

## **UNSCHEDULED VISITS**

If a patient returns to the clinic for a visit outside of the protocol evaluation time points, the Unscheduled Visit Evaluation (UE) form should be completed. One Unscheduled Visit Evaluation form should be completed for each patient evaluation that is performed outside of the scheduled protocol evaluations.

If laboratory tests are performed, the Laboratory Evaluation (LE) form should be completed.

If the visit is due to an adverse event, the Adverse Event (AE) form must be completed.

If the visit is due to a serious adverse event, the following additional forms must be completed:

1. Adverse Event (AE) form
2. MEDWATCH Form, this form must be completed and reported to the Coordinating Center within 24 hours of knowledge of the event.

**UNSCHEDULED VISIT EVALUATION FORM (UE)**

<b>DATA SECTION</b>	<b>COMPLETION INSTRUCTIONS</b>
<b>GENERAL INFORMATION</b>	<p>The Unscheduled Evaluation (UE) Form should be completed when the patient is seen at an unscheduled visit. An unscheduled visit is defined as any visit to the clinical center outside of the protocol evaluation time points, where the patient is seen by Virahep-C study personnel. This form does not have to be completed for hospital admissions or other physician visits when the patient is not seen by Virahep-C study personnel.</p> <p>If the visit is due to a serious adverse event, the Adverse Event Form (AE) and MEDWATCH Form (if necessary) should also be completed. If laboratory tests are performed, a Laboratory Evaluation Form (LE) should be completed.</p> <p>PATIENT ID: Record the Patient ID number on the cover page and in the top right hand corner of page 1.</p> <p>DATE OF EVALUATION: Record the date (month/day/year) of the unscheduled evaluation.</p> <p><u>Reason for visit:</u> Check the box that indicates the reason for the Unscheduled Visit.</p> <p style="padding-left: 40px;"><u>Adverse event:</u> (1) Check if the reason for the unscheduled visit is an adverse event. (2) If yes, complete an adverse event form.</p> <p style="padding-left: 40px;"><u>Serious adverse event:</u> (1) Check if the reason for the unscheduled visit is a serious adverse event. (2) If yes, complete an adverse event form and a MEDWATCH form. <b>The MEDWATCH form must be reported to the Coordinating Center within 24 hours of knowledge of the event.</b></p> <p style="padding-left: 40px;"><u>Lab abnormality:</u> Check if the reason for the unscheduled visit is a lab abnormality that is not considered an adverse event or a serious adverse event.</p> <p style="padding-left: 40px;"><u>Other side effect:</u> Check if the reason for the unscheduled visit is a side effect potentially related to study medications and the side effect is not considered an adverse event or a serious adverse event.</p> <p style="padding-left: 40px;"><u>Other intercurrent illness:</u> Check if the reason for the unscheduled visit is due to an illness that is unrelated to study medications or hepatitis C. If yes, complete question 2 only and do not complete the remainder of the form.</p> <p><u>Laboratory:</u> (1) Check “Yes” if laboratory tests were completed at this evaluation. If not, check “No”. (2) If yes, complete a Laboratory Evaluation (LE) form.</p>
<b>PHYSICAL EXAM</b>	<p><b>SPECIFIC INSTRUCTIONS:</b></p> <p><u>Weight:</u> Record the patient’s weight in pounds at the time of evaluation.</p>

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SYMPTOMS	<p><u>Temperature</u>: Record the patient's body temperature in degrees Fahrenheit at the time of the evaluation.</p> <p><u>Heart rate</u>: Record the patient's number of heart beats per minute at the time of the evaluation.</p> <p><u>Blood pressure</u>: Record the patient's systolic and diastolic blood pressure in mmHg at the time of evaluation.</p> <p><b>GENERAL INSTRUCTIONS:</b></p> <p><u>Section II, questions 1-10</u>: Check "Yes" or "No" to indicate whether the patient currently has the following symptoms. Currently is within 48 hours of evaluation.</p> <p><b>SPECIFIC INSTRUCTIONS:</b></p> <p><u>Fatigue</u>: Defined as a lack of energy or weariness or chronically tired, <i>in the absence of other flu-like symptoms</i>. 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.</p> <p><u>Trouble sleeping</u>: Defined as the inability to sleep, remain asleep throughout the night or feel refreshed by sleep.</p> <p><u>Irritability</u>: Defined as abnormal or excessive response to slight or harmless stimuli.</p> <p><u>Hair loss</u>: Defined as partial or complete loss of hair. Do not include hair loss due to pattern baldness, heredity, or aging.</p> <p><u>Depression</u>: 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.</p> <p><u>Weight loss</u>: Defined as any unintentional loss in weight.</p> <p><u>Flu-like symptoms</u>: These may include but are not limited to fever, <b>cough, headache, muscle aches</b>, chills, sweating, <b>fatigue</b>, congestion, sore throat, <b>nausea, diarrhea</b>, and <b>loss of appetite</b>.</p> <p><u>GI symptoms</u>: Including but not limited to abdominal pain, <b>nausea, diarrhea</b>, vomiting, and <b>loss of appetite</b> <i>in the absence of other flu-like symptoms</i>.</p> <p><u>Injection site reaction</u>: Any redness, inflammation, or <b>itchiness</b> around the injection site area.</p>

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CONCOMITANT MEDICATIONS	<p><u>Rash</u>: Defined as an eruption or change in color or texture of the skin. Symptoms are skin redness or inflammation and skin lesions.</p> <p><u>Joint aches</u>: Characterized as pain or stiffness in one or more joints, <i>in the absence of other flu-like symptoms</i>.</p> <p><u>Respiratory symptoms</u>: Including but not limited to <b>cough</b>, shortness of breath, difficulty breathing, or abnormal breathing, <i>in the absence of other flu-like symptoms</i>.</p> <p><u>Muscle aches</u>: Defined as any pain in the muscles, <i>in the absence of other flu-like symptoms</i>. Do not include pain that is due to recent overuse or exercise.</p> <p><u>Headache</u>: Defined as pain in the head from any cause, <i>in the absence of other flu-like symptoms</i>.</p> <p><u>Itching</u>: Defined as a peculiar tingling or uneasy irritation of the skin which causes a desire to scratch the affected part, <i>other than injection site reactions</i>.</p> <p><u>Other</u>: Any side effect that is not listed above. If yes, record the side effect(s).</p> <p><b>GENERAL INSTRUCTIONS:</b></p> <p><u>Section III, questions 1-3</u>: Check “Yes” or “No” to indicate if the patient is currently taking the following medications.</p> <p><b>SPECIFIC INSTRUCTIONS:</b></p> <p><u>Antidepressant medications</u>: Any medications to treat depression including (but not limited to) Tricyclic antidepressants, SSRI, Wellbutrin, and MAO inhibitors.</p> <p><u>Respiratory agents</u>: Any respiratory medications including (but not limited to) beta-adrenergic inhalers, steroid inhalers, and oral medications.</p> <p><u>Thyroid medications</u>: Any medications for thyroid diseases including (but not limited to) antithyroid agents, and synthetic T3 or T4 products.</p> <p><u>Growth Factor</u>: Any prescribed medications for the treatment of anemia, neutropenia, or thrombocytopenia. If yes, complete the Growth Factor form.</p> <p><u>Herbal supplements</u>: 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.</p>

<b>DATA SECTION</b>	<b>COMPLETION INSTRUCTIONS</b>
DEPRESSION MANAGEMENT	<p><b>GENERAL INSTRUCTIONS:</b></p> <p><u>For Section IV, questions 1-3:</u> 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.</p>
COMMENTS	<p><u>Section V:</u> If there are any comments regarding the unscheduled visit 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.</p>