



SC

NIDDK  
VIRAL HEPATITIS C  
**SCREENING CRITERIA**

2/21/2003  
Version 1.2

FORM KEYS

Patient ID \_\_\_-\_\_\_\_-\_\_\_\_

Time point:

Screen

Re-screen

COMPLETION LOG

Data Collector ID \_\_\_\_\_  
Initials

Data Collection \_\_\_-\_\_\_\_-\_\_\_\_

Date Entered \_\_\_-\_\_\_\_-\_\_\_\_

Date Verified \_\_\_-\_\_\_\_-\_\_\_\_  
MM DD YY

**SCREENING CRITERIA**Date of Evaluation \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yy**SECTION I: INCLUSION CRITERIA**

1. Is the patient between 18 years and 70 years of age inclusive?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Is the patient White/Caucasian or Black/African-American only (not both)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Was the patient born in the continental U.S., Alaska, or Hawaii?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Is the patient genotype 1 (include mixed with genotype 1)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Does the patient have serum HCV quantifiable at > 600 IU (Roche HCV Monitor)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. Has the patient had a liver biopsy confirming diagnosis within the past 18 months and confirmed by study pathologist or meets exception criteria? Date ____/____/____ mm dd yy <b>Exception:</b> cirrhosis on biopsy performed more than 18 months ago, tissue available, and diagnosis confirmed by the study pathologist.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. Does the patient have an AFP value that is <100 ng/ml <b>OR</b> have an abdominal ultrasound, CT scan, or MRI scan without evidence of HCC within 6 months of the Screen 1 visit for patients with an AFP between 100 and 500 ng/ml or patients with cirrhosis or transition to cirrhosis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No or N/A
8. Does the patient use or be willing to use 2 reliable birth control methods?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9. Did the patient provide informed consent for study participation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9.1 Did pt. provide informed consent for the genetic study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9.1.1 If yes, did pt. provide consent to sample storage?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**SECTION II: EXCLUSION CRITERIA**

1. Has the patient ever received interferon or ribavirin?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Has the patient received a solid organ or bone marrow transplant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Is the patient pregnant (or partner pregnant), breastfeeding, or planning pregnancy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No or N/A
4. Does the patient consume more than 2 alcoholic drinks (>20 grams) per day or have evidence of alcohol abuse within the past 6 months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Has the patient abused drugs within the past 6 months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. Is the patient HBsAg positive (within the past 12 months)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. Is the patient anti-HIV positive at screening?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8. Does the patient have a history of other chronic liver disease including metabolic diseases documented by appropriate tests?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9. Does the patient have a history of immunological mediated disease? (e.g. inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune hemolytic anemia, severe psoriasis, rheumatoid arthritis)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**SECTION II: EXCLUSION CRITERIA (cont'd)**

10. Does the patient have the following at screening:	
a. serum creatinine level >1.5 times the upper limit of normal, creatinine clearance <75 cc/min, or currently on dialysis?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. neutrophil count <1000 cells/mm <sup>3</sup> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. hemoglobin <11 g/dl in females or < 12 g/dl in males?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. platelet count <75,000 cells/mm <sup>3</sup> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. albumin <3 g/dl	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. direct bilirubin >1.0 mg/dl	<input type="checkbox"/> Yes <input type="checkbox"/> No
g. PT or INR > 1.5 times normal	<input type="checkbox"/> Yes <input type="checkbox"/> No
h. history or evidence of ascites	<input type="checkbox"/> Yes <input type="checkbox"/> No
i. history or evidence of hepatic encephalopathy	<input type="checkbox"/> Yes <input type="checkbox"/> No
j. history or evidence of bleeding from esophageal varices	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Does the patient have a history of coronary artery or cardiovascular disease or a baseline increased risk for anemia, or a condition that makes anemia medically problematic?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Does the patient have a history of a severe seizure disorder or current anticonvulsant use for control of seizures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Does the patient have a history of poorly controlled thyroid disease on prescribed medication?	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Does the patient have a history or other evidence of retinopathy on physical exam? (history or fundoscopic evidence of retinal hemorrhage, retinal artery obstruction, retinal vein obstruction, cotton-wool spots)	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. Does the patient have a current (within the past 6 months) severe psychiatric disorder such as depression, schizophrenia, bipolar illness, obsessive-compulsive disorder, severe anxiety, or personality disorder?	<input type="checkbox"/> Yes <input type="checkbox"/> No
16. Within the past five years has the patient attempted suicide, been involuntarily hospitalized for psychiatric disease, or had a period of disability or impairment due to a psychiatric disease?	<input type="checkbox"/> Yes <input type="checkbox"/> No
17. Does the patient have a history of chronic use of oral steroids?	<input type="checkbox"/> Yes <input type="checkbox"/> No
18. Does the patient have a history or other evidence of severe illness or any other condition that would make the patient, in the opinion of the investigator, unsuitable for the study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
IF YES <span style="border: 1px solid black; padding: 2px;">18.1 Specify reason_____</span>	

*If the responses to all inclusion criteria are YES (except genetic study consent) and all exclusion criteria are NO, the patient is eligible to participate in the Virahep-C study.*