HALT-C Trial
Adverse Event Report
Form # 60   Version A: 06/15/2000

SECTION A:

A1. Affix ID Label Here →   ⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚⬚

__ __ - __ __ __ - __

A2. Patient initials: __ __ __

SECTION B: ADVERSE EVENT INFORMATION

B1. Event number (assigned sequentially): ⬚⬚

B2. Event code: (from Event Code List) _____

B3. Adverse event description: _____

B4. Date adverse event began: (MM/DD/YYYY)   __ __ / __ __ / __ __ __ __

B5. Adverse event status information:

Initials of Person Completing Log Entry	Date Adverse Event Status was Updated (MM/DD/YYYY)	Date Adverse Event Ended (Enter date ended, MM/DD/YYYY, or check box, if ongoing)	Severity 1 = mild 2 = moderate 3 = serious	Pattern of Events 1 = single event 2 = continuous 3 = intermittent	Relationship to Study Meds 1 = unrelated 2 = remote 3 = possible 4 = probable	Adverse Event Status 1 = resolved, no residual effects 2 = resolved with sequelae 3 = continuing 4 = disability 5 = death	Treatment / Actions Taken (Enter up to five codes per log entry) 1 = none 7 = Pegasys perm. dc'd 2 = add'l. therapy 8 = Ribavirin reduced 3 = add'l. lab tests 9 = Ribavirin temp. dc'd 4 = add'l. meds 10 = Ribavirin perm. dc'd 5 = Pegasys reduced 11 = hosp. needed 6 = Pegasys temporarily dc'd 12 = hosp. prolonged
a.	b.	c.	d.	e.	f.	g.	h.
__ __ __	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Ongoing					___ ___ ___ ___ ___
__ __ __	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Ongoing					___ ___ ___ ___ ___
__ __ __	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Ongoing					___ ___ ___ ___ ___
__ __ __	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Ongoing					___ ___ ___ ___ ___

SECTION C: FINAL ADVERSE EVENT INFORMATION

C1. Final event code: (from Event Code List) _____ (if Event Code is the same as when the event started, enter code from B2 here.)

C2. Final adverse event description: (if adverse event description is same as in B3., write "same as B3" in this space.)_____