Fax this completed form within 24 – 48 hours of hearing of Serious Adverse Event to:

NERI: Margaret C. Bell, RN
Fax: (617) 926-0144
Tel: (617) 923-7747 ext 522

Roche: Cliff Joseph, MD
Fax: (973) 562-3602
Tel: (973) 562-3613

Telephone both parties that fax has been sent.

HALT-C Trial

Serious Adverse Event Report

Form # 61 Version B: 08/20/2001 (Rev. 03/05/2003)

SECTION A: GENERAL INFORMATION **IND #:BB IND 9018 Protocol # NR15963**

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

A2. Patient initials: ____ ____ ____

A3. Event Number (from Form #60, Adverse Event Report): ☐

A4. Initials of person completing form: ____ ____ ____

A5. Date form initially completed (MM/DD/YYYY): ___ ___ / ___ ___ / ___ ___ ___ ___

A6. Date form updated (MM/DD/YYYY): ___ ___ / ___ ___ / ___ ___ ___ ___

A7. Is this the first serious adverse event reported for this patient? Yes.....1
No.....2

SECTION B: PERSONAL DATA (NOT TO BE DATA ENTERED)

B1. Patient's Date of Birth: (MM/DD/YYYY) __ __ / __ __ / __ __ __ __

B2. Patient Gender Male ☐ Female ☐

B3. Patient's Race (Enter code from box below.) __

If other, specify: _____

1. White	4. American Indian or Alaskan Native
2. Black	5. Other (Specify)
3. Asian or Pacific Islander	6. Unknown

B4. Weight: __ __ __.__ kg or __ __ __ lbs

B5. Height: __ __ __ cm or __ __ inches

SECTION C. SERIOUS ADVERSE EVENT (If more than one SAE, complete a separate form)

C1. Type of event: (from Event Code [ICD-9] list) ☐

C2. Brief SERIOUS ADVERSE EVENT description:

_____

_____

C3. Date of onset of this SERIOUS ADVERSE EVENT:(MM/DD/YYYY__ __ / __ __ / __ __ __ __

SECTION D: SERIOUSNESS

D1. Using the code box below, indicate why the event was serious.

(Up to four responses may be chosen.) a. ☐ b. ☐ c. ☐ d. ☐

Seriousness Code List

1. It required intervention to prevent one of the conditions listed below (2-7).
2. It was a congenital anomaly/birth defect.
3. It caused a persistent or significant disability/incapacity.
4. It resulted in a prolonged in-patient hospitalization.
5. It resulted in a new in-patient hospitalization.
6. It was life threatening.
7. It resulted in death.
8. None of the above, but it is medically significant in the opinion of the investigator.

SECTION E: OUTCOME OF SERIOUS ADVERSE EVENT

E1. Outcome of this SERIOUS ADVERSE EVENT: Resolved, no residual effects .....1 **(E4)**

Resolved, with sequelae .....2 **(E4)**

Continuing.....3 **(SECTION F)**

Disability .....4 **(SECTION F)**

Death .....5 **(E2)**

Unknown at this time.....6 **(SECTION F)**

E2. Date of Death: (MM/DD/YYYY) __ __ / __ __ / __ __ __ __

E3. Cause of Death: _____ **(SECTION F)**

E4. Date of SERIOUS ADVERSE EVENT resolution : (MM/DD/YYYY) __ __ / __ __ / __ __ __ __

SECTION F: PEGINTERFERON ALFA-2A

F1. Has the patient taken the initial dose of Peginterferon alfa-2a for the HALT-C Trial?

Yes 1

No.....2 **(SECTION G)**

F2. Start date of Peginterferon alfa-2a for the HALT-C Trial? (MM/DD/YYYY) __ __ / __ __ / __ __ __ __

F3. What was the dose of Peginterferon alfa-2a at the time of the SAE? _____mcg

F4. What was the relationship between Peginterferon alfa-2a and this SAE?

Unrelated 1
Remote 2
Possible 3
Probable 4

F5. Was the dose of Peginterferon alfa-2a altered in response to this SAE?

Yes 1
No .....2 **(SECTION G)**

F6. (NOT TO BE DATA ENTERED)

Peginterferon alfa-2a was altered in response to this SAE:

1. Lowered ☐ Date lowered: __ __ / __ __ /__ __ __ __ Dose: _____
2. Interrupted ☐ Date Stopped: __ __ / __ __ /__ __ __ __ Date restarted: __ __ / __ __ /__ __ __ __
3. Discontinued ☐ Date Stopped: __ __ / __ __ /__ __ __ __

SECTION G: RIBAVIRIN

G1. Has the patient taken the initial dose of Ribavirin for the HALT-C Trial?

Yes 1
No.....2 **(SECTION H)**

G2. Start date of Ribavirin for the HALT-C Trial? (MM/DD/YYYY) __ __ / __ __ / __ __ __ __

G3. What was the dose of Ribavirin at the time of the SAE? _____mg

G4. What was the relationship between Ribavirin and this SAE? Unrelated.....1
Remote.....2
Possible.....3
Probable.....4

G5. Was the dose of Ribavirin altered in response to this SAE? Yes.....1
No .....2 **(SECTION H)**

G6. (NOT TO BE DATA ENTERED)

Ribavirin was altered in response to this SAE:

1. Lowered ☐ Date lowered: __ __ / __ __ /__ __ __ __ Dose: _____
2. Interrupted ☐ Date Stopped: __ __ / __ __ /__ __ __ __ Date restarted: __ __ / __ __ /__ __ __ __
3. Disontinued ☐ Date Stopped: __ __ / __ __ /__ __ __ __

SECTION H: CONCOMITANT MEDICATIONS (NOT TO BE DATA ENTERED)

H1. Was the patient taking any concomitant medications? Yes ☐ No ☐ **(SECTION I)**

H2. Please list any concomitant medications the patient was taking.

	a. Name	b. Total daily dose	c. Suspect causal relationship?	d. Start date (MM/DD/YYYY)	e. Ongoing?	f. Stop date (MM/DD/YYYY)
1.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __
2.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __
3.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __
4.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __
5.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __
6.			☐	__ __ / __ __ /__ __ __ __	☐	__ __ / __ __ /__ __ __ __

SECTION I: SERIOUS ADVERSE EVENT DESCRIPTION

I1. Ongoing progress note regarding the SERIOUS ADVERSE EVENT. Summarize the event as it is known at this time. Please start with the date: (e.g. 3/12/01 Pt's wife telephoned to report that pt complained of chest pain and went to ER on 3/15/01 where he was worked up for possible MI. He is still in hospital. Study drugs stopped on 3/15/01. Will follow.)

I2. Summarize the SERIOUS ADVERSE EVENT. Include dates of hospitalization and severity, if appropriate. Include relevant drug history and outcomes. This is the final summary that will be used to report to the FDA and DSMB.

SECTION J: TREATMENTS/PROCEDURES FOR SAE (NOT TO BE DATA ENTERED)

J1. Were there treatments/procedures done in relation to this SAE? Yes ☐ No ☐

	a. Treatment/Procedure (Specify dose, if applicable)	b. Start date (MM/DD/YYYY)	c. Ongoing?	d. Stop date (MM/DD/YYYY)
1.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
2.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
3.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
4.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
5.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __

SECTION K: RELEVANT LABORATORY/DIAGNOSTIC TESTS (NOT TO BE DATA ENTERED)

K1. Were there any laboratory/diagnostic tests done in relation to this SAE? Yes ☐ No ☐ **(SECTION L)**

	a. Test	b. Date of test (MM/DD/YYYY)	c. Result pending?	d. Result	e. Normal values
1.		__ __/__ __/__ __ __ __	☐		
2.		__ __/__ __/__ __ __ __	☐		
3.		__ __/__ __/__ __ __ __	☐		
4.		__ __/__ __/__ __ __ __	☐		
5.		__ __/__ __/__ __ __ __	☐		

SECTION L: RELEVANT MEDICAL HISTORY (NOT TO BE DATA ENTERED)

L1. Is there any relevant medical history? Yes ☐ No ☐ **(SECTION M)**

	a. Disease / Surgery	b. Disease start date / date of surgery (MM/DD/YYYY)	c. Ongoing?	d. End date (MM/DD/YYYY)
1.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
2.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
3.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
4.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __
5.		__ __/__ __/__ __ __ __	☐	__ __/__ __/__ __ __ __

SECTION M. (NOT TO BE DATA ENTERED)

Principal Investigator Name: _____ Telephone: _____

Clinical Center: _____ Fax:_____

Address: _____

_____ _____

_____

Signature: _____ Date: (MM/DD/YYYY) __ __/ __ __ / __ __ __ __

Investigator Physician