SCREENING CRITERIA FORM (SC)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	The screening criteria form lists all the inclusion/exclusion criteria that determine the patient's eligibility for the study. This form should be completed anytime between the Screen 1 and Screen 2 visits but must be completed prior to the completion of any patient questionnaires at the Screen 2 evaluation. Once the patient has been determined to be eligible, the Screen 2 questionnaires can be completed.
PATIENT ID	Record the Patient ID number on the cover page and in the top right hand corner of each page.
TIME POINT	Check 'Screen' to indicate the initial Screening Criteria form. If the patient is completing the entire screening evaluation for a second time, check 'Re-screen'.
DATE OF EVALUATION	Record the date (month/day/year) that the Screening Criteria form is completed. This date is when all inclusion and exclusion criteria have been determined and patient eligibility is established.
INCLUSION CRITERIA	**GENERAL INSTRUCTIONS:** Section I, questions 1-9: Check "Yes" or "No" to indicate if the patient meets the following inclusion criteria. The response to all inclusion criteria must be YES (except for genetic consent) for a patient to be eligible for participation in Virahep-C. **SPECIFIC INSTRUCTIONS:** Age: Check "Yes" if the patient is between 18 and 70 years of age inclusive. Race: Check "Yes" if the patient self-identifies his/her race as White/Caucasian or Black/African-American only and does not indicate both or any other race (Asian, American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, or other). Born in continental U.S., Alaska, or Hawaii: Check "Yes" if the patient was born in the continental U.S., Alaska, or Hawaii. Genotype 1: Check "Yes" if the patient is genotype 1. Include mixed genotypes with genotype 1 (e.g. 1a&1b or 1&2). HCV quantifiable: Check "Yes" if the patient's serum HCV is quantifiable at 600 IU by the Roche HCV Monitor test. Liver Biopsy: (1) Check "Yes" if: (a) The patient has had a liver biopsy confirming chronic hepatitis C in the past 18 months and the result was confirmed by the study pathologist. OR (b) The patient had cirrhosis on a biopsy performed more than 18 months ago, tissue is available, and the diagnosis is confirmed by the study pathologist. Cirrhosis is defined as an Ishak Score 5-6.

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	(2) If yes, record the month, day, and year of the most recent liver biopsy that confirms the diagnosis of chronic hepatitis C. (3) If the patient does not have a confirmatory biopsy within the past 12 months and cirrhosis was not found on an earlier biopsy, the patient must have a biopsy performed to determine eligibility. Alpha fetoprotein: Check 'Yes' if (1) Alpha fetoprotein is < 100 ng/ml **OR** (2) The patient has had an abdominal ultrasound, CT scan, or MRI scan without evidence of hepatocellular carcinoma within 6 months of the Screen 1 evaluation for patients with patients with an AFP between 100 and 500 ng/ml or patients with cirrhosis or transition to cirrhosis. The AFP level must be stable (within 50ng/ml) or decreasing on repeat testing before enrollment Birth control: Check "Yes" if the patient agrees to use two forms of reliable birth control methods. Forms of reliable birth control include, hormonal (oral, implants, injections), condoms, diaphragm, cervical cap, and IUD. Also check "Yes" for patients who are abstinent, have had tubal ligation or vasectomy, or are menopausal. Study consent: Check "Yes" if the patient provided informed consent for participation in Virahep-C. Genetic study consent: (1) Check "Yes" if the patient provided informed consent for participation in the genetic ancillary study. Consent for the genetic study is not an eligibility requirement for the Virahep-C study. Refusal does not make a patient ineligible for study participation. (2) If yes, check "Yes" if the patient provided consent to indefinite storage of samples. If the patient provided consent to *testing only* check "No".
EXCLUSION CRITERIA	**GENERAL INSTRUCTIONS:** Section II, questions1-18: Check "Yes" or "No" to indicate if the patient meets the following exclusion criteria. The response to all exclusion criteria must be NO for a patient to be eligible for participation in this study. **SPECIFIC INSTRUCTIONS:** Ever received Interferon or Ribavirin: Check "Yes" if the patient has ever received interferon or ribavirin treatment for liver disease or any other disease. Check "No" if the patient has never been treated with interferon or ribavirin. Solid organ or bone marrow transplant: Check "Yes" if the patient has received a solid organ or bone marrow transplant. Pregnancy: Check "Yes" if the patient or patient's partner is pregnant, contemplating pregnancy, or breastfeeding. Alcohol: Check "Yes" if the patient has had more than 2 drinks (>20g) per day or has evidence of alcohol abuse within the past 6 months.

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	Drug abuse: Defined as abuse of recreational drugs or non-prescribed controlled substances within the past 6 months. Check "Yes" if the patient has abused drugs within the past 6 months. HBsAg positive: Check "Yes" if the patient has a positive result within the past 12 months. Anti-HIV positive: Check "Yes" if the patient has a positive result from the test completed at the Screen 1 visit. Chronic liver disease: Check "Yes" if the patient has had a history of other chronic liver diseases including (but not limited to) alcoholic liver disease, autoimmune or other hepatitis, hemochromatosis, or Wilson's disease as determined by liver function blood tests. Immunological mediated disease: Check "Yes" if the patient has a history of immunological mediated disease including (but not limited to) inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune hemolytic anemia, severe psoriasis, and rheumatoid arthritis. Question 10: Refer to the laboratory tests clinical evaluation performed at the Screen 1 evaluation. Evaluate each one individually and check "Yes" if: a. Serum creatinine levels > 1.5 times the upper limit of normal, the creatinine clearance <75 cc/min, or currently on dialysis. b. Neutrophil count <1000 cells/mm3. c. Hemoglobin <11g/dl in females or <12 g/dl in males. d. Platelet count <75,000 cells/mm3. e. Albumin <3 g/dl. f. Direct bilirubin >1.0 mg/dl. g. Prothrombin time or INR **>** 1.5 times the upper limit of normal. h. The patient has a history or evidence of ascites. Defined as an excess of fluid in the peritoneal cavity. i. The patient has a history or evidence of hepatic encephalopathy. Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. Symptoms include changes in mental state, consciousness, behavior and personality, decrease in performance of simple self-care tasks, and muscle spasms or rigidity. Also known as portal-systemic encephalopathy. j. The patient has a history or evidence of bleeding from esophageal varices. Defined as GI bleeding from varices present in the esophagus and/or stomach. Symptoms include vomiting or vomiting blood and black, tarry stools.

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	Cardiovascular or coronary heart disease or baseline increased risk of anemia: Check "Yes" if: (1) The patient has ever been told by a physician that they have any form of cardiovascular or coronary heart disease or (2) An acute decrease in hemoglobin by up to 4 g/dl which would not be well-tolerated or (3) The patient has a baseline increased risk of anemia such as thalassemia, spherocytosis, history of GI bleeding, or a condition that for whom anemia would be medically problematic. Seizure disorder: Check "Yes" if the patient has had a history of severe seizure disorder or is currently taking an anticonvulsant for control of seizures. Thyroid disease: Check "Yes" if the patient has a history of poorly controlled thyroid disease on prescribed medication. Retinopathy: Check "Yes" if by physical exam the patient shows fundoscopic evidence of retinal hemorrhage, retinal artery obstruction, retinal vein obstruction, or cotton-wool spots. Psychiatric disease: Check "Yes" if the patient has a current (within the past 6 months) severe psychiatric disorder which includes depression, schizophrenia, bipolar illness, obsessive-compulsive disorder, severe anxiety, or personality disorder. Suicide/involuntary hospitalization: Check "Yes" if the patient has attempted suicide, has been involuntarily hospitalized for psychiatric disease within the past five years, or had a period of disability or impairment due to a psychiatric disease within the past 5 years. Oral steroids: Check "Yes" if the patient has a history of chronic use of oral steroids. Other condition in the opinion of the investigator: Check "Yes" if the investigator feels that due to some other severe illness or condition the patient is not suitable for study participation. If yes, specify the reason that was given by the investigator.
ELIGIBILITY	If the responses to all inclusion criteria are YES (except genetic consent) and all exclusion criteria are NO, the patient is eligible to participate in the Virahep-C study. The response to all inclusion criteria should be YES and all exclusion criteria should be NO for the patient to be eligible for participation in Virahep-C. Exception: consent for the genetic ancillary study is not a requirement for study participation. If the above criteria are not met, the patient is not eligible for participation and no other study-related tests should be performed or data collection forms completed.