

## HALT-C Trial

### Immunology / Virology Withdrawal Form

Form # 176 Q x Q    Version B: 01/30/2003

**Purpose of Form #176:** This form records that a patient has withdrawn from the entire Immunology / Virology Ancillary Study or from one or more of the five Immunology / Virology sub-studies:

- Cytotoxic T Lymphocyte (CTL)
- Replication
- Neutralizing Antibody (NA)
- Quasispecies
- Lymphoproliferation (LP)

**When to complete Form #176:** This form should be completed when a patient has withdrawn from any or all of the Immunology / Virology sub-studies. Lead-In patients were eligible for the Immunology / Virology Ancillary Study. Express patients were not eligible. Participating sites are listed below:

- 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).

In the HALT-C Data Management System (DMS), Form #176 can be added to any study visit by clicking the "Additional Forms" button on the study visit screen. Data entry of this form by the clinical site removes relevant study forms and samples from future visits in the DMS and on applicable Visit Control Sheets (VCS).

#### **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 date the form was completed in MM/DD/YYYY format.
- A4. Enter the initials of the person filling out the form.

**SECTION B: WITHDRAWAL INFORMATION****Possible Reasons for Withdrawal from the entire Immunology / Virology Ancillary Study:**

- A patient withdraws consent to participate in the Immunology / Virology Ancillary Study.

B1. If the patient is being withdrawn from the entire Immunology / Virology Ancillary Study (all five sub-studies), circle 1 for "Yes" and continue to Question B2.

If the patient is not being withdrawn from the entire Immunology / Virology Ancillary Study (all five sub-studies), circle 2 for "No" and skip to Question B4.

B2. Record the date of withdrawal from the entire Immunology / Virology Ancillary Study in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.

B3. Circle the primary reason why the patient is being withdrawn from the entire Immunology / Virology Ancillary Study. If the reason is not listed, circle 99 for "Other" and specify a reason. 60 characters including spaces and punctuation are available. Skip to question B14.

**Possible Reasons for Withdrawal from one or more of the five Immunology / Virology sub-studies:**

- A patient withdraws consent to participate in one (or more) of the five sub-studies at any time.
- The *initial* samples for the NA, Quasispecies, or LP sub-study were not collected. For example, if an adequate serum specimen was not obtained for the LP sub-study at the W00 visit, the patient should be withdrawn from only the LP sub-study.
- The *initial* samples for the NA, Quasispecies, or LP sub-study were destroyed or lost in shipping.
- If *initial* samples for the CTL or Replication sub-study were not collected, the patient may *remain* in the CTL or Replication sub-study.

→ **NOTE.** Even if all required samples for the CTL or Replication sub-study were not collected at the initial visit (S00 or W00), the patient is still eligible for continuing in that sub-study. Incomplete sample collection at the initial visit does not require withdrawal from the CTL or Replication sub-study. For example, if specimens for the CTL sub-study were not at the S00 visit, but the M24 specimen was collected, the patient can remain in the CTL sub-study. Samples should be also collected at the M48 visit.

**Cytotoxic T Lymphocyte sub-study**

B4. If the patient is being withdrawn from the CTL sub-study, circle 1 for "Yes" and continue to Question B4a.

If the patient is not being withdrawn from the CTL sub-study, circle 2 for "No" and skip to Question B6.

B4a. Record the date of withdrawal from the CTL sub-study, in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.

B5. Circle the primary reason why the patient is being withdrawn from the CTL sub-study. If the reason is not listed, circle 99 for "Other" and specify a reason. 60 characters including spaces and punctuation are available.

**Replication sub-study**

B6. If the patient is being withdrawn from the Replication sub-study, circle 1 for "Yes" and continue to Question B6a.

If the patient is not being withdrawn from the Replication sub-study, circle 2 for "No" and skip to Question B8.

B6a. Record the date of withdrawal from the Replication sub-study, in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.

B7. Circle the primary reason why the patient is being withdrawn from the Replication sub-study. If the reason is not listed, circle 99 for "Other" and specify a reason. (60 characters including spaces and punctuation are available.)

→ **NOTE.** If all required samples for the NA, Quasispecies, or LP sub-study were collected at the initial visit (S00 or W00), the patient is eligible for continuing in that sub-study. Incomplete sample collection at a later visit does not require withdrawal from the LP, Quasispecies, or NA sub-study. For example, if specimens for the LP sub-study were collected at the W00, W24, and M12 visits, but the M24 specimen was not collected, the patient can remain in the LP sub-study. Samples should be collected at the M36, M48, and M54 visits.

**Neutralizing Antibody sub-study**

B8. If the patient is being withdrawn from the NA sub-study, circle 1 for "Yes" and continue to Question B8a.

If the patient is not being withdrawn from the NA sub-study, circle 2 for "No" and skip to Question B10.

- B8a. Record the date of withdrawal from the NA sub-study, in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.
- B9. Circle the primary reason why the patient is being withdrawn from the NA sub-study. If the reason is not listed, circle 99 for "Other" and specify a reason. 60 characters including spaces and punctuation are available.

### **Quasispecies sub-study**

- B10. If the patient is being withdrawn from the Quasispecies sub-study, circle 1 for "Yes" and continue to Question B10a.

If the patient is not being withdrawn from the Quasispecies sub-study, circle 2 for "No" and skip to Question B12.

- B10a. Record the date of withdrawal from the Quasispecies sub-study, in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.
- B11. Circle the primary reason why the patient is being withdrawn from the Quasispecies sub-study. If the reason is not listed, circle 99 for "Other" and specify a reason. 60 characters including spaces and punctuation are available.

### **Lymphoproliferation sub-study**

- B12. If the patient is being withdrawn from the LP sub-study, circle 1 for "Yes" and continue to Question B12a.

If the patient is not being withdrawn from the LP sub-study, circle 2 for "No" and skip to Question B14.

- B12a. Record the date of withdrawal from the LP sub-study, in MM/DD/YYYY format. If the patient withdrew consent, record the date the patient made the request. If there was a problem with the initial samples, record the date the samples were not collected, damaged, or lost.
- B13. Circle the primary reason why the patient is being withdrawn from the LP sub-study. If the reason is not listed, circle 99 for "Other" and specify a reason. 60 characters including spaces and punctuation are available.
- B14. Please enter any additional information regarding the patient's withdrawal. 250 characters including spaces and punctuation are available.