HALT-C Trial Q x Q

Genetic Consent Status Change Form

Form # 9 Version A: 09/20/2004

Purpose of Form #9: This form should be completed for any patient at any clinical site who decides to change his/her status on consent for genetic testing or consent for receiving genetic information. As of September 17, 2004 this form should be used instead of changing a patient's genetic consent on Form # 4 (Screening Checklist) or Form # 94 (Express Screening Checklist).

Where to add Form #9: Add this form to the study visit where the consent status change occurred, except the Screening (S00) visit. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#9: Genetic Consent Status Change" from the pull down menu, and then click the "OK" button. To see where this form has been data entered, please click on the "More" link in the upper right hand corner of the 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. Enter the three-digit code corresponding to this visit.

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: CONSENT FOR GENETIC TESTING AND INFORMATION

B1. Is the patient changing his/her genetic **testing** consent status?

- Circle 1 for YES if the patient **is** making a change at this time on the portion of the HALT-C Main Trial consent form regarding genetic testing. Continue to Question B2.

- Circle 2 for NO if the patient is **not** making a change at this time on the portion of the HALT-C Main Trial consent form regarding genetic testing. Skip to Question B4.

B2. New genetic **testing** consent status:

- Circle 1 if the patient is now giving consent for genetic testing on his/her HALT-C samples.
  - Genetic tests will be conducted from this time forward.

- Circle 2 if the patient is now withdrawing consent to genetic testing on his/her HALT-C samples.
  - All genetic tests that have already been completed will remain in the HALT-C database. No further genetic tests will be conducted from this time forward.

B3. Date of change in genetic **testing** consent status:

- Record the month, day, and year the status changed in MM/DD/YYYY format. This is the date that the patient signed the informed consent form.

B4. Is the patient changing his/her genetic **information** consent status?

- Circle 1 for YES if the patient **is** making a change at this time on the portion of the HALT-C Main Trial consent form regarding receiving reports about his/her genetic information. Continue to Question B5.

- Circle 2 for NO if the patient is **not** making a change at this time on the portion of the HALT-C Main Trial consent form regarding receiving reports about his/her genetic information. Skip to Question B7.

B5. New genetic **information** consent status:

- Circle 1 if the patient is now giving consent to receive reports about his/her genetic information and test results.
  - Genetic reports will be produced for the patient from this time forward.

- Circle 2 if the patient is now withdrawing consent to receive reports about his/her genetic information and test results.
  - Genetic reports will not be produced for the patient from this time forward.

B6. Date of change in genetic **information** consent status:

- Record the month, day, and year the status changed in MM/DD/YYYY format. This is the date that the patient signed the informed consent form.

B7. Explain briefly:

- Record a brief explanation why the patient chose to change his consent status at this time. Two hundred and fifty characters, including spaces and punctuation, are provided. Explanation examples:
  - "IRB required re-consent of HALT-C patients with revised consent form. This patient decided to withdraw his prior consent to genetic testing and receiving genetic information."