ID#_____

Date ___ ___ /___ ___ /___ ___ ___ ___

Visit (check one):

SV3 ☐ 4

RI ☐ 5

IFP/I ☐ 6

IFP/II ☐ 7

IFP/III ☐ 8

SYMPTOMS FORM

Below is a list of problems and complaints people sometimes experience. For each item, check the box that best describes how bothersome the problem was for you **during the past month.**

Be sure to check one box on each line. If you did not have the problem, please check the box under "symptom did not occur". If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = symptom did not interfere with usual activities
Moderate = symptom interfered somewhat with usual activities
Severe = symptom was so bothersome that usual activities could not be performed

Symptom	Symptom Did not Occur	Symptom Occurred and was: Mild	Moderate	Severe
1. Fatigue or low energy level	☐ 1	☐ 2	☐ 3	☐ 4
2. Excessive thirst	☐ 1	☐ 2	☐ 3	☐ 4
3. Poor appetite	☐ 1	☐ 2	☐ 3	☐ 4
4. Lightheadedness when standing up	☐ 1	☐ 2	☐ 3	☐ 4
5. Change in taste	☐ 1	☐ 2	☐ 3	☐ 4
6. Stuffy nose	☐ 1	☐ 2	☐ 3	☐ 4
7. Dry mouth	☐ 1	☐ 2	☐ 3	☐ 4
8. Itchy skin or hives	☐ 1	☐ 2	☐ 3	☐ 4
9. Wheezing	☐ 1	☐ 2	☐ 3	☐ 4
10. Diarrhea / loose stools	☐ 1	☐ 2	☐ 3	☐ 4
11. Constipation	☐ 1	☐ 2	☐ 3	☐ 4
12. Bloating / uncomfortably full	☐ 1	☐ 2	☐ 3	☐ 4
13. Nausea or upset stomach	☐ 1	☐ 2	☐ 3	☐ 4
14. Headache	☐ 1	☐ 2	☐ 3	☐ 4

15. Overall, during the past month, I felt (check one)

much worse than usual ☐ 1
worse than usual ☐ 2
the same as usual ☐ 3
better than usual ☐ 4
much better than usual ☐ 5

16. Other symptoms (specify): _____

17. In the past month, have you had any illness that you considered serious or significant (for example, an illness that led to a doctor's visit, new medication, diagnostic tests or hospitalization?

Yes ☐ 1 No ☐ 2

If participant answered yes to question 17, please complete form #12.

Clinician signature _____ Date _____

Reviewed by (staff ID):_____

Entered by (staff ID):_____

Symptoms Form Administration and Coding Instructions

This form is designed to identify individuals who have symptoms that could either interfere with their further participation in the study or be a result of a food borne illness. Any positive responses should be immediately brought to the attention of a staff clinician, who takes whatever action seems appropriate and also signs the form.

Have each participant complete this form at SV3, during Run-In week 2; and at the end (days 24-30) of each of the 3 Intervention feeding periods. Mark the appropriate box in the upper right corner of the form. A clinic staff member should review the form for completeness write their ID number after "Reviewed by Staff ID." The Staff ID # of the person entering the data should be added to the form at the time the data is entered in the computer.

General Coding Instructions

1) Use correct version of form. The correct version will always be on the file server.
2) Use either black or blue pen on all forms, not pencil.
3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
6) Do not obliterate or erase any entry of the respondent.
7) All corrections are made, by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g. RL, 7/30/97, incorrect ID)
8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
9) Check all lead-in questions for correct skip patterns.
10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Symptoms Coding Instructions

ID #: ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date: Enter the date when the form was completed, use leading zeros as appropriate (08/14/1997 represents the date of August 14, 1997). Be sure to use a four-digit year.

Type of Visit: Check whether the appropriate box has been checked to designate when form was completed (at SV3, during Run-in, Intervention feeding period 1, Intervention feeding period 2, or Intervention feeding period 3). Only one box should be marked.

Items 1-14. Symptoms:
Check to make sure only one response was marked for each symptom.

Item 15. Overall, during the past month, I felt:
Check to be sure only one response was marked.

Item 16. Other Symptoms:
If there is a response, make sure that it is legible. Review any other symptoms with clinician.

Item 17. Significant illness in past month:
If response is YES, Serious AE (form #12) must be completed.

Clinician Signature:
Must be filled in if responses to Items 1-14 include 2, 3 or 4
Must be filled in if response to Item 15 is 1 or 2
Must be filled in if there is a response to Item 16
Must be filled in if response to Item 17 is Yes

Date: Date reviewed by Clinician

Reviewed by: Record the Staff ID # of the person reviewing the form.

Entered by: Record the Staff ID # of the person entering the data in the computer.