HALT-C Trial

Express Screening Checklist

Form #94 Version A: 06/15/2000 (Rev. 02/11/2002)

SECTION A: GENERAL INFORMATION

A1. Affix ID Label Here → ___ ___ - ___ ___ ___ - ___

A2. Patient initials: __ __ __

A3. Visit number: S 0 0

A4. Date Screening Completed: MM/DD/YYYY __ __ / __ __ / __ __ __ __

A5. Initials of person completing form: __ __ __

	Correct	No
B1. The specific aims and general conduct of the protocol reviewed with patient.	**1**	2
B2. Trial ID Assignment, Form #1, completed and data entered.	**1**	2
B3. Patient signed the HALT-C screening and/or combined consent form.	**1**	2
PATIENT MEETS HALT-C INCLUSION CRITERIA, INCLUDING:		
C1. Patient meets all inclusion criteria as listed in the Protocol (or Eligibility Worksheet).	**1**	2
C2 Patient is HCV-RNA positive or serology positive for HCV antibody by a second generation or higher assay.	**1**	2
C3. Most recent adequate treatment, as defined in the Protocol, is noted on Form # 1 (Trial ID Assignment) and documentation is available.	**1**	2
C4. HCV RNA + at least Week 20 or after, as defined in Protocol, and documentation is available.	**1**	2
C5. Patient tolerated previous pegylated interferon therapy.	**1**	2
C6. Patient is willing to use adequate contraception and neither patient nor partner(s) are pregnant: If patient is a women of child bearing potential, she is willing to use adequate contraception during the entire study. If patient is male, he is willing to use adequate contraception during the time he is treated with interferon-ribavirin combination therapy and for 6 months thereafter.	**1**	2
C7. Patient does not meet any exclusion criteria as listed in the Protocol (or Eligibility Worksheet)?	**1**	2
C8. Central Lab - HCV RNA Results received. The patient is positive for HCV RNA.	**1**	2
C9. Screening Biopsy Evaluation, Form # 50, done and Ishak stage fibrosis meets protocol requirements and timing of the biopsy meets protocol requirements.	**1**	2
C10. Screening Medical History Interview, Form # 3, completed and evaluated.	**1**	2
C11. Physical Exam, Form # 11, completed.	**1**	2
C12. AFP Results received and $\leq$ 1000 and Form # 34 is completed. If AFP between 200 and 1000, ultrasound and MRI or CT was negative for hepatic mass.	**1**	2
C13. CTP Score, Form # 15, completed on two separate occasions and at least one score is < 7.	**1**	2
C14. Patient is not participating in any other clinical trial.	**1**	2

Local Lab, Form # 30, and Screening Visit 2 Local Lab, Form # 35, completed and values below are within acceptable limits:	**Correct**	No
D1. Serum chemistries, including: BUN, creatinine, glucose, triglycerides, uric acid.	**1**	2
D2. Liver chemistries, including: AST, ALT, alkaline phosphatase, total bilirubin, albumin, globulin (or total protein), and prothrombin time (INR).	**1**	2
D3. Complete blood count with differentials, including: WBC count, *neutrophil count, *hematocrit, *hemoglobin, and *platelets. (* at either the Screening or Pre-Treatment Visit)	**1**	2
D4. Thyroid stimulating hormone	**1**	2
D5. Urinalysis to include: pregnancy, protein, and heme. Pregnancy is negative, if applicable.	**1**	2

Serological assays to exclude other causes of chronic liver disease:
D6. Iron: ___ ___ ___ µg/dL D7. Date of Test: __ __ / __ __ / __ __ __ __
D8. Total Iron Binding Capacity: ___ ___ ___ µg/dL D9. Date of Test: __ __ / __ __ / __ __ __ __
D10. Serum Ferritin: ___ ___ ___ ___ ng/mL D11. Date of Test: __ __ / __ __ / __ __ __ __
D12. ANA: Positive …….. 1 D12a. If positive, ANA: ___ /: ___ ___ ___ Negative …….. 2 D13. Date of Test: __ __ / __ __ / __ __ __ __ (Date can be historical)
D14. Hepatitis B surface antigen: Positive …….. 1 (Result must be negative) Negative …….. 2 D15. Date of Test: __ __ / __ __ / __ __ __ __ (Must be within last 12 months)
D16. HIV: Positive …….. 1 (Result must be negative) Negative ……. 2 D17. Date of Test __ __ / __ __ / __ __ __ __ (Must be within last 12 months)
D18. Ceruloplasmin: Result is normal or above normal: YES ……. 1 NO ……..… 2
D19. Alpha-1 antitrypsin: Normal value …….. 1 Below normal ……. 2

Patient ID: ___ ___ - ___ ___ ___ - ___

Composite International Diagnostic Interview (CIDI):

E1. Was CIDI administered?: Yes ……. 1 **(E2)**
No …….. 2

E 1a. If NO, why not?:_____**(F1)**

E 2. CIDI IDCODE: __ __ __ __ __ __ __ (0 plus 6-digit pt ID #)

E 3. CIDI administrator: Respondent …….. 1
Interviewer …… 2

	Yes	No
E 4. Were any DSM-IV diagnoses made for this patient by the CIDI program?	1	2 **(F1)**
E 5. If yes, how many DSM-IV diagnoses? ___ ___		

a. Diagnostic Code	**b. Diagnostic Criteria**	**c. DSM-IV diagnosis**		
1. a. __ __ __ . __ __	b. _____	c. _____		
	d. Onset Code	**e. Age of Onset**	**f. Recency Code**	**g. Age of Recency**
	d. _____	e. __ __	f. _____	g. __ __
a. Diagnostic Code	**b. Diagnostic Criteria**	**c. DSM-IV diagnosis**		
2. a. __ __ __ . __ __	b. _____	c. _____		
	d. Onset Code	**e. Age of Onset**	**f. Recency Code**	**g. Age of Recency**
	d. _____	e. __ __	f. _____	g. __ __
a. Diagnostic Code	**b. Diagnostic Criteria**	**c. DSM-IV diagnosis**		
3. a. __ __ __ . __ __	b. _____	c. _____		
	d. Onset Code	**e. Age of Onset**	**f. Recency Code**	**g. Age of Recency**
	d. _____	e. __ __	f. _____	g. __ __
a. Diagnostic Code	**b. Diagnostic Criteria**	**c. DSM-IV diagnosis**		
4. a. __ __ __ . __ __	b. _____	c. _____		
	d. Onset Code	**e. Age of Onset**	**f. Recency Code**	**g. Age of Recency**
	d. _____	e. __ __	f. _____	g. __ __

Attach CIDI print out of diagnoses. (It is optional to fill out the Diagnostic Codes, Criteria, DSM-IV Dx, etc on this paper form.)

	Correct	No
F1. Baseline History, Form #6, completed.	**1**	2
F2. Skinner, Form #41, completed.	**1**	2
F3. Quality of Life, Form #40, completed.	**1**	2
F4. Symptoms Form, #43, completed.	**1**	2
F5. Beck, Form #44, completed and evaluated by PI if score ≥ 15.	**1**	2
F6. If the patient has a history of severe or dose-limiting neuropsychiatric toxicity during prior interferon treatment: A consulting psychiatrist/ psychologist has determined that the patient is currently suitable for this trial, and source documentation confirming this eligibility is available.	**1**	2 (Not applicable:-1)
F7. The patient has not had a suicide attempt or hospitalization for depression within the past five years, and does not have a current (within 6 months) severe or poorly-controlled psychiatric disorder.	**1**	2
F8. The patient is willing to be assessed and followed by a mental health professional if s/he has had a recent (> 6 mo and <5 years ago) severe or poorly-controlled psychiatric disorder, or a suicide attempt or hospitalization for depression > 5 years ago.	**1**	2 (Not applicable:-1)
F9. Screening 1 Aliquot Form, #70, completed.	**1**	2
F10. Screening 2 Aliquot Form, #71, completed.	**1**	2
F11. Ultrasound (MRI, CT) Form, #22, completed and evaluated by PI.	**1**	2

Trial Informed Consent:	**Yes**	No
G1. Patient signed HALT-C Trial informed consent form.	**1**	2
G 2. Did patient sign Genetic Testing – Consent for Testing?	**1**	2
G 3. Did patient sign Genetic Testing – Consent for Information?	**1**	2

Ancillary Study with separate consent forms:	Yes	No
H 1. Quantitative Liver Function Testing Ancillary Study: Is patient eligible to participate in this ancillary study?	1	2 **(end)**
a. Did the patient sign a consent form to participate in this ancillary study?	1	2