HALT-C Trial Q x Q

Immunology/Virology AS Aliquot Form

Form # 175 Version A: 06/15/2000 (Rev. 04/07/2003)

Purpose of Form #175: This form lists the specimens collected for the Immunology/Virology Ancillary Study that are being sent to the Central Repository (BBI). This form should be filled out when blood specimens for the Neutralizing Antibody and Quasispecies sub-studies and liver specimens for the Replication sub-study are collected.

When to complete Form #175: This form is completed following processing and aliquoting of Immunology/Virology Ancillary Study specimens at the following clinical sites. Lead-In patients are eligible for this Ancillary Study. Express patients are not eligible.

- Site 11 (University of Massachusetts / University of Connecticut).
- Site 12 (Saint Louis University).
- Site 16 (University of Texas Southwestern).
- Site 17 (University of Southern California).

Form #175 should be completed for specimens collected at the following study visits:

- Serum for the Neutralizing Antibodies sub-study. One 1 ml aliquot (sequence number 301) at the Baseline (W00), Breakthrough/Relapse Randomization Visit (R00), Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48) study visits.

- Serum for the Quasispecies sub-study. Two 1 ml aliquots (sequence numbers 302 and 303) at the Baseline (W00), Week 24 (W24), Breakthrough/Relapse Randomization Visit (R00), Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54) study visits.

- Liver tissue for the Replication sub-study. 2.5 cm size (sequence number 320) collected in OCT at the Screening (S00), Month 24 (M24), and Month 48 (M48) study visits.

Form #175 is data entered at the clinical sites. Data entry of this form for a patient visit is the first step of the shipping and tracking procedures for HALT-C. All of the specimens will go into a database of specimens available for shipment to the Central Repository for your clinical center. Entry of this form also allows NERI to link the HALT-C Trial ID's and study visits with the Sample ID assigned by the Central Repository.

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. Record the visit number for this visit.

A4. Record the date the form was completed in the MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: BSI ID

B1. Record the BSI ID from the aliquot tube. The BSI ID begins with the letter “D”, followed by a second letter corresponding to the study site, followed by six numbers. The BSI ID is used by NERI and BBI to identify specimens by patient and study visit.

The BSI ID also appears on the shipping manifest received from the BBI Repository in the column named “bsi_id”. On the shipping manifest, the BSI ID is followed by a three-digit sequence number, which does not need to be recorded on the paper form.

B2. Record the date of the blood draw using the MM/DD/YYYY format. This must be the same date that the blood was aliquotted into cryovials and frozen.

SECTION C: SPECIMEN INFORMATION

C1. Please indicate if there were any problems or delays in specimen processing in C1.
- If there was a delay of > 4 hours or problems with specimen processing, circle 1 for "Yes".
- If serum was separated within 2-4 hours of collection with no problems, circle 2 for “No”.

C2. If the answer for C2a is “No”, circle 2 and skip to the sequence number in the next row. If the answer for C2a is “Yes”, circle 1 and follow the directions below.

<u>If C1 = 1 (Yes) and C2a = 1 (Yes)</u>
- Columns C2b, C2c, and C2d must be completed.
- Column C2b must list the total volume in ml of the sample in the cryovial.
- Column C2c must list one of the codes for specimen processing listed in the box below.
- Column C2d must list the data that processing of the sample was completed.

<u>If C1 = 2 (No) and C2a = 1 (Yes)</u>
- Only Column C2b must be completed. Enter the total volume in ml of the sample in the cryovial.

SECTION D: LIVER TISSUE

D1. Please record the date the biopsy was performed in MM/DD/YYYY format. This must be the date the liver was frozen in OCT.

D2. Please indicate if there were any problems or delays in liver specimen processing in D1.
- If there was a delay or problems with specimen processing, circle 1 for "Yes".
- If there were no delays or problems, circle 2 for “No”.

D3. If the answer for D3a is “No”, circle 2. The form is complete.

<u>If D2 = 1 (Yes) and D3a = 1 (Yes)</u>
- Columns D3b, D3c, and D3d must be completed.
- Column D3b must list the length of the liver sample in cm.
- Column D3c must list one of the codes for specimen processing listed in the box below.
- Column D3d must list the data that processing of the liver sample was completed.

<u>If D2 = 2 (No) and D3a = 1 (Yes)</u>
- Only Column D3b must be completed. List the length of the liver sample in cm.

Codes for specimen processing

1. okay
2. hemolysis
3. delay in processing-processed within 4-6 hours of collection
4. delay in processing-processed within 6-8 hours of collection
5. delay in processing-processed within 8-12 hours of collection
6. delay in processing-processed within 12-18 hours of collection
7. delay in processing-processed within 18-24 hours of collection
8. delay in processing-processed within 24-48 hours of collection
9. delay in processing-processed 48+ hours after collection
10. delay in shipping
11. collected in incorrect tube-plasma collected instead of serum
12. delay in snap freezing liver tissue
13. Vacutainer tube stored in refrigerator
99. Other-please specify