

## HALT-C Trial Q x Q

### Histology Shipping Log

Form #505 Version B: 08/08/2002 (Rev. 07/22/2004)

**Purpose of the Histology Shipping Log:** The Histology Shipping Log documents that liver biopsy slides are being sent from a Clinical Center to the Data Coordinating Center (DCC) for the HALT-C Study. Data entry of this form is done by the DCC to add the received slides to HALT-C shipping database and associate the biopsy with a dummy ID used to blind the slides. The DMS uses this database to track all biopsy slides and compile future shipments from the DCC to AFIP.

The progression of the Ishak fibrosis score as determined by a biopsy of the liver is one of the main outcomes of the HALT-C Trial. Therefore, Month 24 and Month 48 liver biopsies are very important data for the HALT-C study.

- Ten unstained slides should be sent to the DCC for blinding.
- Slide boxes will be supplied to Study Coordinators for shipment of slides to the DCC.
- The DCC will blind the unstained slides and forward them to AFIP.
- AFIP will stain the slides in preparation for review by the Central Pathology Committee.

Unstained biopsy slides should be collected for the following HALT-C patients:

- **Screening Phase:** All patients.
- **Randomized Phase:** All patients at the Month 24 (M24) and Month 48 (M48) study visits.
- **Presumed or definite hepatocellular carcinoma (HCC) clinical outcomes:** The HALT-C Outcomes Review Board (ORB) reviews documentation on all presumed HCC or definite HCC events in study patients. If the ORB confirms that a randomized patient meets the outcome criteria for presumed HCC or definite HCC, liver biopsy or explant histology slides are requested for Central Pathology Review.

**When to complete the Histology Shipping Log:** The Histology Shipping Log should be completed when a liver biopsy slide shipment is being prepared. Please fax the Histology Shipping Log to the DCC. Please enclose a copy of the Histology Shipping Log along with the slide shipment to the DCC.

The Histology Shipping Log is **not** data entered at the clinical sites.

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

- A1. Enter the two-digit Clinical Site ID in the space provided. The first two digits on your patients' ID labels represent your Clinical Site ID.
- A2. Record the shipping date of the package in MM/DD/YYYY format.
- A3. Record the initials of the person completing the form.
- A2. Record the number of slide boxes in the package.
- A3. Record the FedEx Tracking number if known.

**SECTION B: To be completed at the Clinical Site****Columns:**

- a. Local Path ID:

**As of 09/30/2003:** In order to comply with HIPAA regulations changes have been made in the way Histology Shipping Logs are completed. To assist with form completion, the Histology Shipping Log Version B Revision (dated 07/22/2004) has –9 printed in all rows of column (a).

**Do not write the Local Pathology ID of the biopsy in column (a) of the Histology Shipping Log.**

- b. Record the patient ID number legibly in the space provided.
- c. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- d. Record the date of the liver biopsy in MM/DD/YYYY format.
- e. Record the visit for which this biopsy is being reviewed.
- f. Record the total number of unstained slides available for shipment to AFIP. Ten unstained slides should be sent to the DCC for blinding.
- g. If unstained slides are not available, Masson, H&E, and Iron stained slides should be sent to the DCC for blinding. Record the total number of stained slides available for shipment to AFIP.
- h. Record the Slide Box number. The DCC supplies slide boxes to be used for shipping.
- j. Record if the slides should be returned to your center after Central Pathology review is complete. If the answer is YES, circle 1. If the answer is NO, circle 2.

**PLEASE FAX THE COMPLETED HISTOLOGY SHIPPING LOG TO:  
DCC Main Fax Number, (617) 926-0144**

**Labeling Slides**

- Each slide will be labeled at the clinical center with the Patient ID – written in pencil.

**Packing and Shipping Slides to the DCC**

- For each patient whose slides are in the shipment, complete the Histology Shipping Log and include a copy in the shipment. This log enables the DCC to track slide shipments.
- Pack slides in standard slide shipping boxes, which hold 25 or 100 slides. These boxes are supplied by the DCC.
- Use tissue paper, or something similar, inside the box, to prevent the slides from moving during shipment.
- Wrap the slide box in bubble wrap, and pack in a shipping box.
- Address the mailer to:

HALT-C Trial - Data Manager  
NERI  
9 Galen Street  
Watertown, MA 02472

**Columns (k), (l), (m) and SECTION C: To be completed at the DCC**

- k. The DCC records the number of unstained slides received for shipment to AFIP.
  - l. The DCC records the number of stained slides received for shipment to AFIP.
  - m. The DCC records the unique dummy ID assigned to this biopsy. The dummy ID is a number from 1 – 5000 and is used to blind the biopsy slides before shipping to AFIP.
- C1. The DCC records the receipt date of the package in MM/DD/YYYY format.