HALT-C Trial Q x Q

Trial Consent

Form # 2 Version A: 11/01/2003

Purpose of Form #2: The Trial Consent Form #2 provides formal verification that a patient has signed all the necessary consent forms to participate in the HALT-C Trial and associated Ancillary Studies. This form will be used in place of Form #4, Screening Checklist, for patients who have failed screening, but have given blood or tissue samples that may be analyzed in the future.

When to complete Form #2: This form should be completed for any patient at any clinical site who:

EITHER Does not have Screening Checklist Form #4 completed and entered in the DMS
OR Does not have Express Screening Checklist Form #94 completed and entered in the DMS
AND Had blood and/or tissue sample(s) collected during the screening process.

Form #2 should be data entered in the Screening (S00) study visit in the DMS.

SECTION A: GENERAL INFORMATION

A1. Affix a patient ID label in the space provided at the top of each page. If a label is not available, record the ID number legibly in ink.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. The visit number, S00, is pre-printed on the form and does not need to be data entered.

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: MAIN TRIAL INFORMED CONSENT

B1. Did patient sign a HALT-C Trial informed consent form?

- Indicate whether the patient has a signed HALT-C consent form. This may be a Screening consent form only or consent form(s) for the Screening and the Main Trial.
- Circle YES if the patient's chart contains a signed consent form to participate in Screening and/or the Main Trial.
- Circle NO if the patient did not sign any consent forms or no consent forms were located in the patient's chart. The form is complete.
- Patients without a signed consent form will have all specimens collected for the HALT-C Trial destroyed.

B2. Did patient sign consent for genetic testing?

- At your institution, this may be a separate document or may be combined with other consents. Check the documents specifically for signed consent to genetic testing.
- Circle YES if there is a signed consent to genetic testing in the patient's chart.
- Circle NO if the patient did not sign genetic testing consent forms or no consent forms were located in the patient's chart.
- All specimens intended for genetic testing will be destroyed if the patient did not give signed consent for genetic testing.

B3. Did patient sign consent to receive information about genetic testing?

- At your institution, this may be a separate document or may be combined with other consents. Check the documents specifically for signed consent to receive information about genetic testing.
- Circle YES if there is a signed consent to receive information about genetic testing in the patient's chart.
- Circle NO if the patient did not sign a consent form to receive information about genetic testing or no consent forms were located in the patient's chart.

SECTION C: ANCILLARY STUDIES CONSENT:

General information on completing Section C

Three Ancillary Studies (Immunology/Virology, Quantitative Assessment of Liver Function, and Cognitive Effects) require informed consents separate from the main HALT-C Trial consent. **Please answer the questions in this section about patient eligibility even if your site is not participating in these Ancillary Studies**.

C1. Immunology/Virology AS: Was patient eligible to participate in this Ancillary study?

- Circle YES for patients at participating sites (Sites 11, 12, 16, and 17) who fulfill eligibility criteria for the Immunology/Virology Ancillary Study. Eligibility criteria for this ancillary study are described in the Manual of Operations, Section K-1. Continue to question C1a.
- Circle NO for patients at participating sites for whom there is inadequate liver tissue, who are Express patients, or who are otherwise ineligible. Skip to question C2.
- Circle NO for all patients at non-participating clinical sites (Sites 13, 14, 15, 18, 19, and 20). Skip to question C2.

C1a. Did the patient sign a consent form to participate in this ancillary study?

- Circle YES if the patient has a signed consent to participate in the Immunology/Virology Ancillary Study.
- Circle NO if the patient does not have a signed consent to participate in the Immunology/Virology Ancillary Study.

C2. Quantitative Liver Function Ancillary Study: Was patient eligible to participate in this ancillary study?

- Circle YES for patients at participating sites (Sites 14, 15, and 19) who fulfill eligibility criteria for the QLFT Ancillary Study. Eligibility criteria for this ancillary study are described in the Manual of Operations, Section K-6. Continue to question C2a.
- Circle NO for patients at participating sites for whom inadequate specimens were collected or who are otherwise ineligible. Skip to question C3.
- Circle NO for all patients at non-participating clinical sites (Sites 11, 12, 13, 16, 17, 18, and 20). Skip to question C3.

C2a. Did the patient sign a consent form to participate in this ancillary study?

- Circle YES if the patient has a signed consent to participate in the QLFT Ancillary Study.
- Circle NO if the patient does not have a signed consent to participate in the QLFT Ancillary Study.

C3. Cognitive Effects Ancillary Study: Was patient eligible to participate in this ancillary study?

- Circle YES for patients at participating sites (Sites 17 and 18) who fulfill eligibility criteria for the Cognitive Effects Ancillary Study. Eligibility criteria for this ancillary study are described in the Manual of Operations, Section K-4. Continue to question C3a.
- Circle NO for patients at participating sites who are Express patients or who are otherwise ineligible. The form is complete.
- Circle NO for all patients at non-participating clinical sites (Sites 11, 12, 13, 14, 15, 16, 19, and 20). The form is complete.

C3a. Did the patient sign a consent form to participate in this ancillary study?

- Circle YES if the patient has a signed consent to participate in the Cognitive Effects Ancillary Study. The form is complete.
- Circle NO if the patient does not have a signed consent to participate in the Cognitive Effects Ancillary Study. The form is complete.