QxQ updated: 05/17/2004

## HALT-C Trial Q x Q

## Glycosylated Hemoglobin - Steatosis AS

Form # 121 Version A: 06/15/2000

<u>Purpose of Form #121:</u> The Glycosylated Hemoglobin form is used to record the glycosylated hemoglobin (HBA1c) results from the local lab report. A copy of local lab report should be attached to Form #121.

When to complete Form #121: The Glycosylated Hemoglobin form will be expected when question B5 (Diabetes?) on Form #3: Screening Medical History Interview is answered "Yes".

Form #121 should be completed during Screening for any patient who has diabetes. Patients who do not have diabetes do not require this form. Form #121 will be data entered at each clinical site.

## **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, S00, is pre-printed on the form. S00 must be data entered.
- A4. Record the date the form was completed in MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

## SECTION B: GLYCOSYLATED HEMOGLOBIN (HbA1c)

B1. Enter the level of glycosylated hemoglobin, in %, as reported on the local lab report. The field allows two numbers before the decimal point. One number **must** be entered after the decimal point.

The normal range is 4.5% to 10.0%. If the result falls outside of this range, please verify the result against the source documentation. If the abnormal result is correct, select the override button. Specify that the data was verified and is correct.

If the test was not done or the result will never be available, set Form #121 to missing in the Data Management System.

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