

HALT-C Trial

Randomization Checklist

Form # 21 Version B: 03/19/2001

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here -> [ ]
A2. Patient initials: [ ]
A3. Visit number: W 2 0
A4. Date Completed: MM / DD / YYYY [ ] / [ ] / [ ]
A5. Initials of person completing form: [ ]

SECTION B: RANDOMIZATION CHECKLIST - To be completed for all patients in the HALT-C Trial.

B1. Ishak fibrosis score (from central review of screening biopsy):

- 2 - 4 ..... 1
5 - 6 ..... 2

B2. Child-Turcotte-Pugh score:

- a. Week 12: [ ] b. Week 20: [ ]
(Note: At least one score must be less than 7 for randomization)

B3. Central HCV RNA test result from week 20:

- Positive ..... 1 (Note: Must be positive for randomization)
Negative ..... 2

B4. Central alpha-fetoprotein result from week 20:

- [ ] ng/mL (Note: Must be less than or equal to 1000 ng/mL for randomization)

B5. Is there evidence of hepatocellular carcinoma?

- Yes ..... 1 (Note: Week 20 ultrasound must have been reviewed.)
No ..... 2

B6. All required week 20 tests or procedures have been done, and results evaluated.

- Yes ..... 1
No ..... 2

B7. Is this patient eligible for randomization?

- Yes ..... 1
No ..... 2 (END OF FORM)

B8. Is this patient willing and appropriate for randomization?

- Yes ..... 1
No ..... 2 Explain: \_\_\_\_\_ (END OF FORM)

B9. Are you sure you want to randomize this patient?

- Yes ..... 1 (Extra verification for use during data entry.)