

BLOCK FOOD FREQUENCY QUESTIONNAIRE (FFQ) AND SUPPLEMENTAL FFQ

1. Purpose:

The primary purpose of the dietary questionnaire is to determine the participant's typical diet so that we can assess the effects of diet on the gut microbiome.

2. Administration of the FFQ & Supplemental FFQ:

Since most sites are sending the FFQ to participants before the clinic visit, it is acceptable if a participant completes the FFQ but declines the stool sample collection at the clinic visit. However, if you already know a participant will decline the stool sample collection, then they do not need to complete the FFQ. It is not required for a participant to complete the FFQ if they do not consent to providing a stool sample.

Prior to administering the FFQ:

- For “Respondent ID Number”, fill in the 4 digits of the participant’s MrOS ID.
- In the box labeled “Please print your name”, write in the participant’s MrOS ID and Acrostic. Do not write the participant’s name.
- Record the Block FFQ ID number on the Microbiome Specimen Collection TELEform. The Block FFQ ID number is located on the bottom of the front page of the FFQ. (When recording the FFQ ID number on the TELEform, start with the first space provided and leave any remaining spaces at the end blank (if FFQ ID is less than nine digits). Do not write any zeros.)

Completing the FFQ:

- Tell the participant to fill in “Today’s Date” with the date they completed the FFQ. If the FFQ is returned without the date completed, follow-up with the participant and ask them for the date they filled out the FFQ.
- If the participant will complete the questionnaire before Visit 4, remember to send the instructions on how to complete it, along with the portion sizes page and Supplemental FFQ TELEform.
- If the participant completes the FFQ and Supplemental FFQ at home and brings these to his Visit 4 clinic visit, please go over the questionnaire to clarify missing, unusual answers and inconsistencies with the participant. This includes identical answers for several consecutive questions. Please clarify to make sure the participant thought about each question before answering.
- If the participant is given the FFQ (along with the Supplemental FFQ, instructions, and portion sizes page) at the end of Visit 4 to take home and complete, during the clinic visit, please go over the instructions on how to complete the FFQ correctly, and answer any questions he may have. Explain to the participant how to mail the FFQ back to your site. It is suggested that completed questionnaires be reviewed for any missing answers or inconsistencies when they are received.

2.2. Specific issues for MrOS

Instructions for participants

MrOS participants will be given a separate instructions sheet (see Appendix A), telling them how to complete the questionnaire. Specific instructions will include:

- time frame covered by questionnaire
- #2 pencil
- filling in the circle
- multivitamin skip routine
- completeness
- seasonality
- results
- other general instructions

Filling in the circles

Participants will be asked to fill in the bubble as completely as they can. If necessary, the clinic staff should finish completely filling in the bubble.

Never eats a particular food

- If a participant says that they "Never" eat a food, the interviewer should not even mention portion size, but simply leave the portion size response blank.
- If a participant says that they rarely eat a food, the interviewer should ask whether this means "A few times per year." If the answer is "Yes", then staff should ask the follow-up question regarding portion size. If "No", interviewer should mark the frequency as "Never."
- If a participant says that they "don't know" if they eat a food, the response should be left blank.
- For questions with "Not Applicable (N/A)" as an option, items should only be marked "N/A" if they do not eat the food. If they "don't know" if they eat a food, the item should be left blank.

Multivitamin questions

If a participant has not taken any vitamins regularly over the past year, then he should skip the questions about vitamins.

Descriptions of specific food items

NutritionQuest has provided us with instructions for completing the questionnaire that includes description of each specific food item. These instructions are included as part of the FFQ protocol. Please realize that the food descriptions are merely to help you if a participant has a specific question. Do not worry about whether the participants fill out the form with the correct descriptions in mind (this would be almost impossible to do without incredible burden). Refer to the description if a specific question comes up.

Do not fold the questionnaire.

Participants should be informed not to fold the questionnaire.

2.3. General dietary protocol instructions

The dietary questionnaire includes questions about the usual eating habits of the participant over approximately the past year. The time frame is meant to be a little vague. It is not expected that a participant will be able to remember exactly what he ate during the past year. Rather, the idea is to establish a usual pattern - his current diet at this point in his life. A respondent may object that he "can't remember what I ate yesterday; how could I tell you what I ate in the past year?" Make clear that the idea is not to remember exactly, but to think about the usual pattern or frequency. He does not have to remember how many times he had eggs in the past year. Instead, what he should be able to tell you with reasonable accuracy is that he has eggs "about twice a week."

If parts of the dietary questionnaire are incomplete, ask the participant if he had difficulty answering these questions, and try to find out the nature of the difficulty. This will help focus the explanation of what information is needed from the participant.

2.3.1. Food Frequencies

Foods that are eaten rarely or never should be recorded as such and not skipped over. The serving size should be left blank.

When two or more foods are included in the same category, i.e., "bread, rolls, crackers," they are to be thought of altogether, i.e., "subject eats bread or rolls or crackers 2 or 3 times every week." In situations where one food in the category is eaten very frequently, i.e., bread twice a week, and the other very infrequently, i.e., crackers twice a year, then record the frequency for the one eaten more often.

If a participant eats a food much more frequently at one time of the year than another, you may need to calculate a weighted average of their consumption. If the participant leaves questions unanswered because he is confused about how to calculate answer, please help him complete the answer.

For example: If he drank milk 7 times a week during the four winter months (hot chocolate), but only 3 times a week during the rest of the year, multiply 7 (times a week) x 4 (weeks per month) x 4 (months) = 112 times. Then multiply 3 (times a week) x 4 (weeks per month) x 8 (months) = 96 times. Add the two (112 + 96 = 208 times during the year). To get an average frequency, you can then divide 208 (times per year) by 52 (weeks per year), which gives about 4 times per week. Record the response category as 3-4 times per week as the average frequency.

Similarly, if a participant eats hot cereal 2 times a week for 6 months only, then this is 1 time a week for the past 12 months.

If the participant says that the frequency "varies" unsystematically from time to time, ask them to choose an average. For example, say: "If you had to choose just one pattern as typical for you, how often would you say you eat [FOOD]?"

For answers on vitamins and minerals taken, if the amount given is not an option on the FFQ, please mark the response closest to the lower amount of the coded amounts.

2.3.2. Serving Size

Some serving sizes are obtained by comparison with quantities labeled A, B, C & D. Pictures should be used to illustrate the portion sizes.

A respondent who checks the same serving size for every food may not be thinking very hard about his answers. The interviewer should query him about the portion sizes to see if the portion size checked is really his best estimate. However, it is not uncommon for most (e.g. 70%) of portion sizes even in a well thought through questionnaire to be the same (usually medium sizes). Only if ALL the portion sizes are the same is there any cause for concern.

See Appendix B for pictures of portion sizes.

2.3.3. Do not expand the categories to include similar foods, e.g., cheese and cheese spreads do not include cottage cheese, because cottage cheese has a lower calcium content per serving. As another example, egg whites are not equivalent to whole eggs, because the whites of large eggs have only 3 mg of calcium while the yolks have about 27 mg of calcium.

Certain foods that are very similar to the food on the list, and have the about the same calcium content, such as nonfat dairy products, can be included. These foods are limited to the following:

Dairy products:

- Low-fat cheese can be included with "cheeses" (Nonfat cheese should not be included as the calcium content may differ greatly from other cheeses).
- Nonfat milk can be included with "milk"
- Nonfat yogurt and frozen yogurt can be included with "yogurt"

Breads:

- Diet breads can be included with "breads"

Sweets:

- Ice milk (194 mg calcium per cup) can be included with "ice cream" (204 mg calcium per cup)

2.3.4. Summary review of diet questionnaire

Review the questionnaire for omissions (skipped foods, missing information) and other special problems. All frequencies should be filled in. Portion size should be completed for all foods except those eaten rarely or never.

Check for unreasonable frequencies (i.e., corn every day) and verify them with the participant.

If the answers are all the same (i.e., all "1 time per day" or all the same serving size) go over each answer with the participant until it can be determined that the answers are valid.

Check to be sure that milk has not been double counted. Milk poured on cereal should not be double counted as milk consumed as a beverage, and vice versa.

2.3.5. Block FFQ Instructions

For further instructions on completing the Block FFQ, refer to the *MrOS Food Frequency Questionnaire Instructions for Interviewers*.

3. Shipments / Data system

All Supplemental FFQ TELEforms should be submitted to the data system with all other Visit 4 forms. All completed Block FFQs should be kept at the clinical sites until the end of Visit 4. At the end of Visit 4, all sites should mail completed FFQs to:

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3181 SW Sam Jackson Park Road, CR113
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Appendix A: Participant Instructions Sheet

Completing the MrOS Brief Food Questionnaire

Some guidelines for completing the food questionnaire

- Please use a #2 (soft lead) pencil to complete the questionnaire.
- Handling the questionnaire booklet: Do not insert any extra sheets of paper or put sticky notes on its pages. Do not punch holes in the booklet or staple it. And, do not fold the questionnaire booklet ready to return it.
- Fill in the answer bubbles completely. Do NOT make a checkmark or an 'X' over the bubble.
- When answering a question about how often or how much was eaten, do not mark two bubbles to answer one question. If there are two answers, both will be ignored by the computer scoring.
- If you have comments, please write them on a separate sheet of paper. Do not write any comments or notes on the questionnaire form.
- The "Respondent ID Number" should already have been filled in. You do not need to write your name in the box on page 1.

IMPORTANT: Please carefully read instructions on the first page of the food questionnaire and look for the enclosed sheet showing serving size choices

This form asks about your *usual eating habits in the past year or so*, including all meals or snacks, at home or in a restaurant or carry-out. The foods listed may not include all of the foods you eat. Please just do your best to answer how often and how much you eat of the foods listed. Don't worry about answering for foods you eat but which are not listed.

There are two kinds of questions to answer for each food.

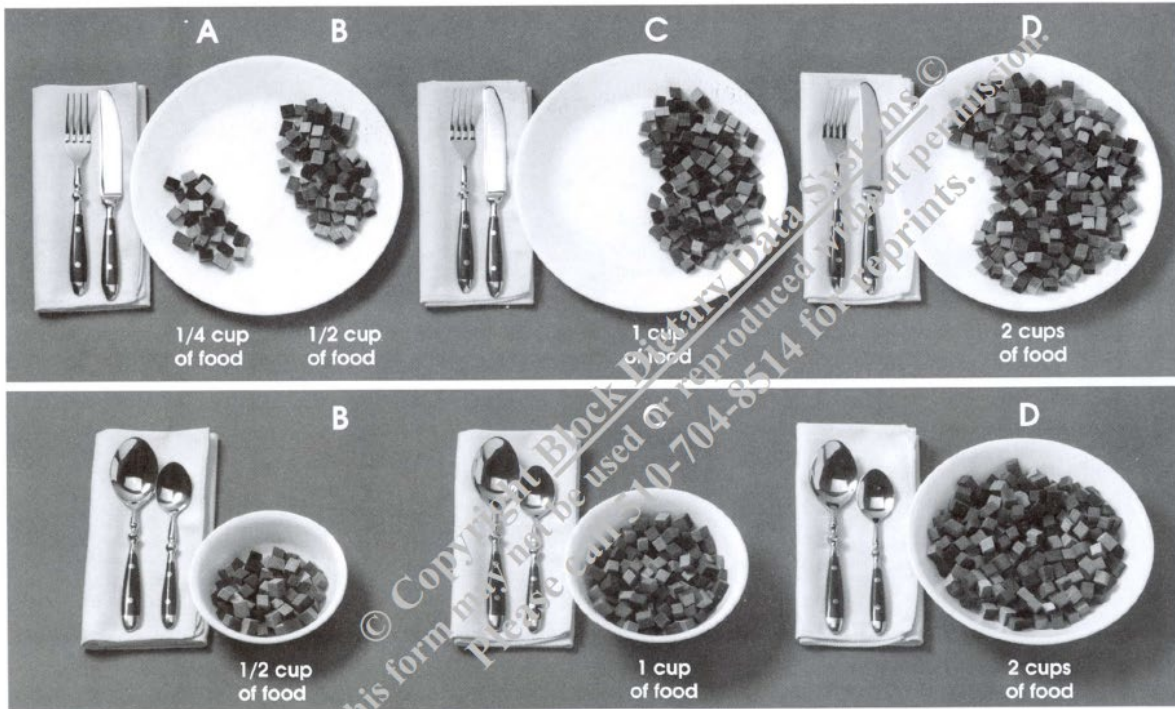
1. **HOW OFTEN**, on average, did you eat the food during the past year?" Choose the answer most closely matching your eating habits. If you are not sure, just make your best estimate. Fill in the bubble for that answer completely.
2. "**HOW MUCH** did you usually eat of the food when you ate it?" Sometimes the form asks how many you eat each time (such as 1 egg, 2 eggs, etc.). Sometimes it asks how much in terms for serving size. For help in answering, please refer to the serving size choices shown in the pictures and labeled at A, B, C, and D.

Appendix B: Portion Sizes

FOOD QUESTIONNAIRE
Serving Size Choices

Keep this in front of you while you are filling out The Food Questionnaire. You may use either the plates or the bowls to help you choose your serving size.

Choose A, B, C or D: **A** = 1/4 Cup of Food **B** = 1/2 Cup of Food **C** = 1 Cup of Food **D** = 2 Cups of Food



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