with protocol |
| * 5.  Variceal hemorrhage | 13. Patient moved to another location |
| * 6.  Hepatic encephalopathy | 99. Other |
| 7.  Other adverse event(s) | |

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B3.    Complete Question B3 only if question B2 was coded 4 - 13 or 99. Record a brief explanation why Peginterferon alfa-2a treatment was terminated prematurely.  One hundred characters, including spaces and punctuation, are provided. Explanation examples:

- "Pt unable to tolerate AE of anxiety. Stopped Peg 90 on 04/01/2004."
- "Pt not seen since 07/13/2003 when 21 vials Peg 90 dispensed. Unknown if pt injected drug."