Manual of Procedures (MOP)
Section 10. Questionnaires

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10.1 INTRODUCTION

Participant physical activity and food intake will be assessed using the International Physical Activity Questionnaire (IPAQ) and the Multicultural Food Frequency Questionnaire (FFQ) respectively. Training on the administration of these questionnaires will take place at the investigators meeting, and during site visits or via webinars, as needed.

10.2 PHYSICAL ACTIVITY QUESTIONNAIRE

The long version of the IPAQ will be used to collect data on physical activity. The IPAQ is a validated questionnaire that covers 5 activity domains and asks questions related to physical activities participants did during the prior 7 days.

Participants will complete the IPAQ at:

- Baseline
- M06 visit
- Annual visits (M12, M24, M36, and M48)

The questionnaire is available in many languages. The D2d study will use the English and Spanish versions, which are found in the Appendix. If a site needs the IPAQ in additional languages, it needs to contact the D2d Coordinating Center (CC) at D2d@tuftsmedicalcenter.org.

10.2.1 IPAQ instructions for staff

✓ Sites need to make copies for use. The site research staff should ensure they have a supply of questionnaires available prior to participant visits.

✓ Prior to asking the participant to complete the IPAQ, the research staff will complete the document header, entering the participant's enrollment ID, name, date of completion, and visit on each page.

✓ The participant will self-administer the questionnaire on paper.

⇒ If the participant is unable to self-administer the form (e.g., due to illiteracy or vision problems), the Research Coordinator or designee may administer the questionnaire by using the Telephone IPAQ version. The rationale for using the Telephone IPAQ must be recorded in the source documents.

✓ If the participant is concerned about not remembering her physical activity over the last 7 days, acknowledge her concerns and encourage her to recall to the best of her ability.

✓ Do not assist the participant with deciding the response to questions. The participant should answer questions independently and the study staff should not assist the participant in deciding the responses to the questions. However, for certain participants, it may be helpful to read the instructions at the top of the questionnaire (first 2 paragraphs) prior to handing them the questionnaire to make sure the participant is clear about the definition of moderate and vigorous activity.

- ✓ Always review the questionnaire for completion while the participant is in the clinic to ensure that all questions are answered.

- ✓ After the IPAQ is completed, research staff will transcribe the responses into the EDC system. Refer to MOP section 15 for specific instruction on entering the date into EDC.

10.2.2 IPAQ instructions for participants

A clear, positive introduction and explanation of the questionnaire is extremely important to obtaining valid information from the IPAQ questionnaire. Such information will also allow the participant to complete the form with minimal frustration.

- ✓ Prior to giving the participant the questionnaire, research staff will tell the participant the following:

"As an important part of this study, we are asking you to complete the International Physical Activity Questionnaire. The questionnaire is designed to measure your physical activity over the last 7 days. Physical activity occurs throughout a day in many different forms. The questionnaire measures different types of physical activity. For the form to be valuable, it must be completed carefully and accurately. It will take you between 5 and 15 minutes to complete the form".

- ✓ Research staff will:

  - o Instruct the participant to answer all questions as best he can. An estimate is better than leaving a question blank.
  - o Instruct the participant to answer the questions in the order shown.
  - o Let the participant know that the amount of time spent on an activity can be answered in hours only, minutes only or a combination of both.

    Example 1: if you walked vigorously for 1 and ½ hours, the form can be completed in the following two ways:

_1_ hours per day 30 minutes per day	or	__ hours per day 90 minutes per day

    Example 2: If you walked vigorously for 1 hour, the form can be completed in the following two ways:

_1_ hours per day __ minutes per day	or	__ hours per day 60 minutes per day

  - o Instruct the participant to answer the questions in the order shown.

10.3 FOOD FREQUENCY QUESTIONNAIRE

The FFQ will be used to collect data on nutrient and caloric intake during the *prior 12* months.

Participants will complete the FFQ at:

- Baseline
- M12 visit in participants free of diabetes
- M36 visit in participants free of diabetes

The FFQ is available in English and Spanish and samples can be found in the Appendix.

10.3.1 FFQ instructions for staff

The FFQ will be self-administered on paper using the forms supplied by the CC.

✓ The CC will provide the actual FFQ forms to the sites in either language based on the sites' projected needs. <u>These forms cannot be copied.</u>

✓ Sites will monitor their supply to ensure that there is always a sufficient supply of English and Spanish forms to last at least 6 weeks. If additional forms are needed, the site should contact the CC to request more forms.

✓ A Food Booklet accompanies the FFQ. The booklet (provided in the Appendix) provides a visual representation of different measures (e.g. teaspoon versus tablespoon) and food portion sizes. The booklet should be provided to the participant and the participant will be instructed to use it as a reference. The site may print out additional copies or laminate a copy for use.

✓ If the participant is unable to read the form (e.g. due to illiteracy or vision problems), the Research Coordinator or designee may help the participant complete the questionnaire by reading the questions and response options. The reason for conducting an interviewer administered FFQ must be recorded in the source documents.

✓ If the participant is concerned about not remembering her overall diet over the last year, acknowledge her concerns and encourage her to recall to the best of her ability.

✓ Provide the participant with the questionnaire and a No. 2 pencil with an eraser.

✓ After the participant has finished completing the form, review the questionnaire for completion while the participant is in the clinic to ensure that all questions are answered.

- If a question was not answered, ask the participant to answer it.
- If a question appears to have 2 answers (2 bubbles filled in for one question), have the participant correct it.
- Look for stray marks or incomplete erasing. If found, ensure they are completely erased.

10.3.1.1 Form Management and Completion

- ✓ Prior to asking the participant to complete the FFQ, the research staff will complete the first page of the questionnaire, and the top of page 2 as shown below.
    - Write neatly.
    - Use all uppercase letters, in block style.
    - Do not use cursive or “fancy” letters.

- ✓ The form must be completed using a **No. 2 pencil**. The form is read by an optical scanner, which will not recognize any ink; therefore, a pen should NOT be used. If the respondent completes the questionnaire in ink, the response must be covered with pencil.

- ✓ Do not apply any tape, staple or hole punch to any part of the form or use a questionnaire that is damaged. If the form is torn, it will not be accepted by the scanner and will need to be transcribed onto another form.

- ✓ Please erase all stray marks. The scanner is very sensitive and will pick up any leftover erasure material and count it as duplicate.

- ✓ Completed FFQs will be shipped to the CC twice a year.

10.3.1.2 Instructions for completing page 1 and 2 of FFQ

Complete page 1 of FFQ as follows:

Study name: *D2d Study*

Participant Name: **do not record** the participant name. These forms will be sent to the CC for analysis. *Record your site name (i.e. Tufts Medical Center)*

Today' Date: *record the date of the visit*, and fill in the corresponding bubbles below.

Protocol Number: leave blank

Visit Number: *record the visit month* as follows:
00 = baseline visit
12 = month 12 visit
36 = month 36 visit
Fill in the corresponding bubbles

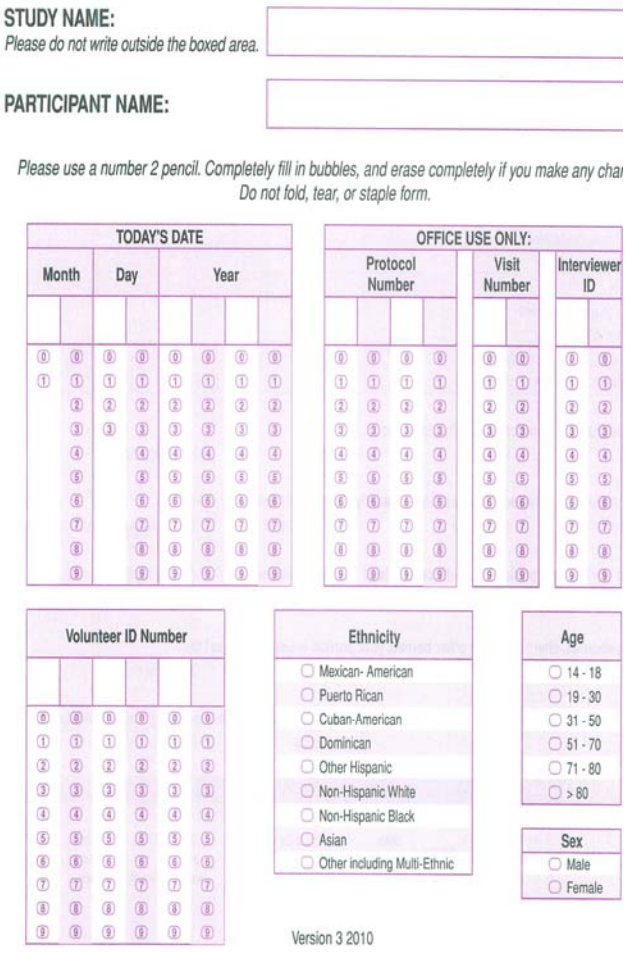
Interviewer ID: leave blank

Volunteer ID Number: enter the *participant's 6-digit enrollment ID*. Fill in the corresponding bubbles.

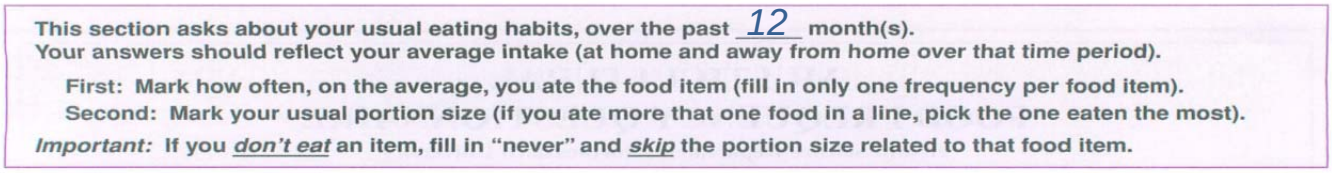
Ethnicity: leave blank

Age: select the correct age range for the participant and fill in the bubble.

Sex: Fill in the bubble for the participant's sex.



At the top of page 2 of the FFQ, record the number "12" on the line.



10.3.2 FFQ instructions for participant

A clear, positive introduction and explanation of the questionnaire is extremely important to obtaining valid information from the FFQ. Such information will allow the participant to complete the form with minimal frustration.

✓ Prior to giving the participant the questionnaire, research staff will tell the participant the following:

"As an important part of this study, we are asking you to complete a food frequency questionnaire. The questionnaire is designed to measure your dietary patterns over the last year. For the form to be valuable, it must be completed carefully and accurately. It will take you between 20 and 40 minutes to complete the form."

✓ Instruct the participant to:
- Answer all questions as best he can. An estimate is better than leaving a question blank.
- Answer the questions in order.
- Completely fill in the bubble in the circle, and only fill in one bubble per question.
- Skip the food in the portion question, if the food is never eaten.

✓ After giving the participant the FFQ, read the instructions at the top of page two to the participant, emphasizing that the questionnaire is referring to their usual eating habits over the past *12 months*. Where it says "First: Mark how often, on the average, you ate the food item" point out the frequency table. Where it says "Second: Mark your usual portion size" point out the questions below the frequency table.

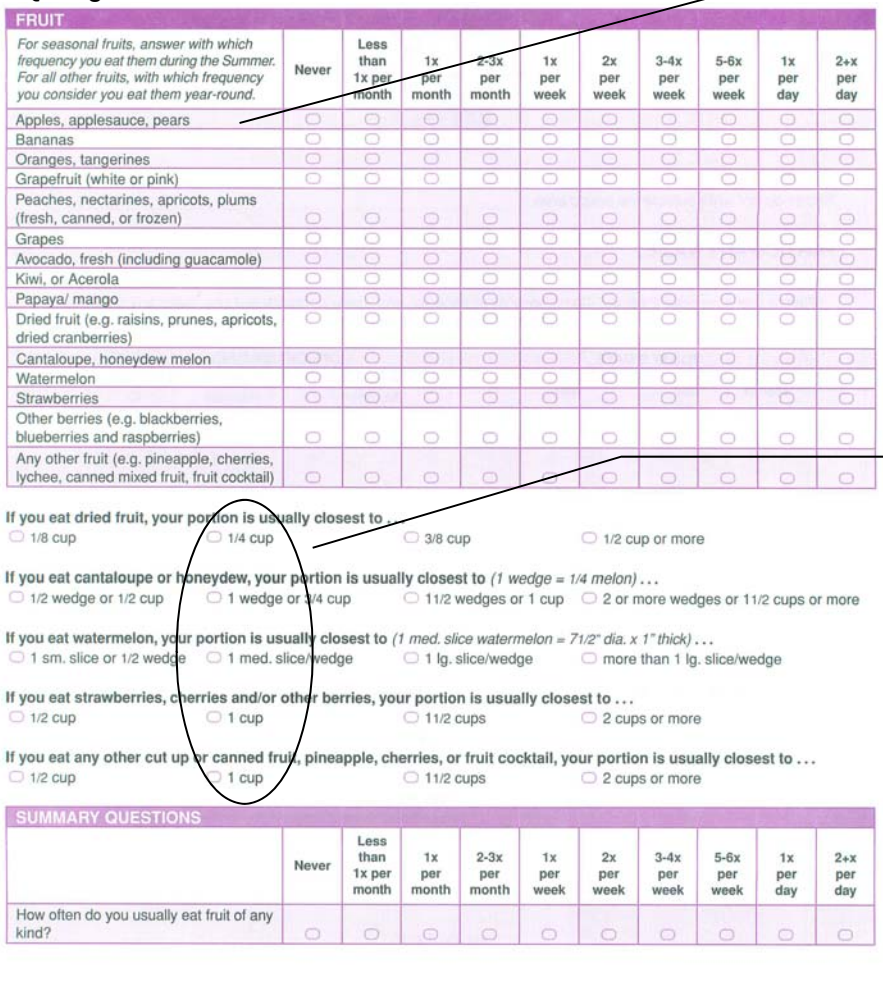
✓ Point out the section instructions at the top left hand corner of the frequency table.

✓ Participants *do not* need to complete the supplements section.

10.3.3 FFQ completion tips

Note: not all FFQ pages are included here.

FFQ Page 2



FRUIT

For seasonal fruits, answer with which frequency you eat them during the Summer. For all other fruits, with which frequency you consider you eat them year-round.	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Apples, applesauce, pears	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Bananas	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Oranges, tangerines	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Grapefruit (white or pink)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Peaches, nectarines, apricots, plums (fresh, canned, or frozen)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Grapes	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Avocado, fresh (including guacamole)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Kiwi, or Acerola	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Papaya/ mango	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dried fruit (e.g. raisins, prunes, apricots, dried cranberries)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cantaloupe, honeydew melon	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Watermelon	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Strawberries	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other berries (e.g. blackberries, blueberries and raspberries)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Any other fruit (e.g. pineapple, cherries, lychee, canned mixed fruit, fruit cocktail)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you eat dried fruit, your portion is usually closest to ...
☐ 1/8 cup ☐ 1/4 cup ☐ 3/8 cup ☐ 1/2 cup or more

If you eat cantaloupe or honeydew, your portion is usually closest to *(1 wedge = 1/4 melon)* **...**
☐ 1/2 wedge or 1/2 cup ☐ 1 wedge or 3/4 cup ☐ 11/2 wedges or 1 cup ☐ 2 or more wedges or 11/2 cups or more

If you eat watermelon, your portion is usually closest to *(1 med. slice watermelon = 71/2" dia. x 1" thick)* **...**
☐ 1 sm. slice or 1/2 wedge ☐ 1 med. slice/wedge ☐ 1 lg. slice/wedge ☐ more than 1 lg. slice/wedge

If you eat strawberries, cherries and/or other berries, your portion is usually closest to ...
☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups ☐ 2 cups or more

If you eat any other cut up or canned fruit, pineapple, cherries, or fruit cocktail, your portion is usually closest to ...
☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups ☐ 2 cups or more

SUMMARY QUESTIONS

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
How often do you usually eat fruit of any kind?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

- 2 -

If the participant only eats one of the food items, fill in the frequency for that one food. If the participant eats more than one of the food items, select the frequency of the food with the highest frequency of consumption.

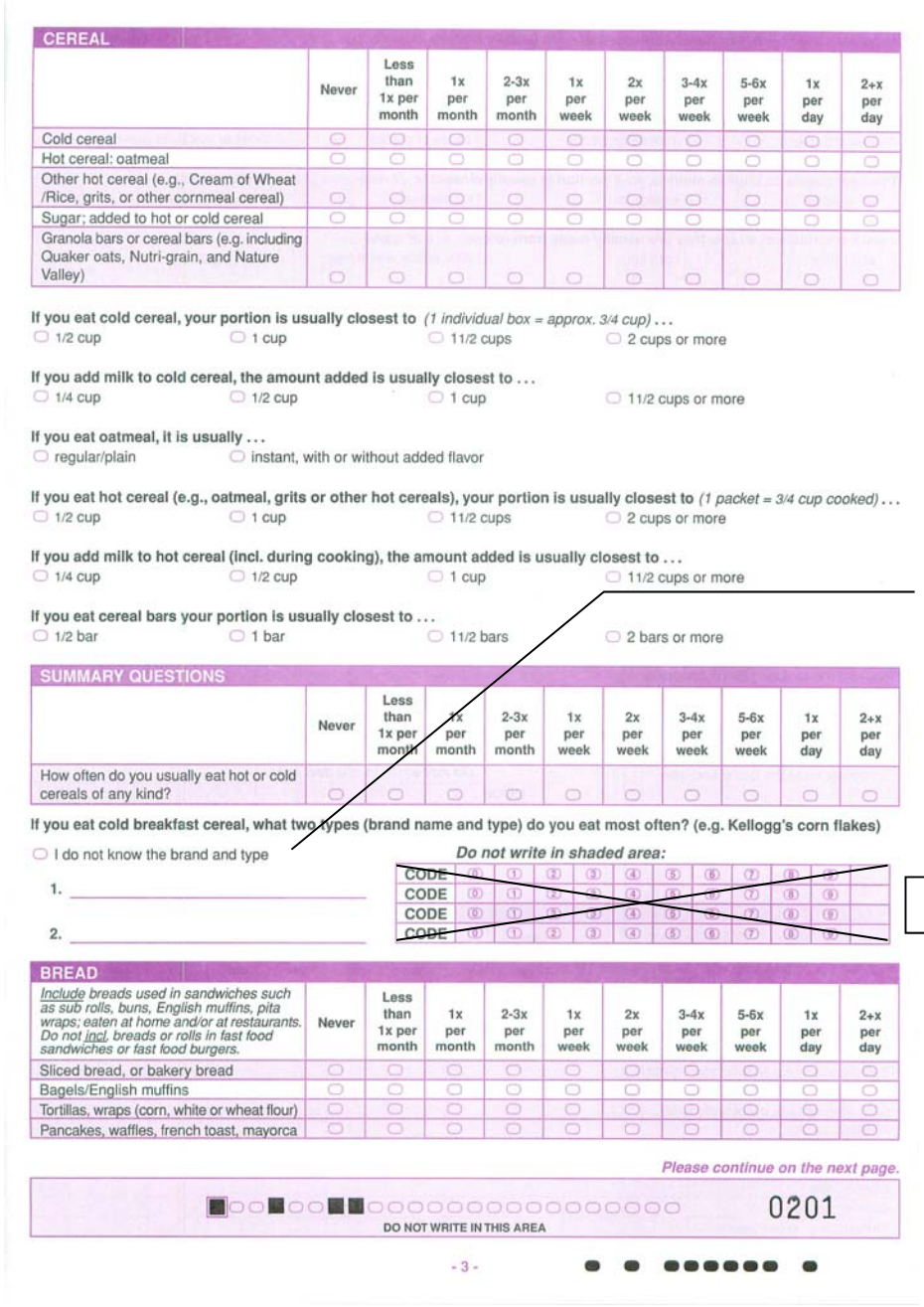
Only *one* answer should be selected for each frequency table line.

Second column is medium serving.

Only *one* answer should be selected for each portion size question *unless* it says otherwise (i.e. "choose all that apply" or "select one or two only").

***Extremely important to complete – these questions take into account if there is any over or under estimation in the frequency table selections.

FFQ Page 3



CEREAL

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Cold cereal	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hot cereal: oatmeal	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other hot cereal (e.g., Cream of Wheat /Rice, grits, or other cornmeal cereal)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sugar; added to hot or cold cereal	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Granola bars or cereal bars (e.g. including Quaker oats, Nutri-grain, and Nature Valley)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you eat cold cereal, your portion is usually closest to *(1 individual box = approx. 3/4 cup)* . . .
☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups ☐ 2 cups or more

If you add milk to cold cereal, the amount added is usually closest to . . .
☐ 1/4 cup ☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups or more

If you eat oatmeal, it is usually . . .
☐ regular/plain ☐ instant, with or without added flavor

If you eat hot cereal (e.g., oatmeal, grits or other hot cereals), your portion is usually closest to *(1 packet = 3/4 cup cooked)* . . .
☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups ☐ 2 cups or more

If you add milk to hot cereal (incl. during cooking), the amount added is usually closest to . . .
☐ 1/4 cup ☐ 1/2 cup ☐ 1 cup ☐ 11/2 cups or more

If you eat cereal bars your portion is usually closest to . . .
☐ 1/2 bar ☐ 1 bar ☐ 11/2 bars ☐ 2 bars or more

SUMMARY QUESTIONS

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
How often do you usually eat hot or cold cereals of any kind?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you eat cold breakfast cereal, what two types (brand name and type) do you eat most often? (e.g. Kellogg's corn flakes)

☐ I do not know the brand and type

1. _____

2. _____

Do not write in shaded area:

CODE CODE CODE CODE

BREAD

Include breads used in sandwiches such as sub rolls, buns, English muffins, pita wraps; eaten at home and/or at restaurants. Do not incl. breads or rolls in fast food sandwiches or fast food burgers.	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Sliced bread, or bakery bread	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Bagels/English muffins	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tortillas, wraps (corn, white or wheat flour)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pancakes, waffles, french toast, mayorca	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please continue on the next page.

0201

DO NOT WRITE IN THIS AREA

- 3 -

Have the participant include both the *brand* and *type* of the two cereals they consumed most often in the past year (i.e. not just "corn flakes" but "Kellogg's Corn Flakes").

Leave blank.

FFQ Page 4

If you eat sliced breads or bakery breads, these are usually *(choose all that apply)* . . .

○ white (includes bakery bread) ○ multi-grain/cracked wheat (light brown) ○ 100% whole wheat (dark brown) ○ rye ○ other

If you eat sliced bread, your portion is usually closest to . . .

○ 1 slice or piece ○ 2 slices or pieces ○ 3 slices or pieces ○ 4 slices or pieces or more

If you eat bagels or English muffins, your portion is usually closest to *(1 medium = Dunkin Donuts bagel)* . . .

○ 1/2 medium ○ 1 medium ○ 11/2 medium ○ 2 medium or more

If you eat tortillas or wraps, they are usually made from *(choose all that apply)* . . .

○ white flour ○ corn flour ○ 100% whole wheat flour ○ unknown type

If you eat tortillas or wraps, your portion is usually closest to *(1 medium = 8" diameter)* . . .

○ 1 medium ○ 2 medium or 1 large ○ 3 medium ○ 4 medium or 2 large or more

If you eat pancakes, waffles, french toast or mayorca, your portion is usually closest to *(1 pancake/waffle = 4" diameter)* . . .

○ 1 pancake, waffle or slice of french toast or less ○ 2 pancakes, waffles or slices of french toast ○ 3 pancakes, waffles or slices of french toast ○ 4 pancakes, waffles or slices of french toast or more

If you add butter or margarine to breads, bagels and/or pancakes, your portion per slice/piece is usually *(1 tsp = 1 pat)* . . .

○ 1/2 pat ○ 1 pat ○ 11/2 pats ○ 2 pats or more

If you add cream cheese to breads and/or bagels, your portion per slice/piece is usually . . .

○ 1 tablespoon ○ 2 tablespoons ○ 3 tablespoons ○ 4 tablespoons or more

SUMMARY QUESTIONS

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
How often do you usually eat breads of any kind (not including tortillas, pancakes, waffles or french toast)?	○	○	○	○	○	○	○	○	○	○

If you eat sliced breads, what two types (brand name and type) do you eat most often? (e.g. Wonder, whole wheat)

○ I do not know the brand and type

1. _____
2. _____

Participant does not need to complete.

Do not write in shaded area:

CODE 0 1 2 3 4 5 6 7 8 9

CODE 0 1 2 3 4 5 6 7 8 9

CODE 0 1 2 3 4 5 6 7 8 9

CODE 0 1 2 3 4 5 6 7 8 9

Leave blank.

VEGETABLES

If you eat garden or other salads, mark the individual vegetables in their separate line items (e.g. mark lettuce in "Salad greens" and tomato in "Tomatoes"). For toppings such as chicken, feta, egg or olives, include in their corresponding food group section (e.g. include chicken pieces in "Poultry" section).	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Salad greens (e.g. lettuce, raw spinach, mixed greens)	○	○	○	○	○	○	○	○	○	○
Cooked greens (e.g. spinach, kale, mustard, turnip)	○	○	○	○	○	○	○	○	○	○
Tomatoes, including canned	○	○	○	○	○	○	○	○	○	○
Mixed vegetables (frozen, fresh, or canned)	○	○	○	○	○	○	○	○	○	○
Carrots, raw	○	○	○	○	○	○	○	○	○	○
Carrots, cooked	○	○	○	○	○	○	○	○	○	○
String beans, green beans	○	○	○	○	○	○	○	○	○	○

Refers only to the lettuce or uncooked greens --- all other ingredients of salad should be listed separately

FFQ Page 7

SUMMARY QUESTIONS

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
How often do you usually eat beans and starchy vegetables prepared any way?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

RICE, PASTA AND PIZZA

If you eat pasta with meatballs, include the pasta in this section and the meatballs in the section "Beef, Pork, and Lamb" under the section "ground beef."	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Rice cooked with beans or pigeon peas (mixed dish)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Rice with chicken, meat, and/or sausage (mixed dish)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other mixed dishes with rice (incl. seafood)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fried rice (incl. Chinese style)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Flavored rice (e.g. Rice-a-Roni, Spanish, rice pilaf)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Plain white rice	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Plain brown rice	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Plain parboiled or converted rice (e.g. Uncle Ben's)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pasta (e.g. spaghetti, macaroni, linguini)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pasta mixed dishes (e.g. lasagna, ravioli, baked ziti)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lo mein or rice noodles (incl. Chinese style)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Macaroni salad, pasta salad	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Mexican foods (e.g. burritos, tacos, tamales, enchiladas)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pizza	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Eggrolls, "empanadillas", meat pies, or other fritters	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If a mixed dish is not listed specifically in the FFQ, the food must be separated into its respective ingredients and included that way.

If you eat mixed dishes made with rice, you usually prepare it *(choose all that apply)* **...**
☐ Latino/Puerto Rican style ☐ Southern/Cajun style ☐ Haitian style ☐ other

When you eat mixed rice dishes, it is usually made with ...
☐ white rice ☐ brown rice ☐ parboiled rice

If you eat mixed dishes made with rice, your portion is usually closest to ...
☐ 1 cup ☐ 2 cups ☐ 3 cups ☐ 4 cups or more

If you eat plain, fried or flavored rice, your portion (cooked) is usually closest to ...
☐ 1/2 cup ☐ 1 cup ☐ 1 1/2 cups ☐ 2 cups or more

If you eat pasta, they are usually made from ...
☐ white flour ☐ 100% whole wheat flour ☐ a whole wheat blend (e.g. Ronzoni Healthy Harvest)

If you eat pasta or mixed pasta dishes (e.g., lasagna), your portion is usually closest to ...
☐ 1 cup ☐ 2 cups ☐ 3 cups ☐ 4 cups or more

What type of sauce do you usually eat with your pasta *(choose all that apply)* **...**
☐ plain (no sauce) ☐ butter and/or olive oil ☐ tomato sauce ☐ tomato and meat sauce
☐ clam sauce ☐ pesto sauce ☐ cream sauce ☐ cheese sauce (e.g., macaroni and cheese)

DO NOT WRITE IN THIS AREA 0201

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RICE, PASTA AND PIZZA *(continued)*

If you eat macaroni salad or pasta salad, your portion is usually closest to . . .
☐ 1/2 cup ☐ 1 cup ☐ 1 1/2 cups ☐ 2 cups or more

If you eat Mexican foods, they are usually *(choose all that apply)* **. . .**
☐ burritos ☐ tacos ☐ tamales ☐ enchiladas ☐ quesadillas

If you eat Mexican foods (incl. burritos, tacos, tamales, enchiladas), your portion is usually closest to . . .
☐ 1 each ☐ 2 each ☐ 3 each ☐ 4 each or more

If you eat pizza, it is usually . . .
☐ plain cheese ☐ with meat ☐ with vegetables ☐ with vegetables and meat

If you eat pizza, your portion is usually closest to *(1 slice = 1/8 of a large pizza)* **. . .**
☐ 1 slice ☐ 2 slices ☐ 3 slices ☐ 4 slices or more

If you eat eggrolls and/or empanadillas, meatpies or fritters, your portion is usually closest to . . .
☐ 1 each ☐ 2 each ☐ 3 each ☐ 4 each or more

SUMMARY QUESTIONS

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
How often do you usually eat rice of any kind prepared in any way?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

BEEF, PORK AND LAMB

If you eat rice and beef/pork dishes, include them in the "Rice, Pasta and Pizza" section (not this section). For homemade burgers, include the meat in this section, and include the bun or roll in the "Bread" section. For fast food burgers, include the whole item in this section.	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Fast food burgers	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ground beef (including homemade beef patty, meatballs, and/or meatloaf)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Mixed dishes with beef (e.g. beef stew, pot pies)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Beef: steak or roast	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Pork: chops or roast	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Mixed dishes with pork	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ham (not including cold cuts/ luncheon meat)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Ribs: beef or pork	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lamb	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Liver (beef)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other organ meats (e.g. tongue, kidney, chitterlings, "cuajito" and "gandinga" dishes)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you eat fast food burgers, they are usually . . .
☐ regular single burger ☐ double or 1/4 pound burger ☐ Whopper ☐ Big Mac
☐ cheese burger ☐ double or 1/4 pound burger w/cheese ☐ Whopper w/cheese

If you eat homemade patties and/or ground beef or pork (incl. meatloaf), the meat is usually . . .
☐ regular ☐ lean ☐ extra lean

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Only include meats that are beef entrees – mixed dishes should be listed under "Rice, Pasta, and Pizza."

Make sure participant only selects one (ex. if the participant typically eats cheese burgers, make sure they fill in only "cheese burger" and not also "regular single burger" – questionnaire respondents tend to pick two if they eat their burgers with cheese).

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CONDIMENTS *(continued)*	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Sweet & sour sauce, duck sauce	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Salsa (Mexican style)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hot peppers (e.g. jalapeño)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Green tomato or green chile sauce	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Gravy or white sauce (on meat, potatoes, rice and/or biscuits)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Lemon, lime: wedge or juice	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Herbs, fresh or dried (e.g. cilantro)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cinnamon	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
"Adobo"	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you use mayonnaise or mayoketchup, it is usually . . .
☐ regular ☐ reduced fat/ light ☐ fat free

If you use mayonnaise or mayoketchup, your portion is usually closest to . . .
☐ 1 tablespoon ☐ 2 tablespoons ☐ 3 tablespoons ☐ 4 tablespoons or more

If you use salad dressing, it is usually . . .
☐ creamy ☐ clear ☐ both

If you use salad dressing, it is usually . . .
☐ regular ☐ reduced fat/ low calorie ☐ fat free

If you use salad dressing, your portion is usually closest to . . .
☐ 1 tablespoon ☐ 2 tablespoons ☐ 3 tablespoons ☐ 4 tablespoons or more

If you use sauces, ketchup, mustard and/or relish, your portion is usually closest to . . .
☐ 1 tablespoon ☐ 2 tablespoons ☐ 3 tablespoons ☐ 4 tablespoons or more

If you use salsa (Mexican style), hot peppers and/or duck sauce, your portion is usually closest to . . .
☐ 1 tablespoon ☐ 2 tablespoons ☐ 3 tablespoons ☐ 4 tablespoons or more

If you use gravy or white sauce, your portion is usually closest to . . .
☐ 1/4 cup ☐ 1/2 cup ☐ 3/4 cup ☐ 1 cup or more

If you cook with garlic and/or herbs, you use mostly . . .
☐ fresh ☐ dried ☐ both

SOUP *If you eat beef stew, include in the "Beef, Pork and Lamb" section (not this section). If you eat chicken stew, include in the "Poultry" section (not this section).*	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
New England clam, cream-based fish chowder, or tomato-based Manhattan clam chowder	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other cream-based soup (e.g. corn chowder, cream of vegetable)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Bean, pea or lentil soup	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Homemade or home-style soup, w/meat or chicken (e.g. gumbo)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

0201
DO NOT WRITE IN THIS AREA

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Soups should be listed here while *stews* should be listed under "meat" or "poultry" sections under mixed dishes.

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SOUP *(continued)*										
If you eat beef stew, include in the "Beef, Pork and Lamb" section (not this section). If you eat chicken stew, include in the "Poultry" section (not this section).	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Homemade or home-style soup, without meat	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Chicken noodle, ramen noodle and/or chicken rice soup: canned or instant	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vegetable and/or tomato based soup: canned or instant (e.g. veg. beef, minestrone)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you eat homemade or home-style soup, with or without meat, your portion is usually closest to . . .
☐ 1 cup ☐ 2 cups ☐ 3 cups ☐ 4 cups or more

If you eat canned or instant soup, your portion (prepared amount) is usually closest to . . .
☐ 1/2 cup ☐ 1 cup ☐ 1 1/2 cups ☐ 2 cups or more

DAIRY PRODUCTS AND EGGS										
	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
Milk, plain (including soymilk; as beverage, not in cereal or coffee/tea)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Chocolate or flavored milk	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cheese, hard (e.g. cheddar, parmesan, swiss)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cheese, soft (e.g. mozzarella, brie, farmer's style)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cheese, processed (American slices, Velveeta)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cheese spreads or dips, or sour cream	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cottage cheese, fresh or farmers	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Yogurt (not frozen)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Eggs (e.g. soft or hard-boiled)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Eggs (e.g. fried, scrambled, omelets)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Egg salad (incl. in a sandwich, sub or wrap)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fast food egg sandwich	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you drink milk and/or flavored milk, it is usually. . .
☐ skim/nonfat or 1% ☐ 2% ☐ whole ☐ soymilk ☐ lactose-free (e.g. Lactaid)

If you drink milk and/or flavored milk, your portion is usually closest to *(8 fl. ounces = 1 cup)* **. . .**
☐ 4 fl. ounces ☐ 8 fl. ounces ☐ 12 fl. ounces ☐ 16 fl. ounces or more

If you eat cheese, it is usually . . .
☐ regular ☐ low/reduced fat ☐ nonfat/fat free

If you eat cheese, your portion is usually closest to . . .
☐ 1 slice or 2 tablespoons ☐ 2 slices or 3 tablespoons ☐ 3 slices or 4 tablespoons ☐ 4 slices or 5 tablespoons or more

If you eat cottage cheese, your portion is usually closest to . . .
☐ 1/4 cup ☐ 1/2 cup ☐ 3/4 cup ☐ 1 cup or more

If you eat yogurt, it is usually . . .
☐ regular ☐ low/reduced fat ☐ nonfat/fat free ☐ light/no sugar added

Please continue on the next page.

Milk or cream added to beverages should be *not* be listed here. Instead, list under "Coffee, Tea and Cocoa"

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BEVERAGES (Please note that the frequency headings are different)

	Never	Less than 1x per month	1-3x per month	1x per week	2-4x per week	5-6x per week	1x per day	2-3x per day	4-5x per day	6+x per day
Orange juice (100% juice, not fruit drinks)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Grapefruit juice (100% juice)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tomato or vegetable juice (e.g.V-8)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Grape juice (100% juice)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Apple juice (100% juice)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cranberry juice (including cranberry juice cocktail)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Nectars (e.g. peach, pear, guava, mango)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other 100% fruit juices and/or blends	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fruit drinks (e.g. Sunny Delight, Hi-C, Crystal Light, lemonade, Kool-Aid)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Soft drinks, regular (e.g. cola, 7-up, ginger ale)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sports drinks (e.g. Gatorade, Powerade)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Energy drinks (e.g. Red Bull)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Non-alcoholic beer (e.g. Malta)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Meal replacement beverages (e.g. Slim-Fast, Atkins)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Water (including tap, filtered, bottled)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

"Soft drinks, regular" refers to both regular calorie and diet drinks. Whether the participant consumes regular calorie or diet drinks is ascertained later under the portion size questions.

If you drink fruit juice and/or vegetable juices, your portion is usually closest to *(8 fl. ounces = 1 cup)* . . .
☐ 4 fl. ounces ☐ 8 fl. ounces ☐ 12 fl. ounces ☐ 16 fl. ounces or more

If you drink fruit flavored drinks and/or sports or energy drinks, it is usually *(choose only one)* . . .
☐ regular ☐ Low-calorie/sugar free

If you drink soft drinks, it is usually *(choose only one)* . . .
☐ regular ☐ diet

If you drink soft drinks, regular or diet, they are usually *(choose all that apply)* . . .
☐ cola ☐ caffeine-free cola ☐ other caffeinated non-cola (e.g. Mountain Dew) ☐ other caffeine-free non-cola (e.g. 7-Up, orange, ginger ale)

If you drink soft drinks and/or other cold beverages (including fruit drinks, sports drinks), your portion (before adding ice) is usually closest to *(1 can = 12 fl. ounce)* . . .
☐ 8 fl. ounces ☐ 12 fl. ounces ☐ 16 fl. ounces ☐ 24 fl. ounces or more

If you drink meal replacement beverages or shakes, they are usually . . .
☐ weight loss type (e.g. Slim-Fast) ☐ high protein type (e.g. Atkins) ☐ standard, balanced nutrition type (e.g. Carnation Instant Breakfast, Ensure, Snapple-a-Day)

If you drink meal replacement beverages or shakes, your portion is usually closest to . . .
☐ 1/2 can or 1/2 scoop powder ☐ 1 can or 1 scoop powder ☐ 1 1/2 cans or 1 1/2 scoops powder ☐ 2 cans or 2 scoops powder

If you drink water, your portion is usually closest to *(8 fl. ounces = 1 cup; 1 liter = 33 fl. ounces)* . . .
☐ 4 fl. ounces ☐ 8 fl. ounces ☐ 12 fl. ounces ☐ 16 fl. ounces or more

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DO NOT WRITE IN THIS AREA

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SUMMARY QUESTIONS (Please note that the frequency headings are different)

	Never	Less than 1x per month	1-3x per month	1x per week	2-4x per week	5-6x per week	1x per day	2-3x per day	4-5x per day	6+x per day
How often do you usually drink fruit juice?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
How often do you usually drink fruit drinks that are not 100% fruit juice?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
How often do you usually drink soft drinks and/or energy drinks?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

COFFEE, TEA AND COCOA (Please note that the frequency headings are different)

	Never	Less than 1x per month	1-3x per month	1x per week	2-4x per week	5-6x per week	1x per day	2-3x per day	4-5x per day	6+x per day
Hot chocolate, cocoa	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Coffee (all types)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tea (all types)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

If you drink coffee, it is usually *(choose all that apply)* . . .
☐ regular ☐ decaffeinated ☐ café con leche ☐ pre-sweetened coffee drinks (e.g. Colado, Dunkin Donuts' Coffee Coolatta, Starbucks' Frappuccino)

If you drink tea (hot or iced), it is usually *(choose all that apply)* . . .
☐ black, regular ☐ herbal ☐ bottled or powdered iced tea, pre-sweetened (not fresh brewed)
☐ black, decaffeinated ☐ green ☐ bottled or powdered iced tea, un-sweetened or diet (not fresh brewed)

If you drink hot chocolate or cocoa, your portion is usually closest to . . .
☐ Small (6 fl. ounces or 3/4 cup) ☐ Medium (12 fl. ounces or 1 1/2 cups) ☐ Large (18 fl. ounces or 2 1/4 cups) ☐ Extra Large (24 fl. ounces or 3 cups) or more

If you drink coffee or tea, your portion (including milk/cream) is usually closest to . . .
☐ 4 fl. ounces or 1/2 cup ☐ sm. (8 fl. ounces or 1 cup) ☐ med. (12 fl. ounces or 1 1/2 cups) ☐ lg. (16 fl. ounces or 2 cups) ☐ extra lg. (24 fl. ounces or 3 cups) or more

If you add sugar to coffee and/or tea, it is usually *(indicate if sugar is for coffee and/or tea by marking below selection)* . . .

☐ 1 teaspoon	☐ 2 teaspoons	☐ 3 teaspoons	☐ 4 teaspoons or more	☐ I use artificial sweetener
☐ coffee	☐ coffee	☐ coffee	☐ coffee	☐ coffee
☐ tea	☐ tea	☐ tea	☐ tea	☐ tea

If you add milk or cream to coffee and/or tea, it is usually prepared *(indicate if milk or cream is for coffee and/or tea by marking below selection)* . . .

☐ dark (very little milk/cream)	☐ light (some milk/cream)	☐ half milk/cream, half coffee	☐ more milk/cream than coffee
☐ coffee	☐ coffee	☐ coffee	☐ coffee
☐ tea	☐ tea	☐ tea	☐ tea

If you add milk or cream to coffee and/or tea, it is usually . . .
☐ milk ☐ half & half creamer ☐ cream ☐ non dairy creamer

SUMMARY QUESTIONS (Please note that the frequency headings are different)

	Never	Less than 1x per month	1-3x per month	1x per week	2-4x per week	5-6x per week	1x per day	2-3x per day	4-5x per day	6+x per day
How often do you usually drink coffee and tea (hot or iced) and/or hot chocolate?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please continue on the next page.

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Milk or cream added to beverages should be accounted for *here* rather than under "Dairy Products and Eggs"

FFQ Page 19

SUMMARY

1. **How often do you add salt to your food at the table?**
   ○ never ○ sometimes ○ often/always

2. **If you add spreads or oil during cooking (incl. vegetables, rice, pasta and/or beans), they are usually** *(specify one or two only)* . . .
   ○ stick margarine ○ lard, salt park or bacon fat ○ olive oil ○ corn oil
   ○ tub margarine ○ butter ○ canola oil ○ other vegetable oil
   ○ margarine-like spread ○ margarine-like spread, light ○ shortening

SUMMARY QUESTIONS (Please note that the frequency headings are different)

	Never	Less than 1x per month	1x per month	2-3x per month	1x per week	2x per week	3-4x per week	5-6x per week	1x per day	2+x per day
3. How often do you eat out (incl. restaurants, fast food and/or take-out)?	○	○	○	○	○	○	○	○	○	○

4a. **Has your health professional prescribed a special diet for you?**
   ○ Yes ○ No (If no, go to Question #5 below)

4b. **If yes, indicate the type of diet prescribed . . .**
   ○ to manage diabetes ○ to manage high-cholesterol ○ to manage hypertension ○ other
   ○ to manage kidney disease ○ to manage allergy ○ weight reduction

4c. **Do you follow this diet?**
   ○ Yes ○ No

5. **Where do you usually eat breakfast?**
   ○ home ○ work ○ cafeteria ○ fast food chain ○ restaurant

6. **Where do you usually eat lunch?**
   ○ home ○ work ○ cafeteria ○ fast food chain ○ restaurant

7. **Where do you usually eat dinner?**
   ○ home ○ work ○ cafeteria ○ fast food chain ○ restaurant

8. **Are there any other foods you eat at least once per week (not mentioned in the previous sections)? If yes, please describe:**

Do not write in shaded area:

1. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
2. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
   CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
   CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

Participant can enter foods that are not listed elsewhere in the questionnaire that they eat *at least once per week*. Make sure they are as specific as possible.

SUPPLEMENT USE

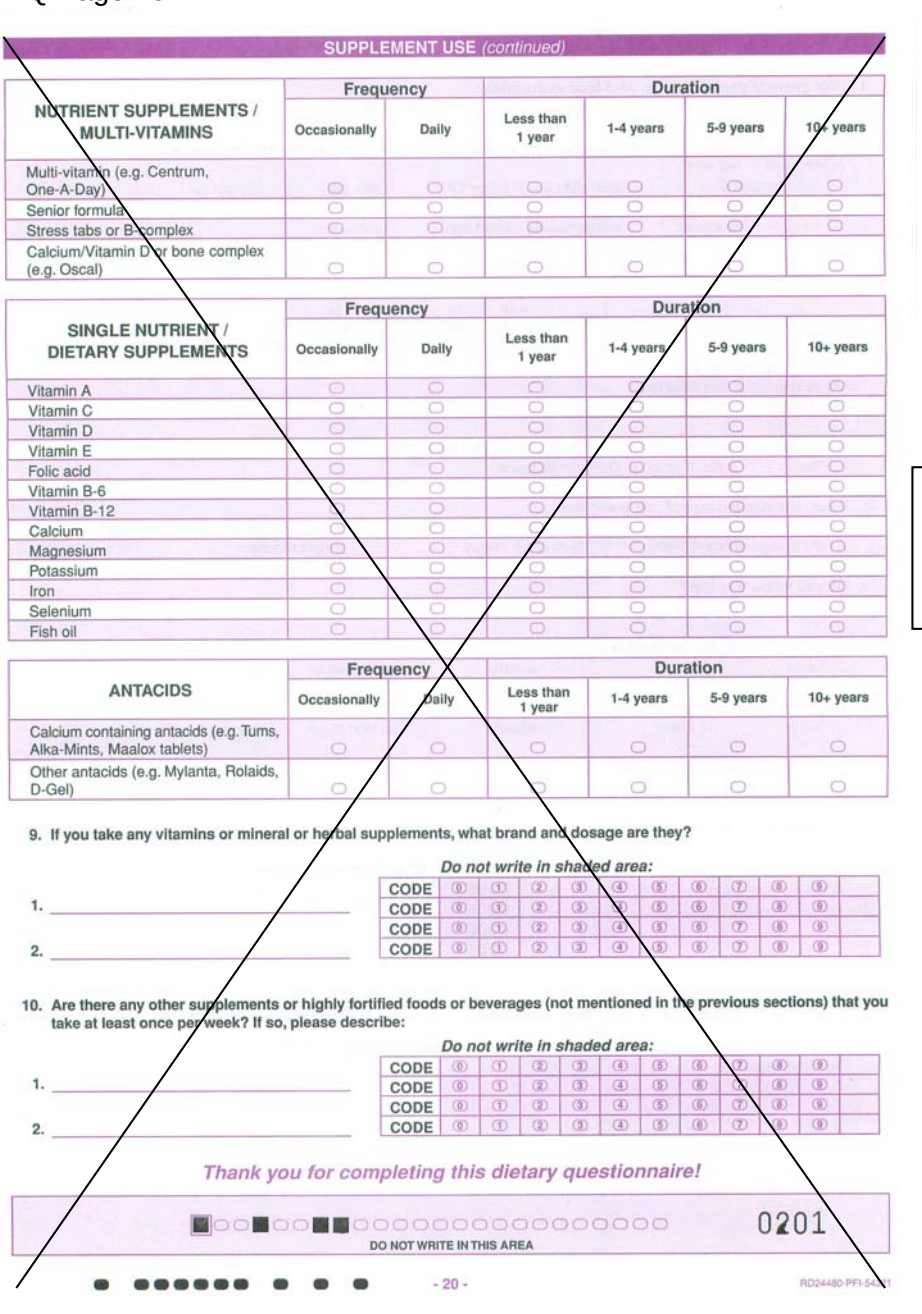
Do you currently take any supplements including vitamins, mineral, herbal supplements and/or antacids?
○ No *(If no, stop here)* ○ Yes

Please continue on the next page.

Participant does *not* need to complete this section. This information is collected elsewhere as part of D2d.

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SUPPLEMENT USE *(continued)*

NUTRIENT SUPPLEMENTS / MULTI-VITAMINS	Frequency		Duration			
	Occasionally	Daily	Less than 1 year	1-4 years	5-9 years	10+ years
Multi-vitamin (e.g. Centrum, One-A-Day)	☐	☐	☐	☐	☐	☐
Senior formula	☐	☐	☐	☐	☐	☐
Stress tabs or B-complex	☐	☐	☐	☐	☐	☐
Calcium/Vitamin D or bone complex (e.g. Oscal)	☐	☐	☐	☐	☐	☐

SINGLE NUTRIENT / DIETARY SUPPLEMENTS	Frequency		Duration			
	Occasionally	Daily	Less than 1 year	1-4 years	5-9 years	10+ years
Vitamin A	☐	☐	☐	☐	☐	☐
Vitamin C	☐	☐	☐	☐	☐	☐
Vitamin D	☐	☐	☐	☐	☐	☐
Vitamin E	☐	☐	☐	☐	☐	☐
Folic acid	☐	☐	☐	☐	☐	☐
Vitamin B-6	☐	☐	☐	☐	☐	☐
Vitamin B-12	☐	☐	☐	☐	☐	☐
Calcium	☐	☐	☐	☐	☐	☐
Magnesium	☐	☐	☐	☐	☐	☐
Potassium	☐	☐	☐	☐	☐	☐
Iron	☐	☐	☐	☐	☐	☐
Selenium	☐	☐	☐	☐	☐	☐
Fish oil	☐	☐	☐	☐	☐	☐

ANTACIDS	Frequency		Duration			
	Occasionally	Daily	Less than 1 year	1-4 years	5-9 years	10+ years
Calcium containing antacids (e.g. Tums, Alka-Mints, Maalox tablets)	☐	☐	☐	☐	☐	☐
Other antacids (e.g. Mylanta, Rolaids, D-Gel)	☐	☐	☐	☐	☐	☐

9. If you take any vitamins or mineral or herbal supplements, what brand and dosage are they?

Do not write in shaded area:

1. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
2. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

10. Are there any other supplements or highly fortified foods or beverages (not mentioned in the previous sections) that you take at least once per week? If so, please describe:

Do not write in shaded area:

1. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
2. _____ CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
CODE ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨

Thank you for completing this dietary questionnaire!

0201

DO NOT WRITE IN THIS AREA

- 20 -

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Participant does *not* need to complete this section. This information is collected elsewhere as part of D2d.

10.4 QUALITY OF LIFE ANCILLARY STUDY

Quality of life (QOL) and mood are outcomes known to be associated with vitamin D status. The Quality of Life Ancillary Study is being implemented to assess QOL and mood at the month 24 visit, utilizing the PROMIS 29 + 1 questionnaire.

10.4.1 Implementation

All D2d sites are expected to participate. Sites will obtain IRB approval prior to implementation of this ancillary study supplement. After receiving IRB approval, the site staff will provide each participant with the opportunity to complete the questionnaire at his month 24 visit. If the participant has already completed the M24 visit, he will *not* be asked at a future visit to complete the questionnaire.

10.4.2 QOL Questionnaire Introduction to Participant

The site Research Coordinator (RC) or research team designee will provide the participant with the QOL/Mood packet. The first page is the participant information/consent page (site specific, as approved by the site IRB). The participant will be instructed to read the participant information/consent page, and, if willing to participate, he will be instructed to complete the questionnaire. If the participant decides not to participate, he will return the blank form to the RC.

10.4.3 Form completion

The questionnaire will be provided in a paper form (English or Spanish, see Appendix) and be completed independently by the participant. It will be completed during the oral glucose tolerance test (OGTT), between the 30-minute and 120-minute blood draws. If the participant has met the diabetes outcome and is not undergoing an OGTT, the questionnaire should be completed after the fasting blood draw. The RC or designee will instruct the participant to read each question and mark one response for each question.

After the participant has completed the form, and prior to the participant leaving the clinic, the RC or designee must review the form for completeness and clarity. If, upon review, the participant has selected more than one response for a single question, the participant should be asked to select just one. The participant responses on the paper form will be transcribed into the e-CRF (see MOP section 15).

10.5 APPENDICES

Appendix 1 International Physical Activity Questionnaire – Long Form | English

Appendix 2 International Physical Activity Questionnaire – Long Form | Spanish

Appendix 3 International Physical Activity Questionnaire – Telephone Form | English

Appendix 4 International Physical Activity Questionnaire – Telephone Form | Spanish

Appendix 5 Multicultural Food Frequency Questionnaire – English

Appendix 6 Multicultural Food Frequency Questionnaire – Spanish

Appendix 7 Multicultural Food Frequency Questionnaire – Food Booklet English

Appendix 8 Multicultural Food Frequency Questionnaire – Food Booklet Spanish

Appendix 9 Quality of Life Questionnaire – English

Appendix 10 Quality of Life Questionnaire – Spanish