

HALT-C Trial
Early Termination of Peginterferon alfa-2a Treatment

Form # 19 Version A: 06/15/2000

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here →
- A2. Patient initials: _ _ _ _
- A3. Visit number: _ _ _ _
- A4. Form completion date: MM/DD/YYYY _ _ / _ _ / _ _ _ _
- A5. Initials of person completing form: _ _ _

SECTION B: EARLY TERMINATION OF PEGINTERFERON ALFA-2A

B1. What date was the last dose of Peginterferon alfa-2a administered?

(MM/DD/YYYY) _ _ / _ _ / _ _ _ _

B2. Primary reason for early termination of Peginterferon alfa-2a treatment: (CHOICES 1-3, END OF FORM)

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

*** Choices 1-6: Complete Clinical Outcome form (#63) and submit source documents to the DCC.**

Choices 4-13, 99: Explain below.

Complete Adverse Event Report form, #60, and Serious Adverse Event Report form, #61, as appropriate. If patient is withdrawing from the HALT-C Trial, also complete form #25, Early Termination from Trial.

B3. Explain why treatment ended: _____

†1999 criteria for UNOS transplant Status 2b defined as:

- presence of a small hepatocellular carcinoma **or**
- Child-Turcotte-Pugh score of 10 or more **or**
- Child-Turcotte-Pugh score of 7 or more **plus** any one of the four items following:
 - 1. Documented unresponsive variceal hemorrhage
 - 2. Occurrence of one episode of spontaneous bacterial peritonitis
 - 3. Hepatorenal syndrome
 - 4. Refractory ascites or hydrothorax unresponsive to treatment