

HALT-C Trial

Screening Biopsy Evaluation

Form # 50 Version C: 10/01/2001

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here →
- A2. Patient initials: _ _ _ _
- A3. Visit number: S 0 0
- A4. Date form completed: (MM/DD/YYYY) ___ / ___ / _____
- A5. Initials of person completing form: _ _ _ _

SECTION B: TO BE COMPLETED BY THE STUDY COORDINATOR

- B1. End date of last course of (most recent) treatment with interferon:
MM/DD/YYYY ___ / ___ / _____
- B2. Date of biopsy: MM/DD/YYYY ___ / ___ / _____
- B3. Was this biopsy performed specifically for entry into the HALT-C Trial?
Yes.....1
No2
- B4. Hospital Accession # of this biopsy: _____

SECTION C: TO BE COMPLETED BY THE SITE PATHOLOGIST

- C1. Initials of pathologist reading biopsy: _ _ _ _
- C2. Date biopsy read: MM/DD/YYYY ___ / ___ / _____
- C3a. Ishak fibrosis score of this biopsy:
0.....0 (END OF FORM. COMPLETE FORM #5, TRIAL INELIGIBILITY)
1.....1 (END OF FORM. COMPLETE FORM #5, TRIAL INELIGIBILITY)
2..... 2 (C3b)
3.....3 (C4)
4.....4 (C4)
5.....5 (C4)
6.....6 (C4)

C3b. Was there a previous biopsy with an Ishak score of 3 or greater?

Yes.....1 **(C3c)**

No.....2 **(END OF FORM. COMPLETE FORM #5, TRIAL INELIGIBILITY)**

C3c1 Date of previous biopsy	C3c2 Ishak Fibrosis score of previous biopsy	C3c3 Hospital Accession Number
___/___/_____	___	
___/___/_____	___	
___/___/_____	___	

C4. Does this patient have steatohepatitis (alcoholic or nonalcoholic)?

Yes..... 1

No 2 **(C6)**

C5. Is the steatohepatitis severe as defined by the presence of all of the following criteria: steatosis (3+ or 4+), Mallory bodies (many), zone 3 pericellular fibrosis (extensive)

Yes..... 1 **(END OF FORM. COMPLETE FORM #5, TRIAL INELIGIBILITY)**

No 2

C6. Presence of 3+ or 4+ hepatocellular stainable iron:

Present 1 **(READ INSTRUCTIONS IN QxQ ON DETERMINING PATIENT ELIGIBILITY.)**

Absent..... 2

C7. Liver histology that is consistent with alpha-1-antitrypsin deficiency (alpha-1-antitrypsin globules):

Present 1 **(READ INSTRUCTIONS IN QxQ ON DETERMINING PATIENT ELIGIBILITY.)**

Absent..... 2

C8. Number of unstained slides available for shipment to AFIP: ____

C9. Number of slides available at site: ____

C10. Is the block available at the site?

Yes.....1

No2

C11. Is there source documentation available?

Yes.....1

No2

RETURN COMPLETED FORM AND 10 UNSTAINED SLIDES TO THE STUDY COORDINATOR.