FOLLOW-UP VISITS

Follow-up evaluations occur at Follow-up weeks 4, 12, 24, 36, and 48 for responders and at weeks 4, 12, and 24 for non-responders or patients who had a premature discontinuation of study medication. Patient and follow-up information will be obtained at each of the specific visits using the Follow-up Evaluation (FE) form which includes interim physical exam and symptoms, and concomitant medications.

In addition to the Follow-up Evaluation form, data will be collected from patient self-administered questionnaires.

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

Sample collection for ancillary studies will also be completed.

To be completed by coordinator:
1. Follow-up Evaluation (FE) form
2. Laboratory tests – see Laboratory Evaluation (LE) form.
3. Sample collection for ancillary studies

To be completed by patient:

	Follow-Up Week			
	4	12	24	48
Symptom Assessment	X	X	X	X
CES-D			X	
Quality of Life			X	
Sexual Functioning			X	

If a patient prematurely discontinues follow-up prior to Follow-up week 24, complete all forms required at Follow-up week 24. If a patient discontinues follow-up after Follow-up week 24, complete all forms required at Follow-up week 48.

FOLLOW-UP EVALUATION FORM (FE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	The Follow-up Evaluation Form is completed at all follow-up visits. Follow-up evaluations for responders occur at Follow-up weeks 4, 12, 24, 36, and 48. For non-responders or patients who had a premature discontinuation of study medications, follow-up visits occur at Follow-up weeks 4, 12, and 24.
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. Premature discontinuation: Patient discontinues study participation during Follow-up. If a patient discontinues prior to Follow-up week 24, complete all forms required at Follow-up week 24. If patient discontinues after Follow-up week 24, complete all forms required at Follow-up week 48.
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 INSTUCTIONS:** Section II, questions 1-10 Check "Yes" or "No" to indicate if the patient had the following symptoms since the last evaluation.

DATA SECTION	COMPLETION INSTRUCTIONS
	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*. 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*.

DATA SECTION	COMPLETION INSTRUCTIONS
	Other: Any side effect that is not listed above. If yes, record the side effect(s).
CONCOMITANT MEDICATIONS	**GENERAL INSTRUCTIONS:** Section III, questions 1-6: 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. Chronic hepatitis C medications: Any prescribed medication(s) for treatment of chronic hepatitis C. 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.
COMMENTS	Section V: If there are any comments regarding the follow-up evaluation, check "Yes" and 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.
STUDY MEDICATION	Last dose: Follow-up Week 4 or Premature Discontinuation of Follow-up prior to Week 4 ONLY: Record the date (month/day/year) and time of the last dose of ribavirin and interferon taken from the study medication vials.