HALT-C Trial Q x Q

Sustained Virologic Responder Follow-up Ancillary Study Consent

Form # 701 Version A: 05/01/2008

Purpose of Form #701: This form verifies that a patient has consented to participate in the HALT-C Trial Sustained Virologic Responder Follow-up Ancillary Study. The form is to be completed for all Sustained Virologic Responder patients.

Eligibility for Sustained Virologic Responder Follow-up Ancillary Study: According to the Ancillary Study Protocol, every patient who was a sustained virologic responder at the Week 72 visit of HALT-C is eligible for the Sustained Virologic Responder Follow-up Ancillary Study.

When to complete Form #701: This form provides formal verification that a patient has consented to participate in the HALT-C Trial Sustained Virologic Responder Follow-up Ancillary Study. A list of patients for whom Form #701 is expected can be obtained by running the Detail Form Status Report in the DMS and selecting only "#701: Extended Follow-up Trial Consent" in the "Select Forms" column.

Data entering Form #701 triggers the Data Management System (DMS) to add the appropriate follow-up forms to the DMS.

Where to data enter Form #701: For eligible patients, Form #701 will be an expected form in the W72 study visit in the DMS.

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. The visit number, W72, 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: HALT-C SVR FOLLOW-UP ANCILLARY STUDY INFORMED CONSENT

B1. Was the patient contacted about participating in the SVR Follow-up Ancillary Study?

- Circle 1 for YES if the patient **was contacted** about participating in the SVR Follow-up Ancillary Study. Skip to Question B2.
- Circle 2 for NO if the patient **was not contacted** about participating in the SVR Follow-up Ancillary Study.

B1a. Reason why patient was **not contacted**.

There may be patients who are eligible for these visits who were not contacted about participating in the SVR Follow-up Ancillary Study.

- Circle 1 if an eligible SVR patient could not be located. End of form.
- Circle 2 if an eligible SVR patient died prior to being given consent form. End of form. Complete Form #763 for Clinical Outcome of death.
- Circle 99 if there is an "other" reason the patient was not given the consent form.

B1b. Specify what the reason is. For example, the patient refuses further contact. End of form.

B2. Did patient consent to the SVR Follow-up Ancillary Study?

- Circle 1 if patient **consented** to participate in the SVR Follow-up Ancillary Study.
- Circle 2 if patient **did not consent** to participate in the SVR Follow-up Ancillary Study. End of form.

B2b. Type of consent.

- Circle 1 if patient **signed an informed consent form** to participate in the SVR Follow-up Ancillary Study.
- Circle 2 if patient agreed to participate in the SVR Follow-up Ancillary Study **by telephone interview**. End of form.