TREATMENT VISITS

Treatment evaluations occur at Treatment days 7, 14, and 28 and at Treatment weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48 or at the time of premature discontinuation of treatment. Patient and treatment information are obtained at each visit using the Treatment Evaluation (TE) form which includes an interim physical exam and symptoms, concomitant medications, and a study medication adherence section.

In addition to the Treatment Evaluation form, data will be collected from MEMS caps and patient self-administered questionnaires.

Laboratory tests are to be performed and results recorded on the Laboratory Evaluation (LE) form.

Biospecimens for ancillary studies and repository will be collected.

To be completed by coordinator at each visit

1. Treatment Evaluation (TE) form
2. Laboratory tests – see Laboratory Evaluation (LE) form
3. Biospecimen collection for ancillary studies and repository
4. Patient adherence

	Day 28	Treatment week										
		8	12	16	20	24	28	32	36	40	44	48
Brief MATI checklist	X		X		X		X		X			
MEMS cap data (electronic)	X	X	X	X	X	X	X	X	X	X	X	X

To be completed by patient at each visit

	Treatment day			Treatment week									
	7	14	28	8	12	16	20	24	28	32	36	40	44	48
Symptom Assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MEMS Questionnaire			X	X	X	X	X	X	X	X	X	X	X	X
Adherence Questionnaire			X		X			X			X			X
CES-D			X		X			X						X
Sexual Functioning			X		X			X						X

If at Week 24 the patient is determined to be a non-responder or at any time during the treatment period there is a premature discontinuation of study medications, the patient will move into the follow-up phase and be followed for 24 weeks.

If the patient is a non-responder, complete all forms and procedures required at Week 24.

If the patient prematurely discontinues study medications during the treatment period, all forms and procedures required at Week 48 must be completed at the time of study medication discontinuation

TREATMENT EVALUATION (TE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	The Treatment Evaluation (TE) form should be completed at: Treatment day 7, 14, and 28 and Treatment weeks 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48 or at the time of premature discontinuation of study medications.
PATIENT ID	Record the Patient ID number on the cover page and in the top right hand corner of page 1.
TIME POINT	Record the time point of the current evaluation on the cover page. Premature discontinuation: Treatment is discontinued prior to 48 weeks other than for those determined to be non-responders at treatment week 24. All forms required at treatment week 48 must be completed at the time that study medication is discontinued.
DATE OF EVALUATION	Record the date (month/day/year) on which the patient was evaluated. Adverse event: (1) Check "Yes" if the patient has had an adverse event since the previous treatment evaluation. If not, check "No". (2) If yes, complete an adverse event form. (3) Serious adverse event: (a) Check "Yes" if the patient has had a serious adverse event since the previous treatment evaluation. If not, check "No". (b) If yes, complete an adverse event form and a MEDWATCH form. **The MEDWATCH form must be returned to the Coordinating Center within 24 hours of knowledge of the event.**
PHYSICAL EXAM	**SPECIFIC INSTRUCTIONS:** 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. Blood pressure: Record the patient's systolic and diastolic blood pressure in mmHg at the time of evaluation.
SYMPTOMS	**GENERAL INSTRUCTIONS:** Section II, questions 1-10: Check "Yes" or "No" to indicate if the patient had the following symptoms since the last evaluation.

	SPECIFIC INSTRUCTIONS: Fatigue: Defined as a lack of energy or weariness or chronically tired, *in the absence of other flu-like symptoms*. 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. Trouble sleeping: Defined as the inability to sleep, remain asleep throughout the night or feel refreshed by sleep. Irritability: Defined as abnormal or excessive response to slight or harmless stimuli. Hair loss: Defined as partial or complete loss of hair. Do not include hair loss due to pattern baldness, heredity, or aging. 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. Weight loss: Defined as any unintentional loss in weight. Flu-like symptoms: These may include but are not limited to fever, **cough**, **headache**, **muscle aches**, chills, sweating, **fatigue**, congestion, sore throat, **nausea**, **diarrhea**, and **loss of appetite**. GI symptoms: Including but not limited to abdominal pain, **nausea**, **diarrhea**, vomiting, and **loss of appetite** *in the absence of other flu-like symptoms*. Injection site reaction: Any redness, inflammation, or **itchiness** around the injection site area. Rash: Defined as an eruption or change in color or texture of the skin. Symptoms are skin redness or inflammation and skin lesions. Joint aches: Characterized as pain or stiffness in one or more joints, *in the absence of other flu-like symptoms*. Respiratory symptoms: Including but not limited to **cough**, shortness of breath, difficulty breathing, or abnormal breathing, *in the absence of other flu-like symptoms*. **Muscle aches**: Defined as any pain in the muscles, *in the absence of other flu-like symptoms*. Do not include pain that is due to recent overuse or exercise. **Headache**: Defined as pain in the head from any cause, *in the absence of other flu-like symptoms*.

	Itching: Defined as a peculiar tingling or uneasy irritation of the skin which causes a desire to scratch the affected part, *other than injection site reactions*. Other: Any side effect that is not listed above. If yes, record the side effect(s).
CONCOMITANT MEDICATIONS	**GENERAL INSTRUCTIONS:** Section III, questions 1-5: Check "Yes" or "No" to indicate if the patient is currently taking the following medications. **SPECIFIC INSTRUCTIONS:** Antidepressant medications: Any medications to treat depression including (but not limited to) Tricyclic antidepressants, SSRI, Wellbutrin, and MAO inhibitors. Respiratory agents: Any respiratory medications including (but not limited to) beta-adrenergic inhalers, steroid inhalers, and oral medications. Thyroid medications: Any medications for thyroid diseases including (but not limited to) antithyroid agents, and synthetic T3 or T4 products. Growth Factor: Any prescribed medications for the treatment of anemia, neutropenia, or thrombocytopenia. If yes, complete the Growth Factor form. Herbal supplements: Any current use of herbal supplements for the treatment of chronic hepatitis C. If yes, record the code(s) to indicate which herbal supplements the patient is taking for chronic hepatitis C.
DEPRESSION MANAGEMENT	**GENERAL INSTRUCTIONS:** For Section IV, questions 1-3: Ask the patient the following questions regarding any depressive symptoms the patient may have since the last evaluation. Check "Yes" or "No" to indicate the patient's response. If the patient responds "Yes" to any of the questions, notify the Principal Investigator.
MEDICATION AND ADHERENCE	**GENERAL INSTRUCTIONS:** From Baseline through Treatment Day 28 the blood sample must be collected prior to the administration of the peg-interferon dose. During this same 28 day period, the ribavirin and peg-interferon must be taken at the same time of day, based on the time of the initial dose at the Baseline evaluation.

	SPECIFIC INSTRUCTIONS: Change in dose or timing: Defined as a change in dose or timing as prescribed by the physician. A missed dose or an isolated interruption in the treatment schedule on the part of the patient should not be counted as a change in dose or timing. (1) Check "Yes" if there has been a prescribed change in dose or timing since the previous evaluation. If not, check "No". (2) If yes, complete the Dose Change form (DC). Most recent dose: Record the date (month/day/year) and time of the most recent dose of ribavirin and interferon taken prior to this evaluation.
COMMENTS	Section VI: Check whether there are comments regarding the treatment evaluation. If yes, write your comments in the area provided. When referring to a specific item on the form, record the section and question number with the comment.