SCREENING EVALUATION FORM (SE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	The Screening Evaluation Form should be completed on all potentially eligible patients at the Screen 1 visit. If a patient is known to be ineligible based on basic prescreen criteria (i.e. race, age, transplant recipient, previous treatment, and genotype), the Screening Evaluation form should not 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 Screen 1 visit. 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) of the Screen 1 visit.
DEMOGRAPHICS	**GENERAL INSTRUCTIONS:** Section I, questions 1-5: Transcribe gender, date of birth, ethnicity, race, and country of birth from the Screening Demographic Form that was completed by the patient. **SPECIFIC INSTRUCTIONS:** Gender: Record if the patient is male or female. Date of birth: Record the month, day, and year of the patient's birth. If any part of the birth date is unknown, record "Unk" in that field and complete the remaining fields. Hispanic, Latino, or Latina: Defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. (1) Check "Yes" if the patient identifies himself/herself as Hispanic, Latino, or Latina. If not, check "No". (2) If Yes, mark the appropriate box that specifies origin. (3) If origin is not Cuban, Mexican, or Puerto Rican mark "Other" and write in the place of origin. Race: Check the appropriate box to indicate the race of the patient. If the patient identifies with more than one race, check all that apply. White or Caucasian: A person having origins in any of the original peoples of Europe, the Middle East, or North America. Black or African-American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African-American".

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	Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment. Native Hawaiian or Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Other: Check this box if the patient's racial background is not listed and specify in the space provided. *If the patient identifies a race other than White/Caucasian only or Black/African-American only the patient is not eligible to participate in this study. The screening evaluation should be discontinued and the remainder of the form should not be completed.* Country of patient's birth: Check "Continental U.S., Alaska, or Hawaii" if the patient was born within the 48 continental states, Alaska or Hawaii. This does not include U.S. territories. If not, check "Other" and specify the country. *If the patient was not born in the Continental U.S., Alaska, or Hawaii, the patient is not eligible to participate in this study. The screening evaluation should be discontinued and the remainder of the form should not be completed.*
LIVER HISTORY	**GENERAL INSTRUCTIONS:** Section II, questions 1-4: Check "Yes", "No", or "Unk" (unknown) to indicate whether the patient has or had the condition. **SPECIFIC INSTUCTIONS:** 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. Check "Yes" if the patient has a history of, or currently has, hepatic encephalopathy. Variceal hemorrhage: Defined as GI bleeding from varices present in the esophagus and/or stomach. Symptoms include vomiting or vomiting blood and black, tarry stools. Check "Yes" if the patient has a history of, or currently has, variceal hemorrhage.

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	Ascites: Defined as an excess of fluid in the peritoneal cavity. Check "Yes" if the patient has a history of, or currently has, ascites. Jaundice: Defined as the presence of bile pigment in the skin, mucous membrane, and sclera. There is a yellow discoloring of the skin, mucous membranes, and eyes. Check "Yes" if the patient currently has jaundice. *If the response to any of the above liver conditions is "Yes", the patient is not eligible to participate in this study. The screening evaluation should be discontinued and the remainder of the form should not be completed.*
MEDICAL HISTORY	**GENERAL INSTRUCTIONS:** Section III, questions 1-4: (1) Check the response that best indicates if the patient has the condition. If the patient has the condition, check the box that indicates the current treatment regimen. (2) Check the response(s) to indicate the medications or supplements that the patient is currently taking and specify the type of medication/supplement if required. **SPECIFIC INSTRUCTIONS:** Diabetes: (1) Check "Yes" if the patient has been told by a doctor that he/she has diabetes. If not, check "No". (2) If yes, check the current treatment being used. None: No treatment regimen is currently being followed Diet: Controlled by dietary management alone Oral: Controlled by oral medications Insulin: Controlled by insulin Hypertension: (1) Check "Yes" if the patient has been told by a doctor that he/she has high blood pressure or hypertension. If not, check "No". (2) If yes, check all the current treatment(s) that apply. None: No treatment regimen is currently being followed. Diet: Controlled by dietary management. ACE inhibitors: Agents that inhibit the circulating and tissue angiotensin-converting enzyme activity, thereby reducing angiotensin II formation. Beta-blockers: Agents that compete with epinephrine for beta-adrenergic receptor sites, reduce heart rate, and lower blood pressure. Calcium channel blockers: Agents that inhibit the transmembrane influx of calcium ions into cardiac muscle and smooth muscle.

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	Diuretics: Agents that cause the body to excrete water and salt and increase urine output. Vasodilators: Agents that widen blood vessels. These are often used in combination with other antihypertensive medications. Other: If yes to other, record the category of the antihypertensive medication. Medications: Check all categories of medication that the patient is currently taking. Lipid-lowering agents: Medications to control cholesterol or triglycerides. Categories include but are not limited to statins, antilipemic, bile acid sequesterants, nicotinic acid, fibrates, and triglyceride-lowering agents. If yes, check if the medication is a statin or other. If other, specify category. Gastro-intestinal medications: Including but not limited to histamine receptor antagonists, proton pump inhibitors, medications for irritable bowel syndrome, or inflammatory bowel disease. If yes, check if the medication is a histamine receptor antagonist, proton pump inhibitor, or other. If other, specify category. Antidepressant medications: Any medications to treat depression. These include (but are not limited to) Tricyclic antidepressants, SSRI, Wellbutrin, and MAO inhibitors. Anxiolytic medications: Any medications to treat anxiety disorders. These include (but are not limited to) tricyclic antidepressants, SSRI, MAO inhibitors, and benzodiazepines. Antipsychotic medications: Any medications to treat psychosis. These include (but are not limited to) Haldol, Risperdal, phenothiazines, and combinations. Respiratory agents: Any respiratory medications. These include (but are not limited to) beta-adrenergic inhalers, steroid inhalers, and oral medications. Thyroid medications: Any medications to treat thyroid disease. These include (but are not limited to) antithyroid agents, and synthetic T3 or T4 products. Methadone: Currently methadone use.

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	Herbal supplements: (1) Check "Yes" if the patient is currently taking any herbal supplements for treatment of chronic hepatitis C. If not, check "No". (2) If yes, record the code(s) that indicate the type of herbal supplement the patient is taking for chronic hepatitis C. If the list does not contain the herbal supplement, contact the Coordinating Center so that a code may be assigned.
SYMPTOMS	**GENERAL INSTRUCTIONS:** Section IV, questions 1-25: Check "Yes" or "No" to indicate whether the patient currently has the symptom. Currently is within 48 hours of evaluation. **SPECIFIC INSTRUCTIONS**: Fatigue: Defined as a lack of energy or weariness or chronically tired. Characterized as prolonged weakness or tiredness that is not relieved by adequate rest, sleep or by the removal of other stressful factors. The patient may feel rested but with daily activity feel tired or feel tired after awakening and throughout the day. Weakness: Defined as a reduction in the strength or the feeling of the loss of strength of one or more muscles. The patient may feel that extra effort is required to move the muscles of the body. Nausea: Defined as the sensation leading to the urge to vomit. Vomiting: Defined as forcing the contents of the stomach through the esophagus and out of the mouth. Poor appetite: Defined as a lack of appetite although there is a physical need for food. This may lead to unintentional weight loss. Weight loss: Defined as any unintentional loss in weight. Muscle aches: Defined as any pain in the muscles. Do not include pain that is due to recent overuse or exercise. Joint aches: Characterized as pain or stiffness in one or more joints. Headache: Defined as pain in the head from any cause. Pain over liver: Pain in the upper right section of the abdomen. Other abdominal pain: Defined as pain in the abdominal area, stomach region, or belly. May also be referred to as stomach pain, belly ache, or abdominal cramps. Rash: Defined as an eruption or change in color or texture of the skin. Symptoms are skin redness or inflammation and skin lesions. Itching: Defined as a peculiar tingling or uneasy irritation of the skin which causes a desire to scratch the affected part.

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	Hair loss: Defined as partial or complete loss of hair. Do not include hair loss due to pattern baldness, heredity, or aging. Fever: Defined as a body temperature of 100 degrees Fahrenheit or above. Chills: Defined as the sensation of cold from exposure to a cold environment, or an episode of shivering with paleness and a feeling of coldness. Night sweats: Defined as periodic sweating at night while sleeping without an obvious cause. Cough: Defined as the sudden forceful release of air from the lungs. Shortness of breath: Defined as difficult or uncomfortable breathing or a feeling of not getting enough air. Irritability: Defined as abnormal or excessive response to slight or harmless stimuli. Trouble sleeping: Defined as the inability to sleep, remain asleep throughout the night or feel refreshed by sleep. Difficulty concentrating: Defined as a lack of focus, ability to maintain attention on tasks, or a feeling of being easily distracted. Depression: Defined as having extreme feelings of sadness, dejection, lack of worth, and emptiness. There may be a loss of sense of pleasure in normal activities, decreased energy, change in sleeping habits, and feelings of hopelessness. Clinical definition of depression is the presence of these symptoms for at least a two week period. Diarrhea: Defined as frequent or loose bowel movements of unformed, watery stools. Constipation: Defined as infrequent or hard stools, or difficulty passing stools. Other: Any side effect that is not listed above. If yes, record the side effect(s).
DEPRESSION MANAGEMENT	**GENERAL INSTRUCTIONS:** For Section V, questions 1-3: Ask the patient the following questions regarding any depressive symptoms the patient may have currently. Check “Yes” or “No” to indicate the patient’s response. If the patient responds “Yes” to any of the questions, notify the Principal Investigator.

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PHYSICAL EXAM	**GENERAL INSTRUCTIONS:** Section VI, questions 1-6: Check "Yes" or "No" to indicate whether the patient currently has the following medical conditions. **SPECIFIC INSTRUCTIONS:** Height: Record the patient's height in inches at the time of evaluation. Weight: Record the patient's weight in pounds at the time of evaluation. Temperature: Record the patient's body temperature in degrees Fahrenheit at the time of the evaluation. Heart rate: Record the patient's number of heart beats per minute at the time of the evaluation. Hip: Record the patient's hip circumference in inches at the time of the evaluation. Waist: Record the patient's waist circumference in inches at the time of the evaluation. Blood pressure: Record the patient's systolic and diastolic blood pressure in mmHg at the time of evaluation. Muscle wasting: Defined as the loss of muscle tissue due to disease or lack of use. Consider a loss of muscle mass due to poor nutrition only (do not include other conditions such as paralysis). Spider angiomata: Defined as a group of abnormal blood vessel that produces the appearance of a spider-web on the surface of the skin. Spider angiomata typically look like a red dot in the center with reddish extensions radiating out for some distance around it (a few millimeters to a centimeter or more) and are most common on the face and trunk. Spider angiomata tend to be common in pregnant women and patients with liver disease. Pedal edema: Defined as an excessive build-up of fluid in the feet, causing swelling. Enlarged liver: Also known as hepatomegaly. Defined as enlargement of the liver beyond its normal size. An indication of enlarged liver is that the liver can be palpated below the costal margin (lower edge of ribs). Tender liver: Defined as discomfort or pain during palpation below the costal margin (lower edge of ribs). Spleen enlargement: Also known as splenomegaly. Defined as the enlargement of the spleen beyond its normal size.

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SEROLOGIES	**GENERAL INSTRUCTIONS:** Section VII, questions 1-6: (1) Check whether the result of each serology test is positive or negative. (2) Record the month, day, and year that the sample was taken. (3) If any of the tests are not completed, check "Not done". **SPECIFIC INSTRUCTIONS:** Anti-HAV: Must have been performed within the past 12 months. If results are not available within the past 12 months, test must be completed at Screen 1 evaluation. Anti-HBs: Must have been performed within the past 12 months. If results are not available within the past 12 months, test must be completed at Screen 1 evaluation. HBsAg: Must have been performed within the past 12 months. If results are not available within the past 12 months, test must be completed at Screen 1 evaluation. Anti-HBc: Must have been performed within the past 12 months. If results are not available within the past 12 months, test must be completed at Screen 1 evaluation. Anti-HIV: Test is to be completed at the time of the Screen 1 evaluation. Anti-HCV: Test is to be completed at the time of the Screen 1 evaluation.
SCREENING LABS	**GENERAL INSTRUCTIONS:** Section VIII, questions 1-8: Record the results in the specified units. If the test is not completed, check "Not done". **SPECIFIC INSTRUCTIONS:** Labs 1-2: These tests are to be completed at the Screen 1 evaluation. Labs 3-6: These tests are to have been completed within the past 12 months. If not, complete these tests at the Screen 1 evaluation. ANA: (1) Check if positive or negative. (2) If positive, record the titer. Labs 7-8: These tests are to have been completed at any time prior to the screening evaluation. If not, complete these tests at the Screen 1 evaluation.
COMMENTS	Section IX: Check whether there are comments regarding the screening evaluation. If yes, record your comments in the space provided. When referring to a specific item on the form, record the section and question number with the comment.