

## HALT-C Trial Q x Q

### Block Food Questionnaire

Preprinted Questionnaire: Version 98.2

**Purpose of this Questionnaire:** The Block Food Questionnaire is a self-administered form used to collect information about the patient's food intake. It is part of the Risk Factors Ancillary Study.

**When to complete this Questionnaire:** All HALT-C patients should complete The Block Food Questionnaire. The Questionnaire should be completed at the following study visits:

- **Screening Phase patients:** S00 visit.  
The Questionnaire should be handed to the patient at the second screening visit. The patient should be asked to complete the Questionnaire at home and bring to the Baseline visit (W00 or R00).
- **Randomized Phase patients:** Month 18 (M18) visit.  
The Questionnaire can either be:
  1. Handed to the patient at the Month 15 visit (M15) to be completed and returned at the M18 visit.
  2. Mailed to the patient before the M18 visit to be completed and returned at the M18 visit.
  3. Completed at the clinical site during the M18 visit.

NOTE: If the patient fails to complete the Questionnaire for the M18 visit, he/she may complete this Questionnaire up through the end of enrollment in the HALT-C trial.

If a patient will never complete a Block Food Questionnaire, please notify the DCC with a reason for the incomplete Questionnaire. Some acceptable reasons for missing Blocks are "patient withdrew", "patient doesn't speak/read English", or "patient refused".

### **PATIENT IDENTIFICATION**

The Block Food Questionnaire, version 98.2, is a copyrighted form. Therefore, the Questionnaire does not have the same format as the other HALT-C forms. It is an 8-page form printed in black and shaded in blue.

Inserted in the form is a separate black and white sheet, with "Serving Size Choices" pictures to help in filling out the Questionnaire. Please check to make sure that the picture is enclosed.

It is important that before you give the patient this form to fill out, that you write in the Patient ID and Visit Number as described below.

- **Use only a No. 2 pencil to fill out this form.** The clinical site may order pencils from the DCC for this use.
- Record the patient's 6 digit ID number and visit number on the form under 'Respondent ID Number' (see example below)

Respondent ID  
Number

1	2	3	4	5	6		0	0
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- Start by recording the first number of the Patient's ID in the first column on the left side of the form, and record all 6 digits up to the sixth column from the left.
  - The seventh column from the left can be left blank
  - In the right-most two columns, record the visit number. Record either 0 0 for the Screening visit or 18 for the Month 18 visit.
  - Under each number of the patient's ID and the visit number fill in the corresponding circle completely, and erase completely if you make any changes.
- In the box asking to print the patient's name, please write the six digit Patient ID code and underneath it the visit # as S00 or M18. Please write this in pencil and remind the patient that she is not to put her/his name on the Questionnaire.

Please print your name in this box.
Pt ID 123456
Visit # S00

### **PATIENT INSTRUCTIONS**

Instructions for completing the Questionnaire are printed on the food Questionnaire. Review the eight pages of the Food Questionnaire with the patient. The patient should understand the following:

- Use only a No. 2 pencil to fill out the form.
  - No other marks should appear on the Questionnaire. Comments or notes should not be written on the Questionnaire.
  - Fill in the answer bubbles (circles) completely. Do not simply make a checkmark or an 'X' over the bubble.
  - Never mark two bubbles for the same answer—this will result in a missing answer.
  - Do not staple anything to the Questionnaire or use staples on the Questionnaire.
  - Do not insert any extra pages or notes into the Questionnaire
  - Do not fold the Questionnaire.
  - Do not punch holes in the Questionnaire.
- Explain to the patient the importance of completing each question. Explain to the patient the one page portion-size pictures, "Serving Size Choices" to assist with the portion-size section of the form. Review the example on Page 2 of the Questionnaire with the patient.
- If the patient is unable to complete the Questionnaire, it may be administered by patient interview using standard interview technique.

### **RETURNING BLOCK FOOD QUESTIONNAIRE**

When a patient returns a completed Questionnaire, please check to make sure that all the questions were answered. Erase any stray marks. Please return the Questionnaire via FedEx to NERI:

HALT-C Data Coordinating Center  
 New England Research Institutes  
 9 Galen Street  
 Watertown, MA 02472  
 Phone: (617) 923-7747