

HALT-C Trial
Trial ID Assignment

Form # 1 Version B: 02/05/2001

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here → _____ - _____ - ____
- A2. Patient initials: _____
- A3. Completion Date: MM / DD / YYYY _____ / _____ / _____
- A4. Initials of person completing form: _____

SECTION B: PATIENT ID INFORMATION

B0. Has Form # 1 been completed for this patient previously?

- Yes 1
- No 2 (B1)

- a. What was the patient's previous patient ID number: _____ - _____ - ____
- b. What were the patient's previous initials: _____

B1. Patient's Date of Birth: (MM/DD/YYYY) _____ / _____ / _____

B2. Patient Gender

- Male 1
- Female 2

B3. Patient's Race

- White 1
- Black..... 2
- Asian or Pacific Islander 3
- American Indian or Alaskan Native 4
- Other 5 Please specify: _____
- Unknown..... 6

a. Source of information:

- Patient 1
- Medical Chart..... 2

B4. Does patient consider himself/herself to be Latino or Hispanic?

- Yes 1
- No 2

a. Source of information:

- Patient 1
- Medical Chart 2

B5. Will this patient be brought in for screening visits for the HALT-C Trial?

- Yes 1 (Section C)
- No 2 (End of form, complete Form # 5 Trial Ineligibility)

SECTION C: PATIENT’S MOST RECENT ADEQUATE COURSE OF TREATMENT WITH INTERFERON

IMPORTANT NOTE: Questions C1-C8 refer to the most recent adequate course of interferon treatment as defined by the HALT-C Protocol. See the QxQ for more information.

C1. Start date of most recent adequate course of treatment with any Interferon:

(MM/DD/YYYY) ____ / ____ / _____

C2. Type of Interferon preparation used for this course of treatment: (From code list, below.)

<u>Medication Code List:</u>	
1. Interferon alone – brand unknown	12. Interferon with Ribavirin – brand unknown
2. Peg Interferon alone – brand unknown	13. Peg Interferon with Ribavirin - brand unknown
3. Infergen (Consensus Interferon) alone	14. Infergen with Ribavirin
4. Roferon alone	15. Roferon with Ribavirin
5. Peg Roferon (Pegasys) alone	16. Peg Roferon (Pegasys) with Ribavirin
6. Intron A alone	17. Rebetron (Intron A with Ribavirin)
7. Peg Intron A alone	18. Peg Intron A with Ribavirin
8. ZN-Intron	19. ZN-Intron with Ribavirin
9. Alferon N alone	20. Alferon N with Ribavirin
10. Wellferon	21. Wellferon with Ribavirin
11. Rebif (beta interferon)	22. Rebif (beta interferon) with Ribavirin
	99. Other SPECIFY: _____

C3. Initial dose of this Interferon treatment: ____ . ____ MU or ____ ____ mcg

C4. Number of doses given per week during this course of Interferon: ____

Patient ID: _____ - _____ - _____

C5. Total number of weeks this course of Interferon given: _____

C6. Was the dose of Interferon adjusted during this course of treatment?

Yes 1
 No 2 (C7)

	For this most recent adequate treatment:	Dosage	Number of Doses per Week	Number of Weeks
		a.	b.	c.
1.	Adjusted Dose of Interferon	____ . ____ MU ____ mcg	____	____
2.	Adjusted Dose of Interferon	____ . ____ MU ____ mcg	____	____
3.	Adjusted Dose of Interferon	____ . ____ MU ____ mcg	____	____
4.	Adjusted Dose of Interferon	____ . ____ MU ____ mcg	____	____
5.	Adjusted Dose of Interferon	____ . ____ MU ____ mcg	____	____

C7. Was Ribavirin given with this course of Interferon treatment?

Yes 1
 No 2 (C11)

C8. Initial daily dose of Ribavirin for this course of Interferon treatment: _____ mg

C9. Total number of weeks Ribavirin given with this course of Interferon treatment: _____

Patient ID: _____ - _____ - _____

C10. Was the dose of Ribavirin adjusted during this course of treatment?

Yes 1

No..... 2 (C11)

	For this most recent adequate treatment:	Total Daily Dosage	Number of Weeks
		a.	b.
1.	Adjusted Dose of Ribavirin	_____ mg	_____
2.	Adjusted Dose of Ribavirin	_____ mg	_____
3.	Adjusted Dose of Ribavirin	_____ mg	_____
4.	Adjusted Dose of Ribavirin	_____ mg	_____
5.	Adjusted Dose of Ribavirin	_____ mg	_____

C11. How was the patient's non-response to treatment determined? (Record code 1-3)

Non-response Codes:

1. A positive test for HCV-RNA ;
or
2. Elevated serum ALT;
or
3. (Code 1 & 2) Both a positive test for HCV-RNA **and** elevated serum ALT.