HALT-C Trial

Screening Medical History Interview

Form # 3 Version B: 12/03/2001 (Rev. 02/14/2002)

SECTION A: GENERAL INFORMATION

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

A2. Patient initials: __ __ __

A3. Visit number: S 0 0

A4. Date of First Screening Visit: MM / DD / YYYY __ __ / __ __ / __ __ __ __

A5. Initials of interviewer: __ __ __ **Signature required**.

Note: Information in section B should be collected by interview or chart review. Sections C, D and E should be completed after the interview.

SECTION B: SCREENING MEDICAL HISTORY

SECTION B NOTE: THIS SECTION IS A COMBINATION OF EXCLUSION CRITERIA QUES-TIONS (QUESTION NUMBERS ARE **BOLDED AND CIRCLED**) AND GENERAL MEDICAL HISTORY. IF ANY OF THE EXCLUSION CRITERIA QUESTIONS IN THIS SECTION ARE ANSWERED "YES", MENTALLY NOTE THIS AND CONTINUE THE INTERVIEW. THE ANSWERS ARE TO BE OBTAINED BY ASKING THE PATIENT, OR THROUGH CHART REVIEW. THE PERSON SIGNING THEIR NAME AT THE END OF THE FORM IS VERIFYING THAT THEY HAVE OBTAINED THE DATA ASKED FOR.

NOTE: COMPLETE ONLY UNSHADED "SPECIFY" FIELDS.

Has a doctor, nurse, nurse practitioner or physician's assistant ever told the patient that s/he has:

	YES	NO	DON'T KNOW	IF YES, SPECIFY:
B1. Chronic liver disease other than hepatitis C, such as hepatitis B, auto-immune hepatitis, auto-immune cholestatic liver disorder, Wilson's disease, alpha-1-antitrypsin (AAT) deficiency, hemochromatosis, secondary iron overload, steatohepatitis, or drug-induced liver disease?	1	2	-8	
B1a. Gilbert's syndrome?	1	2	-8	
B2. Bleeding from esophageal varices (bleeding from varicose veins in your esophagus)?	1	2	-8	
B3. Bleeding from gastric varices (bleeding from varicose veins in your stomach)?	1	2	-8	
B4. Any other stomach or intestinal disease or abnormality?	1	2	-8	
B5. Diabetes (problems with blood sugar requiring medication or diet changes)?	1	2 **(B6)**	-8 **(B6)**	
B5a. Is the diabetes uncontrolled?	1	2	-8	

Patient ID: ___ ___ - ___ ___ ___ - ___

Has a doctor, nurse, nurse practitioner or physician's assistant ever told the patient that s/he has:

	YES	NO	DON'T KNOW	IF YES, SPECIFY:
B6. Hemophilia (bleeding disorder)?	1	2	-8	
B7. Any other blood disease or abnormality?	1	2	-8	
B8. Systemic auto-immune disorder such as rheumatoid arthritis or systemic lupus?	1	2 **(B9)**	-8 **(B9)**	
B8a. Is the disorder active?	1	2	-8	
B9. Any other immune system disease or abnormality?	1	2	-8	
B10. A malignancy (cancer)?	1	2 **(B11)**	-8 **(B11)**	
a. Was it a local squamous or basal cell cancer (skin cancer) treated by local excision (removal)?	1**(B11)**	2**(B10b)**	-8 **(B10b)**	
b. Has it been adequately treated and does it have an excellent chance for cancer-free survival in the opinion of the oncologist?	1	2	-8	
c. When was the cancer diagnosed? (MM/YYYY) __ __ / __ __ __ __				
d. When did treatment for the cancer end? (MM/YYYY) __ __ / __ __ __ __				
B11. Serious heart, cerebrovascular or lung disease?	1	2	-8	
B12. Any other heart disease or abnormality?	1	2	-8	
B12a. Any significant and stable heart disease?	1	2	-8	
B13. Any other lung disease or abnormality?	1	2	-8	
B14. Seizure disorder or epilepsy?	1	2 **(B15)**	-8 **(B15)**	
B14a. Have there been any periods during the past two years when the seizures have not been well controlled (still having seizures) even with the use of anti-seizure medication?	1	2	-8	
B15. Any other nerve or brain disease or abnormality?	1	2	-8	
B16. Drug allergies?	1	2	-8	

Patient ID: ___ ___ - ___ ___ ___ - ___

Has a doctor, nurse, nurse practitioner or physician's assistant ever told the patient that s/he has:

	YES	NO	DON'T KNOW	IF YES, SPECIFY:
B17. A hormonal abnormality?	1	2	-8	
B18. Muscle or bone disease or abnormality?	1	2	-8	
B19. Genital or urinary disease or abnormality?	1	2	-8	
B20. Skin disease or abnormality?	1	2	-8	
B21. An eye disease or abnormality, other than vision problems, not corrected by eyeglasses.	1	2	-8	
B22. Ear, nose or throat disease or abnormality?	1	2	-8	
B23. High cholesterol or high triglycerides (high amount of fat in your blood stream)?	1	2 **(B24)**	-8 **(B24)**	
B23a. Did s/he ever use medication to treat high cholesterol or high triglycerides?	1	2	-8	
B24. Has the patient ever had surgery to lose weight, such as stapling of the stomach or intestinal bypass?	1	2	-8	
B25. Does the patient require the use of coumadin (medication used to thin your blood) or immunosuppressive medication such as corticosteroids, methotrexate or azathioprine?	1	2	-8	
B26. Has the patient ever received an organ, limb or bone marrow transplant?	1	2	-8	
B27. (FOR WOMEN) Is she pregnant? (FOR MEN) Is his partner pregnant?	1	2	-8	
B28. (FOR WOMEN) Is she currently breast feeding? (FOR MEN) Is his partner currently breastfeeding?	1	2		
B29. Is the patient or patient's partner(s) unable to have children? (post-menopausal, hysterectomy, sterilized)	1 **(B31)**	2	-8	

Patient ID: ___ ___ - ___ ___ ___ - ___

Has a doctor, nurse, nurse practitioner or physician's assistant ever told the patient that s/he has:

	YES	NO	DON'T KNOW	IF YES, SPECIFY:
B30. (FOR WOMEN) Is she willing to use adequate contraception (adequate method of birth control) during the entire 4 years of the study? (FOR MEN) Is he willing to use adequate contraception (adequate method of birth control) during time he is treated with interferon-ribavirin combination therapy and for 6 months afterward?	1	2		
B31. Is s/he participating in any other clinical trial?	1	2		
B32. Has the patient used illicit drugs (such as heroin, cocaine, angel dust, etc.) within the past 2 years?	1	2		
B33. Major depression (that was diagnosed and required treatment)?	1	2 **(B34)**	-8 **(B34)**	
B33a. Was s/he hospitalized as a result of the depression?	1	2 **(B34)**	-8 **(B34)**	
B33b. Was this hospitalization less than five years ago?	1	2	-8	
B34. Any severe or poorly controlled psychiatric disorder, such as schizophrenia, obsessive-compulsive disorder, severe anxiety or personality disorder?	1	2 **(B35)**	-8 **(B35)**	
B34a. Is this disorder current (within 6 months)?	1 **(B35)**	2	-8	
B34b. Is this disorder more than 6 months but less than 5 years ago.	1	2	-8	
B35. Is there any other psychiatric disorder (depression, bipolar illness, other) treated with medication? Specify illness and med(s).	1	2	-8	
B36. Has s/he ever attempted suicide?	1	2 **(B37)**		
B36a. Has s/he attempted suicide within the past 5 years?	1	2		
B37. If suicide attempt or hospitalization for depression more than 5 years ago, or severe or poorly-controlled psychiatric disorder, is s/he unwilling to be assessed and followed (if recommended) by a mental health professional while on study drug?	1	2	-1	

END OF PATIENT INTERVIEW.

IF APPROPRIATE, HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.

Patient ID: ___ ___ - ___ ___ ___ - ___

REVIEW METHODS OF CONTRACEPTION WITH THE PATIENT.

SECTION C: CONTRACEPTION

C1. What method(s) of contraception will the patient and/or the patient's partner(s) be using? ☐ ☐ ☐ ☐

Specify other: _____

1. Oral contraceptives
2. Nor-plant implant
3. IUD
4. Depo-provera injections
5. Barrier method (diaphragm, condom or cervical cap) plus contraceptive jelly
6. Patient or patient's partner(s) not of childbearing potential

99. Other

SECTION D: OTHER CONDITIONS

	YES	NO
D1. After chart review and patient interview, are you aware of any significant conditions, not listed above, that the patient currently has or had in the past ?	1	2

IF YES, SPECIFY CONDITIONS:

_____

_____

_____

_____

SECTION E: EXPRESS VERSUS LEAD-IN ENROLLMENT

	EXPRESS	LEAD-IN
E1. Is the patient (if eligible) an Express patient, or will the patient participate in the Lead-in?	1	2

SECTION F: FOR STUDY COORDINATOR OR PRINCIPAL INVESTIGATOR USE

	YES	NO
F1. Were any of the exclusion criteria questions (those circled and bolded, with the exception of B30) in Section B answered "Yes" or "Don't know")?	1	2 **(END OF FORM)**
F2. Although one (or more) exclusion criteria questions in Section B was answered "Yes" or "Don't know", should this patient be eligible to enroll in the HALT-C Trial?	1	2 **(END OF FORM. COMPLETE FORM #5, TRIAL INELIGIBILITY.)**

F3. Specify the reason(s) that allow the patient to be eligible for the HALT-C Trial even though exclusion criteria questions in Section B were answered "Yes".

Question answered Yes	Explanation of why patient should be eligible for HALT-C Trial	Exemption requested?
		Yes….1 No…..2 N/A…..3
		Yes….1 No…..2 N/A…..3
		Yes….1 No…..2 N/A…..3
		Yes….1 No…..2 N/A…..3

Signature of HALT-C staff completing Sections B, C, D and E:

_____
Signature