HALT-C Trial Q x Q

Randomized Phase Aliquot Form

Form # 73 Version C: 06/15/2004

Purpose of Form #73: The Randomized Phase Aliquot form is used to record specimens collected for a randomized phase visit that will be sent to the Central Repository (BBI). Specimens that will be tested at local labs are not recorded on this form.

Data entry of Form #73 adds specimens to the HALT-C shipping database. The DMS uses this database to track all specimens and compile future shipments from the clinical centers to the central repository and to track what specimens should be in the freezer at the clinical site.

When to complete Form #73: This form should be completed following processing and aliquotting of specimens for each Randomized phase visit: Month 09 (M09) through 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 code corresponding to this visit.

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

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

SECTION B: SAMPLE ID

At each visit, select the appropriate randomized phase label packet supplied by BBI. Labels contain the patient ID, visit number, sample ID, and sequence number.

B1. Record the sample ID for this patient and this visit in the space provided. An extra aliquot label from the label packet used for this patient may be placed on the form. If the label is not available, record the sample ID number legibly.

BBI and the DCC rely on the sample ID as a link between the patient ID, the study visit, and location of collected specimens. It is very important that the sample ID is recorded and data entered accurately.

B2. Record the date when the blood sample was collected using MM/DD/YYYY format.

Note: If the blood draw was completed on a different date than the blood draw recorded on Form #30 (Local Lab), please add a form level comment about the patient's fasting status when completing data entry in the DMS. The comment should include information on the data and time of day when the blood sample was collected and the date and time of day when the when the patient reported he or she last ate or drank (other than water).

SECTION C: SPECIMEN INFORMATION

C1. Indicate if there were any problems or delays in specimen processing in C1.

Circle "No" for C1 if serum was separated within 2-4 hours of collection.
- Questions C2a and C2b, C3a and C3b, and C4a and C4b must be completed for each aliquotted specimen.
- Questions C2c and C2d, C3c and C3d, and C4c and C4d do not need to be completed.

Circle "Yes" for C1 if there was a problem with specimen processing.
- Questions C2a-d, C3a-d, and C4a-d must be completed for each aliquotted specimen.
- Question C2c, C3c, and C4c should be completed with one of the codes for specimen processing listed in the code box below.

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

General Instructions on Tables C2, C3, and C4:

Because Form #73 is used for all randomized phase study visits, all possible specimens collected during the randomized phase are listed. Each specimen is given a sequence number, purpose, and an expected volume in Tables C2, C3, and C4.

The study visit column shows which study visits require collection of specimens with that sequence number. Only complete rows that pertain to a specific study visit. For example, when Form #73 completed at the M09 visit, only complete the rows for sequence numbers 110, 111, 115, 116, 140, and 141 as indicated on the form.

NOTE: PBMC Specimen Collection: sequence numbers 001, 002, and 007

In February 2003, there was a change in the protocol. It was decided that:
- Patients who have consented to participate in the Immunology / Virology Ancillary Studies have PBMC specimens collected at the Month 21 (M21) and Month 45 (M45) visits.
- Patients who had M21 PBMC specimens collected before February 1, 2003 will have PBMC specimens collected at the M45 visit.
- All other patients will not have PBMC collected at the M21 or M45 visits.

Information in the Visit Control Sheet for the M21 and M45 visits will enumerate specifically which patients will require M21 and M45 PBMC collection.

General Instructions on spare sequence numbers:

Extra whole blood collected.
If extra whole blood was collected, use the spare ID sequence number 005.

Extra frozen serum collected.
If extra frozen serum was collected, use the spare ID sequence numbers 123 and/or 124.

Extra frozen whole blood for DNA collected.
If extra frozen whole blood was collected, use the spare ID sequence numbers 142 and/or 143.

SECTION D: LIVER TISSUE

D1. Record the date the biopsy was performed for this visit in MM/DD/YYYY format. Biopsies are performed at the M24 and M48 visits.

D2. Indicate if there were any problems or delays in liver specimen processing in D2.

Circle "No" for D2 if there were no problems with processing of the liver specimen.
- Questions D3a and D3b must be completed.
- Questions D3c and D3d do not need to be completed.

Circle "Yes" for D2 if there was a problem with processing of the liver specimen.
- Questions D3a-d and D4a-d must be completed.
- Questions D3c and D4c should be completed with one of the codes for specimen processing listed in the code box below.

NOTE: Liver Tissue Collection: sequence numbers 130 (snap frozen) and 132 (frozen in OCT)

The HALT-C Steering Committee approved a change in the protocol for handling of liver biopsy specimens. Effective June 15, 2004, all HALT-C Clinical Sites should follow the revised liver biopsy protocol:

PRIORITIES:

1. The top priority for use of the biopsies will continue to be at least a 20 mm core for histological interpretation for the Main HALT-C trial.

2. For excess liver tissue:
   - First priority: continue the current practice, whenever possible, to place 3.0 mm (or larger) cores of biopsies into cryovials, flash-frozen in liquid nitrogen at the bedside, and later transferred to dry ice (-80^{0}C or colder) for long-term storage.

   - Second priority: whenever possible, embed any remaining liver tissue (preferably $\geq$ 4.0 mm cores) from HALT-C biopsies at the bedside into Tissue-Tek OCT prior to freezing in liquid nitrogen. A detailed procedure on how to collect liver in OCT is provided in in Numbered Memo 27.

HOWEVER, the four clinical sites (UMass/UConn, SLU, USC, UTSW) currently embedding biopsy samples into OCT as part of the Immunology-Virology AS will continue to do so. Unlike the other clinical sites, the first priority for excess biopsy tissue specimens will be fresh tissue for the CTL substudy and for the already approved Replication substudy. If additional tissue is available, liver biopsies will also be collected and flash frozen whenever possible.