HALT-C Trial Q x Q

Local Lab

Form # 30 Version C: 04/22/2004

Purpose of Form #30: The Local Lab form is used to record the results of complete blood count, serum chemistries, uric acid, liver chemistries, prothrombin time, thyroid stimulating hormone, and urine and pregnancy tests from the local lab report. Form #30 also collects information on the date and time patients last ate or drank to determine fasting status.

A copy of the clinic note (with results from the urine dipstick and pregnancy test) and local lab reports (other labs) should be filed in the patient chart.

When to complete Form #30: Upon receiving the results from your local lab, Form #30 should be completed and data entered for all study patients. Form #30 should be used each time labs are drawn for a study visit and sent to your local lab, with the exception of Screening Visit 2 (S00). For Screening Visit 2 (S00) ONLY use form #35, Screening Visit 2 Local Labs.

The Visit Control Sheet lists the lab tests required at each visit. All results should be reviewed to see if they are within the reference range specified. A value outside the reference range may indicate that further evaluation is required.

When a patient is unable to come into the HALT-C clinical center, lab tests are occasionally done at an outside laboratory. Outside laboratory results can be recorded on Form #30 with a brief explanation written on the form and data entered as a form level comment in the Data Management System (DMS)

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the patient number legibly.

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

A3. Enter the three-digit code that corresponds to the visit number.

A4. Record the date that this form was completed in MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

A6. Record the date of the blood draw.
- If blood was drawn on more than one day, record the date of the first blood draw.

SECTION B0: FASTING INFORMATION

B0a. Record the time of day when the blood sample was collected. Circle 1 for AM or 2 for PM. Circle 1 for Midnight. Circle 2 for Noon.

B0b. Record the date when the when the patient reported he or she last ate or drank (other than water) using MM/DD/YYYY format.

B0c. Record the time of day when the patient reported he or she last ate or drank (other than water). Circle 1 for AM or 2 for PM. Circle 1 for Midnight. Circle 2 for Noon.

- After data entry of Questions A6, B0a, B0b, and B0c, the DMS automatically runs a "validity check" that compares the blood draw date and time to the fasting date and time. The validity check assumes that a patient would typically fast for 24 hours or less.

- If the entered data indicates that patient fasted for more than 24 hours, a help text box will pop up with the following message: **The date and time the patient last ate/drank is expected to be within 24 hours before the date and time of the blood draw.**

- Upon seeing the pop up message, the data manager must verify that Questions A6, B0a, B0b, and B0c have been completed and data entered correctly.

- If the patient truly fasted for more than 24 hours prior to the blood draw, the data manager can override the validity check. Provide a clear succinct explanation in the "Override reason" box: "Verified that pt did not eat/drink for 30 hours prior to blood draw".

General Instructions for completing and data entering Sections B through I:

The DMS has been set up to expect a certain range for most lab values. If an obtained value falls outside of this range, it should still be recorded on the paper form and data entered.

- Upon entering an out of range value in the DMS, a data entry validation error screen will appear. If the data entered value is the actual obtained value recorded on the Form #30, then this out-of-range value may be overridden. Type a brief explanation in the "Reason" box (e.g., "Confirmed with lab source documentation"). Enter your initials and click the "Set Override" button.

If a particular lab test was not done or the results will never be available write "not done", or "not available" on Form #30 with a brief reason in the margin. When data entering Form #30 in the DMS, enter the value "-9". A data entry validation error message will appear on the screen.

- If the value will never be obtained in the future, type a concise explanation in the "Reason" box. Enter your initials in the space provided and click on the "Set Override" button.

- If the value may be obtained in the future, click on the "Ignore Value" button. An edit report will be generated after the rest of the form is entered. The form will have a "Pending Edits" status until the value is completed and data entered, or is determined to be unobtainable and an override "Reason" provided.

There may be occasions when a repeated lab value must be entered on a Form # 30 (i.e., if platelets clump). If a second test result is completed, cross out the previous value and write in the new value for the appropriate test on the paper Form #30. Write the new blood draw date next to the new lab value. Initial and date each edit. File relevant source documentation in the patient chart. Enter the new value in the DMS. Add a field level comment briefly explaining the change (e.g. Platelets clumped. Retested on 01/01/2004.)

SECTION B: COMPLETE BLOOD COUNT

The following are needed from the Complete Blood Count (CBC) report:

- white blood cell count (WBC)
- neutrophils (ANC)
- hematocrit (Hct)
- hemoglobin (Hgb)
- platelets

CBC results should be completed on Form #30 at the following study visits:

- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00), every clinic visit from Week 2 (W02) through Week 24 (W24).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization phase:** every clinic visit from Month 9 (M09) through Month 54 (M54).
- **Responder phase:** every clinic visit from Week 30 (W30) through Week 72 (W72).

B1. Record white blood cell count as $x10^3/mm^3$. Range is 2.0 to 14.0.

B2. Record neutrophils as $x10^3/mm^3$. Range is 0.800 to 10.000.

B3. Record hematocrit in %. Range is 30.0 to 55.0.

B4. Record hemoglobin in g/dL. Range is 10.0 to 18.0.

B5. Record platelets as $x10^3/mm^3$. Range is 35 to 500.

SECTION C: SERUM CHEMISTRIES

The following are needed from the serum chemistry report:

- blood urea nitrogen (BUN)
- creatinine
- glucose
- triglycerides

Serum chemistry results should be completed on Form #30 at the following study visits:

- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00) and Week 20 (W20).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization phase:** every six months at Month 12 (M12), Month 18 (M18), Month 24 (M24), Month 30 (M30), Month 36 (M36), Month 42 (M42), and Month 48 (M48).
- **Responder phase:** Week 48 (W48), Week 60 (W60), and Week 72 (W72).

C1. Record BUN in mg/dL. Range is 0 to 40.

C2. Record creatinine in mg/dL. Range is 0.0 to 2.0.

C3. Record fasting glucose in mg/dL. Range is 50 to 300.

C4. Record triglycerides in mg/dL. Range is 30 to 600.

SECTION D: URIC ACID

Uric acid results should be completed on Form #30 at the following study visits:
- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00) and Week 20 (W20).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Responder phase:** Week 48 (W48).

D1. Record Uric acid in mg/dL. Range is 3 to 10.

SECTION E: LIVER CHEMISTRIES

The following are needed from the liver chemistry report:
- AST (SGOT) result and upper limit of normal
- ALT (SGPT) result and upper limit of normal
- alkaline phosphatase result and upper limit of normal
- total bilirubin result
- albumin result
- result for either globulin or total protein

Liver chemistry results should be completed on Form #30 at the following study visits:
- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00) and Week 4 (W04) through Week 24 (W24).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization phase:** every clinic visit from Month 9 (M09) through Month 54 (M54).
- **Responder phase:** every clinic visit from Week 30 (W30) through Week 72 (W72).

E1. Record AST (SGOT) in U/L. Range is 0 to 500.

E1a. Record the AST upper limit of normal documented on the lab report. Range is 0 to 100.

E2. Record ALT (SGPT) in U/L. Range is 0 to 500.

E2a. Record the ALT upper limit of normal documented on the lab report. Range is 0 to 100.

E3. Record alkaline phosphatase in U/L. Range is 0 to 350.

E3a. Record the alkaline phosphatase upper limit of normal documented on the lab report. Range is 0 to 200.

E4. Record total bilirubin in mg/dL. Range is 0.0 to 6.0.

E5. Record albumin in g/dL. Range is 2.5 to 6.0.

E6. Record either globulin in g/dL (range is 1.2 to 5.0), or total protein in g/dL (range is 4.0 to 9.0).
- Data entry of globulin: Enter the globulin value. The DMS will skip automatically to the next section.
- Data entry of total protein: Enter a -1 for Globulin and the DMS will go to the total protein field. Then enter the Total Protein value.

SECTION F: PROTHROMBIN TIME

Prothrombin Time (PT) results should be completed on Form #30 at the following study visits:
- **Screening phase:** Screening 1 (S00).
- **Lead-in phase:** Baseline (W00), Week 12 (W12), and Week 20 (W20).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization phase:** every clinic visit from Month 9 (M09) through Month 54 (M54).
- **Responder phase:** Week 36 (W36), Week 48 (W48), Week 60 (W60), and Week 72 (W72).

F1. Record Prothrombin Time in INR (International Normalized Ratios). Range is 0.5 to 2.0.

SECTION G. THYROID STIMULATING HORMONE

Thyroid Stimulating Hormone (TSH) results should be completed on Form #30 at the following study visits:
- **Lead-in phase:** Week 12 (W12), and Week 20 (W20).
- **Randomization phase:** every six months at Month 12 (M12), Month 18 (M18), Month 24 (M24), Month 30 (M30), Month 36 (M36), Month 42 (M42), and Month 48 (M48).
- **Responder phase:** Week 36 (W36), Week 48 (W48), and Week 72 (W72).

G1. Record TSH in mU/L. Range is 0.25 to 8.00.

SECTION H. URINALYSIS BY DIPSTICK

Protein and heme results by dipstick should be completed on Form #30 at the following study visits:
- **Randomization phase:** Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).
- **Responder phase:** Week 48 (W48).

H1. Protein: circle one code that corresponds to the amount of protein found in the urine.

H2. Heme: circle one code that corresponds to the amount of heme found in the urine.

SECTION I: PREGNANCY TESTING

Complete this section for female patients. Do not complete this section for male patients.

Pregnancy tests are performed for women of childbearing potential and completed on Form #30 at the following study visits:
- **Lead-in phase:** Baseline (W00) and Week 4 (W04) through Week 24 (W24).
- **Express/Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization phase:** Month 9 (M09) and Month 12 (M12).
- **Responder phase:** Week 30 (W30), Week 36 (W36), Week 42 (W42), and Week 48 (W48).

I1. Pregnancy test:
- Circle "1" if the test was Positive. If positive, consult the DCC for instructions.
- Circle "2" if the test was Negative.
- If the female patient is not of childbearing potential, circle "-1" for Not Applicable.