

HALT-C Trial Trial Ineligibility

Form # 5 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 form was completed: MM / DD / YYYY ___ / ___ / _____
- A5. Initials of person completing form: _____

SECTION B: REASON FOR TRIAL INELIGIBILITY

Please select the reason(s) why the patient is ineligible: (Choose up to four reasons from the list below.)

<p>B1 ___</p> <p style="text-align: center;">If ans = 99, specify:</p> <p>_____</p>	<p>B2 ___</p> <p style="text-align: center;">If ans = 99, specify:</p> <p>_____</p>	<p>B3 ___</p> <p style="text-align: center;">If ans = 99, specify:</p> <p>_____</p>	<p>B4 ___</p> <p style="text-align: center;">If ans = 99, specify:</p> <p>_____</p>
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Ineligibility Reason Codes

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| <ol style="list-style-type: none"> 1. Age < 18 years 2. HCV Serology negative 3. Previous IFN treatment dose or duration insufficient 4. Previous IFN treatment response 5. HCV RNA negative by Core Virology Lab 7. Liver biopsy – biopsy does not meet entry criteria 8. Not willing to use adequate contraception 9. Hepatitis B surface antigen positive 10. Auto-immune hepatitis 11. Auto-immune cholestatic disorders 12. Wilson's disease 13. Alpha-1-antitrypsin deficiency 14. Hemochromatosis or secondary iron overload 15. Severe steatohepatitis 16. Drug-induced liver disease 17. Child-Turcotte-Pugh Score \geq to 7 18. History of bleeding from either esophageal or gastric varices 19. Platelet count < 50,000/ mm³ 20. Neutrophil count < 1,000/mm³. 21. Hematocrit <33% or hemoglobin <11 gm/dL 22. Alpha-fetoprotein > 200 ng/mL or >1000 ng/mL for Express patients 23. Hepatic mass lesion suspicious for hepatocellular carcinoma 24. Renal insufficiency 25. A positive test for HIV 26. Diabetes not under control 27. Hemophilia 28. Organ, limb or bone marrow transplant | <ol style="list-style-type: none"> 29. Use of chronic medications such as immunosuppressive meds (corticosteroids, methotrexate, azathioprine) or coumadin 30. Active systemic auto-immune disorders 31. Malignancy diagnosed and/or treated within the past 5 years (other than localized squamous or basal cell cancer) 32. Serious cardiac, cerebrovascular or pulmonary disease 33. Underlying hematologic abnormalities that would preclude treatment with interferon 34. Seizure disorder not well controlled by medication within past 2 years 35. Patient is pregnant or breast feeding 36. Male partner of a woman who is pregnant or breastfeeding 37. Active alcohol abuse within the past 12 months 38. Illicit drug use within the past 2 years 39. Does not meet psychiatric disorder criteria per protocol 40. Intolerance to previous interferon therapy 41. Unable to provide informed consent 42. Signed informed consent, but no longer willing to participate 43. Unwilling to undergo three liver biopsies over 4 years 44. Serum bilirubin > 2.5 mg/dL that is not due to Gilbert's syndrome or ribavirin 45. Participating in another clinical trial 46. Prior non-response to interferon treatment not appropriately documented 47. Unwilling to participate due to possible side effects of medication 48. Unwilling to participate due to possibility of being randomized to control (untreated) group 49. Unwilling to participate due to long duration of Trial 50. Unwilling to participate in an experimental research study 99. Other (Specify above in B1 – B4) |
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