

## HALT-C Trial Q x Q

### Serotonin as a Serum Marker of Mood Status – Cognitive Effects AS

Form # 156 Version B: 05/12/2004 (Rev. 09/23/2004)

**Purpose of Form #156:** To record the collection and results of research assays of plasma cortisol and whole blood serotonin in randomized patients, W20 responders, and Breakthrough/Relapsers.

**When to complete Form #156:** This form should be completed only at Site 18 (University of Michigan) as part of the Cognitive Effects of Long-term Peginterferon alfa-2a Ancillary Study.

Form #156 should be completed for the following study visits:

- **Lead-In Phase patients:** Baseline (W00), Week 4 (W04), and Week 24 (W24).
- **W20 Responder Phase patients:** Week 48 (W48) and Week 72 (W72).
- **Breakthrough/Relapser patients:** Randomization visit (R00) if it is more than one month after the most recent Neuropsychiatric Testing (Form #152).
- **Randomized patients:** Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54).

#### **SECTION A: GENERAL INFORMATION**

- A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using the MM/DD/YYYY format
- A5. Enter the initials of the person completing the form.

#### **Patient Preparation**

In order to obtain valid data, it is imperative that patients be properly prepared for sample collection. Patient preparation includes:

1. Instruct patients receiving Pegasys™ to take their medication dose at least **2 days** prior to blood collection.
2. All patients should have blood drawn between 08:00 AM and 10:00 AM.
3. All patients should fast from 12:00 midnight on the evening before blood sample collection.

#### **Sample processing- Whole Blood Serotonin**

1. Draw 10 ml of blood into a purple-topped tube and keep on ice during processing.
2. Mix well 5 times.
3. Aliquot 3 ml of the whole blood into 3 separate screw topped storage tubes and freeze at  $-80^{\circ}$  C within 1 hour of sample collection.

**SECTION B: SAMPLE COLLECTION AND FASTING INFORMATION**

- B1. Record the date when the blood sample was collected using MM/DD/YYYY format.
- B2. Record the time of day when the blood sample was collected. Circle 1 for AM or 2 for PM.
- B3. Record the date when the when the patient reported he or she last ate or drank (other than water) using MM/DD/YYYY format.
- B4. Record the time of day when the patient reported he or she last ate or drank (other than water). Circle 1 for AM or 2 for PM.
- B5. Record the date at which the last dose of Peginterferon alfa-2a was administered in MM/DD/YYYY format.

**SECTION C: ASSAY RESULTS**

Whole blood serotonin levels will be assayed in batches at the University of Michigan and data entered when results become available.

- C1. Record the results of whole blood serotonin levels in nmol/L. The field allows three numbers.

The normal range of whole blood serotonin levels is 010 to 999 nmol/L. If the result falls outside of this range, please verify the result against the source documentation. If the abnormal result is correct, select the override button. Specify that the data was verified and is correct.