QxQ updated: 06/29/2004

HAI T-C Trial Q x Q

QLFT AS Withdrawal Form

Form # 194 Version A: 06/15/2000

<u>Purpose of Form #194:</u> The QLFT AS Withdrawal form documents which patients have withdrawn from the study and the reason for doing so. Additionally, data entry of this form removes relevant study forms from future visits in the DMS.

When to complete Form #194: This form should be completed upon withdrawal of a patient from the QLFT study. This form can be added to any study visit by clicking on the "Additional Forms" button on the study visit screen.

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 using MM/DD/YYYY format.
- A4. Enter the initials of the person completing the form.

SECTION B: WITHDRAWAL INFORMATION

- B1. Record the date that the patient withdrew from the QLFT study using MM/DD/YYYY format.
- B2. Circle the primary reason why the patient withdrew from the QLFT ancillary study. If the reason is not listed, circle "99" for OTHER and specify a reason (sixty characters including spaces and punctuation are available).
- B3. Please enter any additional information regarding the patient's withdrawal from this study in as much detail as necessary (two hundred fifty characters including spaces and punctuation are available). If there is not additional information, record "Not applicable" on the paper form and data enter "-1" in the HALT-C Data Management System (DMS).