HALT-C Trial

Alternative Study Visit

Form # 924 Version B: 10/10/2006

SECTION A: GENERAL INFORMATION

A1. Affix ID Label Here → __ __ - __ __ __ - __

A2. Patient initials: __ __ __

A3. Visit Number M __ __ __

A4. Contact Date: MM / DD / YYYY __ __ / __ __ / __ __ __ __

A5. Initials of person completing form: __ __ __ **Signature required**

A6. Date of last version of consent signed: MM / DD / YYYY __ __ / __ __ / __ __ __ __

IF A PATIENT MISSES A VISIT, IT IS IMPORTANT TO COLLECT DATA ON ANY LIVER RELATED FINDINGS THAT MAY BE AN OUTCOME OF THE STUDY. IT IS ALSO IMPORTANT TO KNOW IF THEY ARE TAKING ANY INTERFERON. USE THIS FORM IF THE PATIENT HAS MISSED TWO CONSECUTIVE RANDOMIZED VISITS.

SECTION B: POTENTIAL SERIOUS ADVERSE EVENTS, CLINICAL OUTCOMES, ULTRASOUND/ MRI/CT AND LIVER BIOPSIES AND ENDOSCOPIES

B1. Was the site able to obtain information on the patient since the last study visit?

Yes ..... 1 **(B2)**

No 2

B1a. Describe briefly why you were unable to obtain information from the patient. **(END OF FORM)**

_____

_____

_____

B2. Since the last study visit was the patient admitted to the hospital overnight for any reason?

Yes ..... 1 (COMPLETE AE FORM #60, AND IF APPLICABLE SAE FORM # 61, OR CLINICAL OUTCOME FORM #63)

No 2

B3. Since the last study visit has the patient had any liver related imaging such as an ultra-sound/MRI/CT which may indicate a possible study outcome?

Yes ..... 1 (COMPLETE FORM #22*, AND IF APPLICABLE SAE FORM # 61, OR CLINICAL OUTCOME FORM #63)

No 2

___ ___ - ___ ___ ___ - ___

B4. Since the last study visit has the patient had a liver biopsy?

Yes..... 1 (COMPLETE BIOPSY FORM # 52*)

No 2

B5. Since the last study visit has the patient had an endoscopy?

Yes..... 1 (COMPLETE ENDOSCOPY FORM # 23*)

No 2

B6. Since the last study visit has the patient had any changes in her/his health that may be considered a clinical outcome (SEE INSERT BELOW)?

Yes..... 1 (COMPLETE CLINICAL OUTCOME FORM #63)

No ..... 2 **(SECTION C)**

Clinical Outcomes

Death from any cause
Development of hepatocellular carcinoma
CTP score of 7 or higher at two consecutive study visits
Variceal hemorrhage
Ascites
Spontaneous bacterial peritonitis
Hepatic encephalopathy

Liver transplant

Development of **presumed** hepatocellular carcinoma

B7. Are you requesting source documentation for a possible clinical outcome?

Yes..... 1 **(SECTION C)**

No 2

B7a. Describe briefly why you are not requesting source documentation.

_____

_____

***IF APPROPRIATE, HAVE THE PATIENT SIGN A MEDICAL RECORD RELEASE FORM.**

__ __ - __ __ __ - __

SECTION C: TRIAL MEDICATION(S)

RECORD WHETHER THE PATIENT IS ON ANY TYPE OF INTERFERON, EITHER PEGASYS FOR HALT-C OR ANY OTHER TYPE OF INTERFERON. RECORD DOSE.

C1. Is the patient currently (within the last 10 days) taking any kind of interferon?

Yes..... 1

No ..... 2 **(END OF FORM)**

C2. Dose of this current Interferon is:

90 mcg 1

180 mcg 2

Other ..... 99 specify: ___ ___ ___ mcg

C3. Type of Interferon preparation currently being taken:

Pegasys® prescribed by HALT-C physician as part of the treatment group.... 1 **(END OF FORM)**

Interferon (any type) prescribed by a physician outside of HALT-C 2

Other.....99

SPECIFY: _____

C4: Start date of interferon currently taken, if not prescribed by HALT-C Trial physician:

(MM / DD / YYYY)__ __ / __ __ / __ __ __ __

REMEMBER TO COMPLETE A DOSE ADJUSTMENT FORM # 28 IF PEGASYS FOR HALT-C TRIAL HAS BEEN STOPPED FOR ANY REASON SINCE PATIENT WAS LAST SEEN.

Signature of Interviewer: _____