HALT-C Trial

Screening Checklist

Form # 4 Version B: 12/03/2001

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 ELIGIBILITY CRITERIA, INCLUDING:		
C1. Patient meets all inclusion criteria as listed in the Protocol (or Eligibility Worksheet), ***or Exemption Request granted.***	**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 is noted on Form # 1 (Trial ID Assignment) and documentation is available.	**1**	2
C4. Non-response to most recent adequate treatment and documentation is available.	**1**	2
C5. Patient tolerated previous 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), ***or Exemption Request granted***.	**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.	**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 ≤ 200 and Form # 34 is completed.	**1**	2
C13. CTP Score, Form # 15, completed and score < 7.	**1**	2
C14. Patient is not participating in any other clinical trial.	**1**	2
C15. There is no undetectable HCV-RNA within 4 weeks prior to or 6 months after discontinuing the most recent adequate course of interferon.	**1**	2

Patient ID: ___ ___ - ___ ___ ___ - ___

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.	**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 above limit of normal: Yes …….. 1 No …….. 2	
D19. Alpha-1 antitrypsin: Normal or above normal…….. 1 Below normal …….. 2	

Patient ID: ___ ___ - ___ ___ ___ - ___

Composite International Diagnostic Interview (CIDI):

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

E1a. If NO, why not?:_____

E2. CIDI IDCODE: __ __ __ __ __ __ __ (0 plus 6-digit pt ID #)

E3. CIDI administrator: Respondent …….. 1
Interviewer …….. 2

	Yes	No
E4. Were any DSM-IV diagnoses made for this patient by the CIDI program?	1	2 **(F1)**
E5. 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.)

Patient ID: ___ ___ - ___ ___ ___ - ___

	Correct	No
F1. Baseline History, Form # 6, is 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)
F 9. Screening 1 Aliquot Form, # 70, completed.	**1**	2
F 10. Screening 2 Aliquot Form, # 71, completed.	**1**	2
F 11. Baseline visit (W00): Scheduled within 14 weeks of Screening visit #1, or exemption has been obtained if not scheduled within this time period?	**1**	2
F 12. 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 Studies with separate consent forms:	**Yes**	No	
H1. Immunology/Virology Ancillary Study: Is patient eligible to participate in this ancillary study?	1	2	**(H2)**
a. Did the patient sign a consent form to participate in this ancillary study?	1	2	
H 2. Quantitative Liver Function Testing Ancillary Study: Is patient eligible to participate in this ancillary study?	1	2	**(H3)**
a. Did the patient sign a consent form to participate in this ancillary study?	1	2	
H 3. Cognitive Effects 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	