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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)**

Reason Codes

* 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
	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)	

*** 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