SECTION 10

DIETARY ASSESSMENT

INTRODUCTION

Assessment of nutrient intake in free-living populations is a difficult problem in dietary intervention research. There are no "gold standard" or criterion measures, and assessment methods differ in reliability, accuracy, costs, participant burden, and susceptibility to bias. Three instruments are used to monitor food and nutrient intake in WHI: (1) the Food Frequency Questionnaire, (2) the food record, and (3) the dietary recall.

Form 60 - Food Frequency Questionnaire (FFQ) assesses group and individual-level intakes of selected nutrients, in particular the proportion of total energy from different macronutrients. The FFQ is self-administered and inexpensive to process. However, the fixed list of foods may not be appropriate for all participants, some women find it difficult to estimate frequency of intake and portion sizes, and this instrument provides no information on eating patterns or all nutrients.

Form 62 - Four-Day Food Record (4DFR) is an open-ended assessment instrument that provides detailed data on food consumption and can estimate intake of total energy, nutrients, and food components such as fatty acids and carotenoids. However, food records can be subject to bias because the participant may change what she eats during the period she is keeping records. This potential bias is a particular concern in dietary intervention studies. In addition, this assessment instrument has high participant burden and is expensive to administer and analyze.

24 Hour Recall (24HR) - Like a food record, the telephone-administered 24-hour dietary recall provides detailed information about a participant's food and nutrient intake. However, because participant's cannot change what they ate retrospectively, no alteration in usual diet should occur. This assessment technique has lower respondent burden than a food record, but does rely on participants' memory. Because the recalls are administered and analyzed centrally by the CCC, the technique is more standardized and somewhat less expensive than a food record.

From a scientific perspective, the major disadvantage of records and recalls is that they only measure short-term food intake, which may not reflect usual diet. Multiple days of records or recalls can improve the estimate of usual diet, but dramatically increase respondent burden and costs. Therefore, in this study, we use all three assessment methods (FFQs, records, recalls) to minimize cost and participant burden, while providing appropriate and state-of -the-art data to aid in study evaluation.

The FFQ is used to assess dietary intake of all participants at baseline, to screen participants for eligibility into the DM, and to assess dietary intake of participants at follow-up visits. The 4DFR is used at baseline to assess the participant's ability to participate in the DM Intervention. The food record is also used to assess diet in a DM cohort subsample at baseline and one-year follow-up. To minimize clinic and participant burden, the cohort follow-up at years 3, 6, and 9 consists of two centrally administered 24-hour dietary recalls. Finally, a dietary recall is administered to a one percent random sample of participants each year to assess control and intervention group differences in the DM. A small proportion of these participants receive two recalls to allow us to assess intra- vs. inter-variability in intake, use that information to adjust our nutrient variance estimates, and thereby estimate the distribution of nutrient intakes in the sample.

Together, these measures support hypotheses related to the effects of dietary intervention on nutrient intake, maintenance of intervention-control group differences, and associations of nutrient intake with biochemical parameters, morbidity and mortality.

The Clinical Coordinating Center (CCC) uses the University of Minnesota's Nutrition Data System (NDS) for entry and analysis of dietary assessment data collected for the Women's Health Initiative (WHI). The NDS consists of data entry software, analysis software, and a comprehensive food and nutrient database, which is updated annually by the University of Minnesota Nutrition Coordinating Center (UM-NCC). The data entry software provides standardized prompts for entering dietary records, thus standardizing data entry procedures

and increasing the comparability of the data across Clinical Centers (CCs). The NDS is used for data entry of all dietary data collected by the 4DFR and the 24HR; the food and nutrient database is used in the analysis of FFQs, allowing for comparison of various methods of dietary assessment for WHI.

10.1 The Four-Day Food Record (4DFR) (Required)

The *4DFR* is a detailed documentation of the food that the participant eats over four days. The main objective of the *4DFR* is to obtain a complete list of a participant's dietary intake during the selected time period. The *4DFR* is kept by the participant, ideally as she consumes her meals and snacks, for a period of four alternate days (e.g., Monday, Wednesday, Friday, Sunday). This method provides the most detailed, individual-level data on nutrient intake of all of the dietary assessment tools used in the DM. It provides the most accurate individual assessment of total energy, macronutrients, micronutrients and specific food components such as types of fatty acids. Food records also provide the best information on culturally-specific foods and food preparation methods. They are, however, subject to potential bias because study participants may change what they eat during the record-keeping period and four days of records may not reflect "usual diet."

A more accurate picture of true dietary intake would be obtained from a longer period of record keeping (e.g., seven or even 14 days). However, this is not practical due to excessive burden on the participants and extensive costs to the DM in terms of documenting and coding the additional days. Four days are a commonly-accepted representation of an individual's usual macronutrient intake and are frequently used in research settings. For key nutrients in WHI, such as dietary fat, four days provide an adequate estimate of intake. We selected alternate day record-keeping rather than four consecutive days for several reasons. Alternate days yield better estimates of usual intake, due to the correlation (often negative) between sequential days. Also, we found in previous studies that participants find it less burdensome to keep records every other day. Lastly, using alternate days allows a participant to begin her record on any assigned day and still include a weekend day. This adds considerable flexibility to CC schedules and follow-up CC visits, and gives the participant a more personal choice on when to begin her record.

Food records are kept by all potential DM participants between the Screening Visit 2 (SV2) and Screening Visit 3 (SV3), and by a subsample of the DM participants at the annual CC visit in year 1. At baseline (before randomization) the records serve as part of the determination of a woman's willingness and ability to participate in the detailed tasks of the DM. At baseline and during follow-up DM visits these records also provide estimates of individual nutrient intake and dietary change for a subsample of DM participants. The *4DFR* subsample is identified at the time of randomization. The *4DFRs* from this subsample are documented, peer reviewed and analyzed.

The *4DFR* booklet consists of the following sections:

- The front page for the participant's name, assigned dates for keeping the record, name and telephone number of the CC contact person, and the next appointment date and time.
- Two pages of instructions on keeping accurate *4DFRs*.
- A page requesting information on the vitamin and mineral supplements taken during the record-keeping period.
- A page of general questions on types of fats and oils used throughout the *4DFR*.
- A sample day's record.
- A number of lined pages on which to list and describe the foods and beverages consumed during the record-keeping period and columns to designate the meal, place prepared (home, restaurant or other) and the amount eaten.
- A few pages for detailed listing of recipes prepared during the assigned days.
- A shaded box on the back page for specific data items ("Office Use Only").

Adjacent to each page on which the participant records her food intake is a lined page for CC Dietary Assessment staff to document and describe in detail the foods and beverages consumed, and two columns to document fat added to foods in preparation and at the table (see *Section 10.1.4 - Baseline Food Record Documentation*). This documentation is critical for accurate representation of what the participant actually ate during the specified time period. Participants often do not provide adequate detail on food preparation or the amount of food they eat. In addition, it is common to forget to include condiments or beverages consumed

with meals, and fats added in preparation or at the table. The CC Dietary Assessment staff is responsible for obtaining this information in detail at the time the record is documented with the participant.

10.1.1 Activities at SV2

All potential DM participants keep a *4DFR* between SV2 and SV3. Dietary Assessment staff certified for the *4DFR* show the WHI video "Keeping Track of What You Eat" to all potential DM participants. The video instruction should take 20-25 minutes and covers:

- General instructions for keeping food records.
- How to describe foods and beverages consumed, including ingredients used in preparation and preparation methods.
- How to measure and/or estimate quantities consumed.
- How to describe homemade recipes and foods prepared by others.
- The importance of not changing one's eating habits and recording everything one eats during the record keeping period.

After the participant watches the video, Dietary Assessment staff certified for the *4DFR*:

- Answer questions.
- Distribute the *4DFR* and *Form 69 - Keeping Track of What You Eat* and show participants the sample records printed in these materials.
- Provide measuring cups and spoons to women who do not have these materials at home.
- Ask participants to practice recording a meal and review it for adequacy of completion.
- Assign four alternating days and dates for the participant to keep her *4DFR* and write this information on the front of the *4DFR*.

The participant must complete the *4DFR* before SV3. CC staff apply a computer-generated label containing the woman's ID number and visit number to the back of each *4DFR* before distribution.

10.1.2 Activities at SV3

Before randomization, a certified Lead Nutritionist, Dietary Assessment staff or Group Nutritionist must use the *DM Eligibility Checklist* to assess a woman's ability and willingness to complete the DM Intervention activities. This review process takes approximately 20 minutes. For detailed instructions on this review process and a copy of the *DM Eligibility Checklist*, see *Section 6.2 - SV3 Assessment of DM Eligibility*.

Following randomization, Dietary Assessment staff, certified for the *4DFR*, document individual *4DFR*s for women identified in the *4DFR* subsample of the DM. Post SV3, a second Dietary Assessment staff member, certified for the *4DFR*, reviews the *4DFR* as described in *Section 10.1.8.1 - CC Documentation and Peer Review Procedures for Documented 4DFRs*.

10.1.3 Follow-Up Visit Record Completion

The participants in the *4DFR* subsample are asked to keep a *4DFR* at the annual CC visit in year 1. Participants in this subsample are selected at the time of randomization. Clinical Center staff can print a participant visit plan from WHILMA before the annual visit. The visit plan identifies whether a woman is to keep a *4DFR* before the annual visit. Two weeks before the annual visit, CC staff:

- Contact the participant to inform her that she will need to complete a *4DFR*.
- Assign the days on which the *4DFR* is to be kept and write the days and dates on the front of the *4DFR*.

- Affix the participant ID label with barcode to the back of the *4DFR*.
- Mail the *4DFR* and instruction pamphlet *Form 69 - Keeping Track of What You Eat* to the participant along with the other forms mailed two weeks before the annual visit.

The woman brings the completed *4DFR* with her to the annual visit and meets with Dietary Assessment staff certified for the *4DFR* who documents the *4DFR*.

10.1.4 Baseline Food Record Documentation

Dietary Assessment staff certified for the *4DFR* document the completed *4DFR* with each participant identified in the *4DFR* subsample. Ideally, staff are completely blinded to the randomization status of the participant. If this is not possible, ensure that the documentor is blinded until after the *4DFR* is documented. The randomization status should not be revealed to the participant until documentation of the *4DFR* is complete. It is also important to document the *4DFR* as soon as possible after the last day of recording to maximize the woman's memory of what she ate during the record-keeping period. Documentation of the *4DFR* should take 30-45 minutes to complete.

Complete descriptions of foods, preparation methods, ingredients, and portion size are critical in the accurate assessment of dietary intake. Dietary Assessment staff should use the following guidelines to document *4DFRs*:

- Use the *WHI 4DFR Documentation Checklist* to document the *4DFR* with the participant. See *Figure 10. 1 - WHI 4DFR Documentation Checklist*.
- Obtain brand names for food products indicated whenever possible. This information is particularly important for fats and oils, fat modified products, and commercial frozen entrees.
- Probe for spreads, sauces, and fillings that may be sources of additional fat.
- Carefully check portion sizes and dimensions provided by the participant.
- Use the Fat Added Columns to document sources of fat consumed by the participant (see *Figure 10.2 - Guidelines for Documenting the Fat Added Columns of the 4DFR*).

A second Dietary Assessment staff certified for the *4DFR* reviews each *4DFR* before sending the records to the CCC for processing (see *Section 10.1.8.1 - CC Documentation and Peer Review Procedures for Documented 4DFRs*).

10.1.5 Follow-Up Visit Food Record Documentation

Dietary Assessment staff certified for the *4DFR* document the completed *4DFR* with the participant at the CC annual visit. Ideally, at the follow-up visit, the documentor is blinded to the DM randomization status of the woman; at a minimum, the documentor must not be the Group Nutritionist for the participants whose *4DFRs* she documents. A second Dietary Assessment staff certified for the *4DFR* peer reviews each *4DFR* before sending the records to the CCC for processing.

The 4DFR data collected at AV1 is a critical evaluation tool. The four-day food records provide information on control minus intervention differences at the one-year visit and are an important check on the reliability of the data from the FFQ. To be accurate, the record must be reflective of the participant's dietary intake at the one year timepoint. This is important for two reasons: (1) because of the potential for drift to a higher fat diet post-intervention, and (2) to capture data on temporal changes in the diet of control participants.

Every effort should be make to collect the 4DFR at the annual visit. If an annual 4DFR is NOT completed within six months after the annual visit (e.g., due to participant/family illness, lost 4DFR, unable to contact participant, scheduling difficulties, etc.) staff can discontinue efforts to obtain the 4DFR. The Lead DA Nutritionist should email the CCC Dietary Assessment Research Nutritionist the participant ID# and the reason the 4DFR will not be sent to the CCC. These 4DFRs will be recorded as "missing data".

10.1.6 Common Problems and Solutions

10.1.6.1 A Participant Does Not Complete Her Baseline 4DFR

If the baseline *4DFR* is partially complete, make every attempt to complete the record with the woman while she is in the CC. A *4DFR* with 3-days is acceptable. However, if fewer than three days are recorded, randomization should be delayed until the participant completes an acceptable *4DFR*. Ask the woman to complete the record in the upcoming week and re-schedule the randomization visit. If the woman does not return the *4DFR*, she is not eligible for DM. Complete the Staff Impression for DM question on *Form 6 - Final Eligibility Assessment*. Mark the "ineligible" box and enter staff ID code. Record the reason as "Did not return *4DFR*".

10.1.6.2 A Participant Fails to Return Her Follow-Up 4DFR

Dietary Assessment staff should make every effort to obtain a completed *4DFR* from participants in the *4DFR* subsample. If a participant completes her follow-up *4DFR*, but does not bring it with her to the CC annual visit, give her a stamped envelope for return. If a participant has not completed her follow-up *4DFR*, give her another *4DFR*, assign new days and dates for completion, and provide a stamped envelope for return. Ask the participant to make a copy of the completed 4DFR so that she will have it to refer to when the documentor calls to clarify the information she has recorded. Dietary Assessment staff certified for the *4DFR* document the *4DFR* by telephone as soon as the record is received. If the *4DFR* is not received within two weeks after her CC visit, call the participant and ask her to mail the *4DFR* as soon as possible. If the *4DFR* is not received within three weeks after her CC visit, make a second reminder telephone call.

10.1.6.3 A Baseline 4DFR is Unacceptable

If a *4DFR* is determined to be unacceptable (see *Section 6.2 - SV3 Assessment of DM Eligibility*), thank the woman for her interest and explain that she is ineligible for the study.

10.1.6.4 A Participant is Sick During the Record Keeping Period

If a woman is sick during the entire week of her *4DFR*, ask her to call the CC and reschedule her *4DFR* days. However, if she is sick for only one day she should keep the *4DFR*, and make note of her illness on the day she is sick.

10.1.6.5 A Participant Does Not Record Alternate Days of Intake

The importance of recording alternate days of intake should be stressed to participants at SV2. However, a *4DFR* kept on consecutive days is acceptable.

10.1.7 4DFR Processing

10.1.7.1 CC Procedures for Processing Documented 4DFRs

Clinical Center staff:

- Peer review all documented *4DFRs* for the subsample of DM participants (see *Section 10.1.8.1 - CC Documentation and Peer Review Procedures for Documented 4DFRs*).
- Key-enter the shaded section on the last page of each *4DFR* into WHILMA (see *Vol. 5 - Data System, Appendix B.3. - Step-By-Step Task Instructions*).
- Photocopy all *4DFRs* of participants who are in the *4DFR* subsample and file the copies at the CC. This is essential for two reasons: 1) When the CCC requests clarification or additional information, the CC has a copy of the record to refer to, and 2) a copy is available in case an original is lost in the mail or elsewhere.

- Complete the *4DFR* packing slip.
- Send the original *4DFRs* for the subsample of DM participants to the CCC weekly via Federal Express.
- File the copies of documented *4DFR*s for the *4DFR* subsample and all original non-documented *4DFR*s at the CC.

10.1.7.2 CCC Procedures for Processing Documented 4DFRs

- Log each *4DFR* into the database upon receipt using the procedures described below.
- Analyze all *4DFR*s collected from the subsample of women in the DM using the NDS.
- Send *Form 68 - Food Record Inquiry* to the CC Lead Nutritionist when food items or quantities in the *4DFR* need clarification.
- Send a 5% sample of analyzed *4DFRs* to the UM-NCC annually. UM-NCC re-analyzes these food records and provides feedback regarding discrepancies in data entry of *4DFRs* to the CCC as a quality assurance procedure.
- Archive all original documented *4DFRs* for the *4DFR* subsample at the CCC.

10.1.7.3 CCC Review Procedures for Documented 4DFRs Received from the CCs

The CCC Data Control Technician reviews each *4DFR* received from the CCs using the *4DFR Screening Checklist* and:

- Forwards acceptable *4DFRs* to the Nutrition Assessment Shared Resource Unit (NASR) for data entry and analysis of nutrient intake. The NASR provides trained and certified staff to process *4DFR* data using standardized data-entry procedures.
- Notifies the CC Lead Dietary Assessment Nutritionist by email which *4DFRs* are unacceptable and the specific error to be corrected.

A *4DFR* is unacceptable by the CCC for any one of the following reasons:

- Illegible *4DFR*. See *Section 10.1.2 - Activities at SV3.*
- Less than three days of records. See *Section 10.1.2 - Activities at SV3.*
- Entire section for Vitamin and Mineral Supplements (page 4) incomplete and/or supplements not recorded on the days taken in the daily record.
- Entire section for General Questions (page 5) incomplete.
- Shaded section on the back of *4DFR* booklet (page 40) incomplete and/or data items incorrectly key-entered (see *Vol. 5 - Data System, Appendix B.3. - Step-by-Step Task Instructions*).

10.1.7.4 Lead Nutritionist Procedures for Unacceptable Documented 4DFRs

The CC Lead Nutritionist:

- Reviews the items identified by the CCC Data Control Technician with the original documentor and the peer reviewer.
- Instructs the documentor to complete the documentation specified and contact the participant if necessary.
- Emails the information requested to the CCC Data Control Technician within five working days of receipt.

10.1.8 Quality Assurance of 4DFRs (Required)

Quality assurance is based on procedures developed and tested for the Women's Health Trial Feasibility Study in Minority Populations. These procedures were developed and are maintained as a cooperative activity among the CCs, the CCC and the UM-NCC. To assure high quality food intake data, the CCC monitors all CC *4DFR* collection and documentation activities using the procedures described in the following sections.

10.1.8.1 CC Documentation and Peer Review Procedures for Documented 4DFRs

Within each CC, quality assurance will be based on peer review. After a Dietary Assessment staff member documents a *4DFR* with the participant, a different Dietary Assessment staff member reviews the *4DFR* within three working days of the date documented. In this way, most problems can be corrected before the *4DFR* is analyzed and archived by the CCC. It is important that all CC staff involved in the collection of *4DFRs* develop and maintain a high level of proficiency in accurate and complete documentation of *4DFRs*.

- Dietary Assessment staff must use the *WHI 4DFR Documentation Checklist* (see *Figure 10.1 - WHI 4DFR Documentation Checklist*) to document the *4DFR* with the participant and to conduct the peer review.
- The *4DFR* Screening Checklist (see *Figure 10.3 - 4DFR Screening Checklist*) must be used by staff who conduct the peer review.

10.1.8.2 4DFR Documentation Performance Standards

Acceptable performance for documentation and peer review of *4DFR*s is defined as:

- Fewer than four documentation errors *(Form 68 - Food Record Inquiry)* per booklet for 75% of *4DFRs* documented.
- Fewer than six unacceptable *4DFRs* per year (see *Section 10.1.7.3 - CCC Review Procedures for Documented 4DFRs Received from the CCs*).

The *Dietary Assessment Quality Assurance Reports* monitor these standards. Additional training is required for documentors who are unable to meet these performance standards.

10.1.8.3 Dietary Assessment Quality Assurance Reports

The CCC prepares quarterly Quality Assurance Reports for each CC. Data for the reports are compiled from *Form 68 - Food Record Inquiry* and the *4DFR Screening Checklist*. These reports provide feedback to the CC Lead Nutritionist on the accuracy of *4DFR* documentation and monitor the performance of Dietary Assessment staff certified for the 4DFR. A description of each report follows:

- **Clinic Performance for Books Archived (*WHIP 0935):*** Details the occurrence of each documentation error type within the 4DFR books archived (documented) for each WHI Clinical Center. Data for this QA report is compiled from *Form 68 - Food Record Inquiry*.

- **Documentor Performance for Books Archived (*WHIP 0940*):** Details the total number of *4DFR* books archived (documented) and the number of errors found within those books for each CC Dietary Assessment staff. Data for this QA report is compiled from *Form 68 - Food Record Inquiry*.

- **4DFR Screening Checklist Error by Clinic *(WHIP 0949)*:** Details the occurrence of each screening error type within the *4DFR* books archived (documented) for each WHI Clinical Center. Data for this QA report is compiled from *Figure 10.3 - 4DFR Screening Checklist*.

- **4DFR Screening Checklist Error by Employee (*WHIP 0950*):** Details the occurrence of each screening error type within the 4DFR books archived (documented) for each CC Dietary Assessment staff. Data for this QA report is compiled from *Figure 10.3 - 4DFR Screening Checklist.*

10.1.8.4 Quality Assurance of 4DFR Data Entry (Required)

The UM-NCC provides quality assurance services for the coding and data entry activities at the CCC. The UM-NCC will process a 5% sample of all analyzed *4DFRs* using a comprehensive software system to compare double-entered NDS records. The CCC reviews reports from this system and conducts supplemental training as needed for NASR staff. The CCC Dietary Assessment Supervisor also meets regularly with the NASR Manager and Coding Nutritionists to review coding questions and documentation errors.

10.2 The FFQ (Required)

The *FFQ* is labeled Food Questionnaire for ease of understanding by the participant. The *FFQ* is used to assess usual dietary habits. It is a self-administered assessment of the participant's usual food intake over the previous three months. The *FFQ's* main purpose is to assess group-level and individual-level intakes of selected nutrients, in particular the percent of total kilocalories from macronutrients, beta-carotene, vitamins C, E, and A, dietary fiber, calcium, and iron.

The *FFQ* is used as a screening tool for the DM component of the trial at SV1. Women are ineligible for DM if their *FFQ* nutrient analysis report is (1) less than 32% calories from fat, or (2) less than 600 kcalories, or (3) more than 5,000 kcalories. (See *Section 6.1 - DM Eligibility Issues.*) The screening *FFQ* becomes the baseline *FFQ* for women entering any WHI component. During the study the *FFQ* will be administered according to the schedule in *Figure 2.1 - Frequency of CC Tasks*.

The *FFQ* includes a data section, participant instructions, and three sections on food. Each section has different questions:

- The data section is on the front page. Clinical Center data staff complete the shaded area (see *Vol. 3 - Forms, Instructions for Form 60*).

- Page 2 contains written instructions for the participant and an example.

- The first section of the *FFQ* (pages 2-4) consists of 19 questions on types of foods and preparation methods which permit the analysis software to interpret the use of specific food items.

- The second section of the *FFQ* (pages 5-11) includes individual food items arranged in food groups and, for each item, the participant indicates the usual portion size and frequency of consumption. Frequency choices range from "never or less than once per month" to "2+ times per day" for food items, and "6+ times per day" for beverages. The portion size allows the participant to choose between "small, medium and large." A medium serving size is given as an example on the *FFQ*; a small serving is equal to one-half of the medium serving or less, and a large serving is equal to one-and-one-half times the medium serving or more.

- The third section consists of four summary questions which ask about the usual consumption of fruits, vegetables and fats used in cooking. When given a list of foods, people often report eating more foods in a given category than they actually consume. Answers to the summary questions permit the analysis program to adjust responses to individual item frequencies so that the sum of all items in a food group are the same as the reported usual frequency of consumption for these foods.

It is not possible for the *FFQ* to incorporate all the foods that people eat. The food items on the *FFQ* were chosen using the following criteria: (1) data-based identification of major contributors of macro- and micro-nutrients in the US diet (Block etal. Am. J. Epidemiol 1985:122:13-20); (2) adequate items to reflect regional and ethnic eating patterns; (3) enough low-fat and fat-free modified foods to capture intervention results, and (4) incorporation of suggestions made by the Vanguard Clinical Centers (VCC). The *FFQ* is not intended to ascertain specifically what a person eats, but rather to get an overview of a woman's usual pattern of food intake (i.e., her usual frequency of consuming the listed foods and beverages).

Form 61 - How to Fill Out the Food Questionnaire provides additional instructions and nine pictures depicting small, medium, and large servings of three food items to help the participant estimate usual portion sizes to complete the serving size column of the *FFQ*. This is the only instruction sheet to be used for the *FFQ*.

10.2.1 Distributing and Completing the FFQ

The mailing, processing and storage of the *FFQ* is the responsibility of the CC. The baseline (screening) *FFQ* can be mailed to all potential participants and returned by the participant at or before the SV1 to determine

DM eligibility. Clinical Centers may also use the Screening Visit 0 (SV0) for distribution and/or completion of the *FFQ*. See *Section 3.7 - Visit (SV0)*. Follow up *FFQ*s are mailed to participants identified in the *FFQ* subsample before all follow-up CC visits, completed and returned to the CC at the scheduled annual visit.

The *FFQ* is a mark-sense form and must be completed using a #2 pencil. The form should not be folded or it will not scan properly.

10.2.1.1 Baseline (Screening) FFQ

All women who are interested in the trial complete an *FFQ* no later than SV1. Clinical Centers that mail the *FFQ* should use the procedures listed in *Section 3.6 - Mailing Initial Baseline Forms.*

10.2.2 Processing the FFQ

The CCs process the completed *FFQs* during the CC visit. This allows the reviewer to return the *FFQ* to the participant for completion or clarification and immediately identifies participants who are eligible (or ineligible) for the DM component. If screening *FFQs* are returned by mail before SV1, Dietary Assessment staff may need to call the participant to clarify any issues before determining eligibility.

Clinical Center staff certified for the *FFQ* review the completed *FFQs*. See General Instructions (#4) for the *FFQ*. The data staff scans the *FFQ* using the OpScan5 (see *Vol. 5 - Data System, Section 7.2 - Scanning*).

10.2.3 Reviewing and Editing the FFQ

Editing the *FFQ* involves the following:

- Cursory Review
- Pre-Scan Edit
- Computer Scanning of the *FFQ*
- Post-Scan Edit

10.2.3.1 Cursory Review

A cursory review is done quickly to catch obvious errors, such as large amounts of missing data or handwritten notes. This review should take no more than 30 seconds unless there are stray marks, handwritten items or numerous ovals that need to be darkened. Complete the Cursory Review using the procedures specified in General Instructions (#4.1. - 4.4.) for the *FFQ*. If there are many missing items (see *Section 10.2.5 - FFQ Error Report*), the reviewer should declare the *FFQ* unacceptable before it is burst and scanned. Return the unacceptable *FFQ* to the participant for completion.

10.2.3.2 Pre-Scan Edit

The pre-scan edit is conducted by a staff person certified for *FFQ* review (see *Form 465 - Food Frequency Questionnaire Certification*). A thorough review includes checking the form for inconsistencies, multiple marks and missing items, in addition to the items completed during the cursory review. The *FFQ* reviewer does not need to check each individual food item because the computer scanner can find double marks and count the number of missing items more accurately and efficiently. This review should take about two minutes, but it may take longer if many items need clarification by the participant. Complete the pre-scan edit using the procedures specified in the General Instructions (#4.5. - 4.7.) for the *FFQ*.

10.2.3.3 Guidelines for Interviewing Participants

Clinical Center staff certified for the *FFQ* may need to clarify information with the participant following the pre-scan and post-scan edits (see *Section 2.11.4.1 - Interview Techniques*). Use the guidelines below to facilitate the interview and obtain the information needed in an unbiased manner:

- Use non-leading questions (i.e., those that do not suggest an answer but guide the participant to report actual intake). See *Section 10.2.3.4 - Non-Leading Questions.*
- Ask one question at a time and concentrate on listening carefully to the answers rather than thinking ahead to the next question.
- Allow adequate time for the participant to think about her responses.
- Be neutral in your responses and avoid communicating verbal or nonverbal approval/disapproval of the participant or her dietary intake.
- Rephrase questions when the participant hesitates or does not seem to understand the question.
- Do not offer advice or dietary counseling.

10.2.3.4 Non-Leading Questions

Use the following examples as a guide to clarify responses with the participant:

Missing Food Items

- "There are several blank items on this page of the Food Questionnaire. It is important that each food item have a response. Please look at the foods you didn't mark. If you did not eat the food in the last three (3) months, fill in the oval under the column called 'never or less than once per month.' If you ate the food in the last three (3) months, please mark 'how often' you ate the food and the 'amount' you ate. Thank you."

Same Frequency Marked for a Substantial Number of Foods

- "Would you please look at the foods on this page of the Food Questionnaire again. Think about 'how often' you ate each food during the last three (3) months. Be sure your answer shows how often you ate each food during this time. Thank you."

Same Portion Marked for a Substantial Number of Foods (e.g., all "small" portions)

- "Would you please look at this page of the Food Questionnaire again. Please look at the medium serving size listed for each food. Think about how it compares to the amount you ate. If you ate this amount, your serving size is 'medium.' If you ate **half** this amount (or less) your serving size is 'small." If you ate more than **(1 and 1/2 times)** this amount, your serving size is 'large.' Please review the amounts you marked again. Thank you."

Multiple Marks

- "This question can have only one response. You have marked more than one response (oval). Please read this question again and choose one response. Thank you."

10.2.4 Computer Scanning of the FFQ

Scan the completed *FFQs* according to procedures specified in *Vol. 5 - Data System, Section 7.2.2 - Some Tips for Successful Scanning* and *Section 7.2.3 - Scanning a Mark-Sense Form*. If analysis of the *FFQ* is successful, a report is generated indicating whether the participant is eligible (or ineligible) for DM. If the analysis of the *FFQ* fails, an *FFQ Error Report* is automatically sent to the printer. Clinical Center staff give

the *FFQ Error Report* and the *FFQ* to CC staff certified for *FFQ* review. This person conducts the post-scan edit using the procedures specified in *Section 10.2.5.1 - Post-Scan Edit*.

10.2.5 FFQ Error Report

The *FFQ Error Report* indicates that the form was scanned, but not analyzed, and therefore results such as eligibility cannot be determined (see *Figure 10.4 - Sample of FFQ Error Report*). Errors for individual *FFQs* are listed only if they require judgments by the CC staff or if they are sufficient to make an *FFQ* unacceptable. Thus if only a few food items are missing in a section, they will not be listed on the *FFQ Error Report*. Error conditions identified by the computer scanner and listed on the *FFQ Error Reports* are outlined below:

- Any adjustment question or sub-question (pages 2-4 of the *FFQ*) not completed.
- Any summary question (page 12 of the *FFQ*) not completed.
- Multiple marks for any food item (pages 5-11 of the *FFQ,* Frequency of Consumption Column only).
- Multiple marks for any adjustment question or any adjustment sub question requiring a single response.
- Less than 90% of the frequency fields are completed on the entire *FFQ* or more than half of the food items in any section have a missing frequency.
- Less than 90% of the food items are completed on the entire *FFQ*.

All errors identified on the *FFQ Error Report* must be corrected before the *FFQ* is rescanned. Some errors may be corrected according to the procedures listed in the following section. For other errors it may be necessary to contact the participant for clarification.

10.2.5.1 Post-Scan Edit

Clinical Center staff certified for *FFQ* review correct each error on the *FFQ Error Report* using the procedures specified below. The corrected *FFQ* is then rescanned. *Note:* The *FFQ* should be rescanned only in response to an *FFQ Error Report.* Clinical Center staff should not query participants declared ineligible.

The most common errors identified on the *FFQ Error Report* are for missing data and multiple marks.

- **Missing Data Errors**

  The *FFQ Error Report* notes excessive blanks in any section of the *FFQ* (including the adjustment questions on pages 2-4 and the summary questions on page 12). Clarify missing data errors (e.g., missing food items, missing frequencies, missing portion sizes, and missing responses to adjustment and summary questions) with the participant using the guidelines provided in *Section 10.2.3.4 - Non-Leading Questions*.

- **Multiple Mark Errors**

  Multiple marks refer to situations where the participant marks (1) two adjacent items on a single line (e.g., two frequencies are marked for one food), or (2) more than one response for any adjustment question (or sub-question) requiring a single response. Clarify multiple mark errors with the participant if she is present in the CC using the guidelines provided in *Section 10.2.3.4 - Non-Leading Questions*. Otherwise, correct the multiple marks using the guidelines provided in the General Instructions (4.6.) for the *FFQ*.

  Note: These errors may also indicate the *FFQ* was completed using pen rather than pencil. If that is the case, pull the original *FFQ* and use a #2 pencil to mark over those items completed in pen. When rescanned, the scanner should pick up the pencil marks.

10.2.6 FFQ Analysis Results

All *FFQs* that pass the error checks are analyzed to provide nutrient intake data. This information is not given to the participant. Clinical Center staff may tell women who are ineligible only that the amount of fat reported is too low for the study, or that the kcalories reported are "out of range" for the study.

10.2.7 FFQ Storage

Store the scanned *FFQ* in the participant's file or in an easily retrievable manner.

10.2.7.1 Follow-Up FFQs

A subsample of participants in the DM complete the *FFQ* at the annual CC visit (see *Figure 2.1. - Frequency of CC Tasks*). OS participants complete the *FFQ* at their three year visit. Clinical Centers mail the *FFQ* and *Form 61 - How to Complete the Food Questionnaire* to women identified in the *FFQ* subsample along with other questionnaires for completion before the CC visit (see *Section 16.3.3.2 - Two Weeks Before the Annual Visit*). Women complete the *FFQ* at home and bring it with them to the annual visit. If a participant has not completed her *FFQ*, ask her to do so at the CC visit. Process the completed *FFQ* according to the procedures in *Section 10.2.3 - Reviewing and Editing the FFQ*.

10.3 The 24HR (Required)

The 24-hour recall is an attempt define and quantify food intake during the day just before the interview. Interviews begin at breakfast of the preceding whole day and work forward. Telephone interviews are conducted by trained interviewers at the Clinical Coordinating Center using a standardized data entry software (NDS), probing techniques, and portion size tools. A random ten percent sample of all interviews are monitored by a research nutritionist or interview specialist to ensure the quality of interviewing techniques and data collection. Some advantages of the dietary recall are that the technique is open-ended; participants need not be literate; and they cannot change what they ate retrospectively, therefore no alteration in usual diet should occur.

Recalls are administered annually to a random one percent (1%) sample of DM participants (with replacement) beginning 6 months post-randomization. The sample is stratified by treatment (Intervention and Control); 43% complete two recalls, the remainder complete only one. The cohort subsample of DM participants complete two dietary recalls at years 3, 6, and 9. In the 24 HR cohort, the recalls will be separated by no more than 3 weeks and reflect weekdays and weekends. The size of the 24-hour recall sample allows study-wide estimation of the intervention effect, and the repeated recalls allow estimation of the intra-individual variability and thus statistical adjustment of the variance.

CC staff should inform women in the DM that there is a small probability that they will be called to provide this information. Clinical Centers are responsible for updating WHILMA to reflect changes in participant address and phone number.

10.3.1 CC Procedures for 24HR Cohort

- Discuss the potential of completing the 24 hour recall with DM-interested women during administration of the DM Consent. (See Vol. 1 for Revised DM Consent Form).

- Give participants in the 24HR Cohort the one page information update to read at their next visit. (See the new Model Summary of Changes for Participants in the 4DFR Subsample Appendix E.5.13).

- Develop a tracking system to ensure that participants in the 24HR Cohort receive this information.

- Print *WHIP0963 – 4DFR Cohort Participants Due for Annual Visit 3, 6, or 9* monthly and verify phone number, address, and preferred language for each participant listed. Key enter new information into WHILMA before the last working day of each month. Database updates ensure current participant information for the 24 HR telephone interview.

10.3.2 CCC Procedures for 24HR

- Mail each participant a personal letter advising them that staff from the WHI Coordinating Center in Seattle will call to conduct one or two short interviews in the next few weeks.

- Mail each participant a portion size booklet. This booklet contains pictures of commonly consumed foods in several different serving sizes, a graphic of an eight ounce glass, a ruler, and a meat thickness indicator. Participants use this booklet to help estimate portion sizes during the telephone interviews.

- Send a thank you letter to each participant after the 24HR recalls are completed.

Figure 10.1

WHI 4DFR Documentation Checklist

Food Group:	Did You Specify:	Did You Probe for Additions and Amounts of:	Preferred Serving Size Measure:
Beverages			
Coffee, Tea	Brewed, instant, decaf, herbal, cereal type (i.e., Postum)	Sweetener, whitener, cream (type)	vol
Cocoa	Type (i.e., regular, sugar-free or low-cal) Made with milk (% fat) or water	Marshmallows Whipped topping (dairy or non-dairy)	vol
Beer	Regular, light or low alcohol		vol; can
Liquor, Mixed Drinks, Liqueur	Name of mixed drink/liqueur Amount of liquor and amount of mixer With or without ice If margarita, blended or strained	Mix (juice, other non-alcoholic beverage) Cherry, olive, etc.	vol
Wine	Dinner or dessert, red or white		vol
Carbonated Beverages	Cola or non-cola, caffeine-free, diet With or without ice		vol
Cafe Mochas	Specify with or without whipped cream Specify if made with chocolate syrup or cocoa powder		vol
Dairy/Non-Dairy Products			
Milk, Cream, Coffee Creamer, Toppings	% fat, dairy or non-dairy, If non-dairy: powder, liquid or aerosol If evaporated: diluted or undiluted	Sweetener, cocoa mixes, etc.	vol
Cheese	Natural or processed Kind (i.e., Cheddar, Swiss, etc.) If low-fat, brand or % fat If mozzarella, whole, part skim, or skim milk If parmesan, dry or fresh		wt; cube; wedge; vol if grated
Yogurt	% fat, plain or flavored Frozen or refrigerated	Fruit, nuts, etc.	vol; wt of container
Ice Cream, Ice Milk, Frozen Treats	Flavor % fat, hard or soft If cone, specify type (i.e., sugar, wafer, waffle, etc.)	Topping or Coating	vol * if standard size bar, specify number
Milk Shakes, Malts	Homemade or restaurant Flavor Ice cream or ice milk Specify if non-fat		vol * if restaurant, specify sm, med, or lg
Egg, Egg substitute	Method of preparation If substitute, powder or liquid Milk (% fat) Fat in preparation (kind) and amount	Cheese, vegetables, meat, etc.	vol; egg equivalent

Food Group:	Did You Specify:	Did You Probe for Additions and Amounts of:	Preferred Serving Size Measure:
Desserts, Baked Goods			
Puddings, Custards	Low-cal or regular Mix or scratch Milk (% fat) With or without egg	Topping	vol
Cookies	Kind (i.e., sandwich, wafer, etc.) Flavor Brand Ingredient fat	Nuts Icing Creme filling	sm, med, or lg
Cakes	Kind Layer, sheet or cupcake Ingredient fat, additional oil	Frosting, filling, topping (Specify kind)	cube; wedge
Pies	Kind (filling) Single or double crust Ingredient fat for filling and crust	Topping	wedge; portion of whole
Shortcake	Specify type of fruit Specify type of cake (i.e., biscuit, sponge, etc.)	Topping	cube; wedge; diameter
Cobbler	Specify type of fruit Specify type of crust (i.e., crumble, biscuit, pie, etc.)	Topping	cube; vol
Gelatin Desserts	Low-cal or regular	Topping, other additions (fruit, etc.)	vol
Fats			
Oil, Shortening	Brand and/or type of fat		vol
Salad Dressing	Brand, type (i.e., regular, low-cal, fat-free, etc.) Creamy or clear		vol
Margarine, Butter	Brand or major oil Regular, low-cal, low-fat, fat-free Form (stick, tub, squeeze, whipped, spread)		vol
Cream Cheese	Specify if whipped or solid		vol
Fruits/Fruit Juices	Ready to drink, frozen, or fresh Sweetened or unsweetened Fresh, canned, or dried Syrup (light or heavy), juice, or water packed With or without peel		vol *if fresh fruit, specify sm, med, or lg

Food Group:	Did You Specify:	Did You Probe for Additions and Amounts of:	Preferred Serving Size Measure:
Grain Products			
Bread, Rolls	Kind (white, whole wheat, rye, etc.)	Butter, margarine, other spread	standard size slice *if rolls, specify sm, med, or lg
Breadsticks	Bread or cracker type	Butter, margarine, other spread	LI
French Toast	Egg or egg substitute Fat in preparation Kind of bread Commercial, homemade, frozen	Butter, margarine, syrup, etc.	standard size slice
Sweet Rolls, Doughnuts	Yeast or cake-type Baked or fried (i.e., turnover)	Frosting, glaze, nuts, preserves	dia; sm, med, or lg
Pancakes, Waffles, Biscuits, Muffins	Kind (i.e., whole wheat, buckwheat, bran, etc.) Mix, scratch, commercial, or frozen Fat in preparation (kind)	Butter, margarine, syrup, etc. Topping (i.e., fruit, nuts, etc.)	dia
Cereal, Granola	Kind, Brand If hot cereal, fat in preparation, made with milk or water	Milk (% fat) Sweetener, fat, fruit, etc.	vol *if cooked cereal, specify vol BC or AC
Pasta, Rice	Kind (i.e., spaghetti, spinach, egg, brown, etc.) Fat in preparation (kind)	Fat (kind), sauce, cheese, etc.	vol, specify BC or AC
Crackers	Kind, Brand	Spread	number if standard size; sm, med, or lg
Tortilla	Corn or flour Fat used if fried Ingredient fat for homemade tortillas Preparation method: plain or fried	Filling Fat added at the table	dia
Gravies, Sauces	Kind (i.e., beef, chicken, pork, etc.) Mix or scratch Made with milk (% fat) or water Fat (i.e., meat drippings)		vol
Meat, Poultry, Fish			
Meat	Kind, cut Trimmed or untrimmed, % fat of hamburger or type of ground beef (i.e., ground chuck) Fat in preparation (kind) Visible fat eaten Marinade Breaded or battered and fried Fresh or cured Preparation method If hamburger, drained or rinsed	Sauce, gravy, etc. If breaded, was the coating eaten?	cube; wt * if wt, specify BC or AC, w/ or w/o bone

Food Group:	Did You Specify:	Did You Probe for Additions and Amounts of:	Preferred Serving Size Measure:
Meat, Poultry, Fish (Cont.)			
Meatloaf, Meatballs	Kind, % fat or type of meat (i.e., ground round) Fat in preparation (kind)	Sauce, gravy, etc.	cube; wt * if wt, specify BC or AC *if meatballs, specify diameter
Poultry	Light, dark, or mixture of meat Name of part Skin eaten or not Breaded or battered and fried Fat in preparation (kind) Marinade Preparation method	Sauce, gravy, etc. If breaded, was the coating eaten?	wt; sm, med, or lg piece * if wt, specify BC or AC, w/ or w/o bone
Fish	Kind Breaded or battered and fried Fat in preparation (kind) Fresh, canned, or frozen If canned, water or oil pack; drained, undrained, or rinsed Marinade Preparation method	Sauce, etc. If breaded, was the coating eaten?	cube; wt; vol * if wt, specify BC or AC, w/ or w/o bone
Bacon	Specify type (i.e., beef, pork)		number of slices
Cold Cuts, Luncheon Meats	Kind, % fat, brand		wt
Meat Substitutes			
Tofu	Firm or regular		vol
Mixed Dishes	Mix, scratch, or commercial Fat in preparation (kind) Meat, kind, and % fat Sauce or gravy (type) Milk or cheese (% fat or kind) Pasta or vegetables If Chow Mein, with or without noodles, noodles fried or soft	Topping (i.e., croutons, crackers, cheese, etc.)	vol
Frozen Entrees	Brand Complete name of entree		wt of pkg and portion of pkg eaten
Pizza	Deep dish, thick, or thin crust Restaurant, fast food, package, or homemade Brand Specify type (i.e., pepperoni, cheese only, vegetarian, etc.)	Topping, extra cheese	wedge; portion of whole
Restaurant Meals	Name of restaurant if fast food Name of menu item Method of preparation Price range of restaurant	Additions at the table With or without cheese	*if fast food, portion of standard size order

Food Group:	Did You Specify:	Did You Probe for Additions and Amounts of:	Preferred Serving Size Measure:
Seasonings/Condiments	Jelly (specify type) Pickle, relish, catsup, mustard, steak sauce, etc.		vol
Snacks			
Candy	Kind, brand Filling (type)	Nuts	number if standard size pieces
Popcorn	Commercial, home popped, or microwave Brand, flavor If light, indicate if for salt, fat, or both Fat in preparation (type) Amount in cups	Topping (i.e., cheese, fat [type], etc.)	vol; wt of pkg and portion of pkg eaten
Potato Chips	Thick or Thin type		vol; number eaten; wt of package and portion eaten
Nuts	Type Raw or roasted If roasted, oil or dry		vol; number * if vol, indicate if shelled or unshelled
Soups	Ready to serve, diluted, undiluted Milk (% fat) or cream added Chunky or regular Noodles or pasta Specify if low-fat Meat (kind)	Croutons, crackers, cheese, etc.	vol; wt of can
Vegetables	Method of preparation Fresh, frozen or canned Fat in preparation (kind)	Fat (kind), cheese, sauce, nuts, dip, etc.	vol, specify if cooked or raw
Salads	Kind (major vegetables) Lettuce (type) If potato or tuna, with or without egg If potato or coleslaw, mayonnaise or vinegar dressing	Dressing, kind and/or brand Croutons, seeds, etc.	vol
Baked Potato	Skin eaten or not	Butter, sour cream, etc.	sm, med, or lg; LI
French Fries	Frozen, fresh, restaurant	Catsup, other condiments	vol; number and thickness (i.e., shoestring, steak) * if fast food, size of order (sm, med, or lg) and portion of order eaten

Record portion sizes in the following standard measurements:

Weight (wt) in grams (gm) or ounces (OZ)
Volume (vol) in fluid ounces (FO), cups (CP), tablespoons (TB), or teaspoons (tsp)
Fraction of the whole (i.e., 1/8 of 9" pie)
Size: Small (sm), Medium (med) or Large (lg) for food items such as fresh fruit, potatoes, chicken breast.

Record dimensions for the following shapes:

Label and verify all dimensions. Write "DV" (documentor verified) for very large or very small portions.

Shape	Measurement Needed	Example
Sphere	Diameter (dia)	Meatball, 3" dia
Cylinder or disk	Diameter (dia) x thickness (th)	Meat patty, 4" dia x 1/2" th
Rectangle or cube	Length (L) x height (H) x width (W)	Lasagna, 3" L x 2" W x 1" H
Wedge	Length (L) x height (H) x width of arc (arc)	Layer cake, 4" L x 3" H x 2" arc

APPROVED ABBREVIATIONS
Use these and other standard abbreviations when documenting food intake on *Four-Day Food Records*.

AC - after cooking	H - height	RTE - ready to eat
amt - amount	hyd - hydrogenated	s - saturated
approx - approximate	L - length	sl - slice
avg - average	LC - low calorie	sm - small
BC - before cooking	LF - low-fat	swt - sweetened
brd - breaded	lg - large	TB - tablespoon
cnd - canned	LI - linear inch	tsp - teaspoon
choc - chocolate	mayo - mayonnaise	th - thickness
chpd - chopped	med - medium	TVP - textured vegetable protein
ckd - cooked	misc - miscellaneous	ukn - unknown
comm - commercial	NA - nothing added	veg - vegetable
crax - cracker	NFS - not further specified	vol - volume
CP - cup	NVF - no visible fat	W - width
dia - diameter	OZ - ounce	w/ - with
DV - documentor verified	pkg - package	wt - weight
FF - fat free	pc - piece	w/o - without
FO - fluid ounces	prep - prepared	
gm - gram	poly - polyunsaturated	
gr - ground	RTD - ready to drink	

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Figure 10.2
Guidelines for Documenting the Fat Added Columns of the 4DFR

How to Use the Fat Added Columns

It is very important that the *4DFR* include all sources of fat consumed by the participant. Two of the major sources of fat in the diet are in food preparation and as additions to food at the table. For this reason, two columns are on the documentor's page of the *4DFR*. One column asks, "Was fat added in preparation?," and the other column asks, "Was fat added at the table?" The purpose of these columns is to remind the documentor to ask the participant these questions for foods that commonly contain fat or have fat added to them.

Use these columns to document fat only (e.g., oil, shortening, salad dressing, margarine, butter, mayonnaise, etc.) added to foods, and ingredient fat in foods (e.g., butter in cookies). It is appropriate to leave both columns blank for foods that DO NOT typically have fat added to them (e.g., catsup, jelly, carbonated beverages, fresh fruits, and juices, etc.)

Follow the steps listed below as the *4DFR* is documented with the participant. Use the examples provided for each column to assist you.

Column 1: Was fat added in preparation?

Ask the participant if fat was added in the preparation of food items.

- Enter the participant's answer in the "Was fat added in preparation?" column. Write a **Y** in the column if the answer is yes, an **N** for no, and a **U** for unknown.
- If a participant knows the item was prepared with fat, write the type and amount of fat on the documentor's line for that food item.
- Ask the participant if the amount of fat was for her portion only. If it was not for her portion only, write the total amount prepared or adjust the amount to match her portion accordingly.
- For most commercial products the type and amount of fat will be unknown, therefore, do not mark the column for these products.
- For fat free commercial products, write "fat free" as a description for the item and do not mark in the column.

Column 2: Was fat added at the table?

Ask the participant if fat was added to the food at the table or prior to eating.

- Enter the participant's answer in the "Was fat added at the table?" column. Write a **Y** in the column if the answer is yes, an **N** for no, and a **U** for unknown.
- If a participant added fat, write the type and amount of fat on the documentor's line for that food item.
- If the participant wrote the added fat on a separate line, write a **Y** in the column titled "Was fat added at the table?," and draw an arrow to the line where the fat is written.
- Ask the participant if the amount of fat was for her portion only. If it was not for her portion only, write the total amount prepared or adjust the amount to match her portion accordingly.

Figure 10.2. (Continued)

Figure 10.2. (Continued)

Figure 10.3
4DFR Screening Checklist

1. **Participant ID Number:** ___ ___ - ___ ___ - ___ ___ ___ - ___
2. **Clinical Center Number:** ___ ___

Check all *4DFRs* for the following before sending to NASR for processing:

5. ERROR CODE	6. ITEMS TO BE CHECKED	7. YES	8. NO
1	Participant ID barcode label attached in space indicated on page 40 of *4DFR*.		
2	Participant ID number on all odd numbered pages (7 - 39) of *4DFR* (i.e., write the number, stamp the number, or affix a label to the page).		
3	Assigned dates and days for recording match with those listed by the participant in the *4DFR*. If the participant kept her *4DFR* on days other than those assigned, correct the days and the dates on the front of the book.		
4	The participant completed a minimum of three food record days.		
5	Entire section for Vitamin and Mineral Supplements is complete (*4DFR* page 4). • "Yes" box checked and remainder of page completed if participant took a supplement. • Supplements recorded on the days taken in the daily record. • "No" box checked if participant did not take a supplement.		
6	Entire section for General Questions is complete or verified by documentor (*4DFR* page 5). • Information is complete for each item listed. • Documentor has verified (written NA and initialed) those items that the participant does not use.		
7	Back page of *4DFR* (page 40) completed. • Shaded section complete and data items correctly key-entered. • Intake and Reliability Information complete.		
8	Food labels are in a sealed envelope or clear plastic bag, and stapled to page 39 of the *4DFR*.		
9	Documentor used a different colored pen than the participant.		
10	Documentor is certified to document *4DFRs*.		
11	The *4DFR* is stapled and correctly assembled.		
12	The date peer reviewed is within 3 working days of the date documented.		
13	The 4DFR is mailed to the CCC within 2 weeks of date received at the CC.		

Figure 10.4
Sample of FFQ Error Report

MEMBER:31 10000 A BOOKLET #:00125477 VISIT CODE:1 DATE COMPLETED:
PRINTED:9/30/1993

WHI FFQ ERROR REPORT

ERROR DESCRIPTION	(STARTS ON) PAGE	ITEM DESCRIPTION
INVALID	1	Booklet number can not be read, or pages have different numbers
INVALID	1	Date
BLANK	4	Adjustment 16
TOO MANY BLANK ITEMS	7	MEAT SECTION
ENTIRE ITEM BLANK	7	Shellfish, not fried
ENTIRE ITEM BLANK	7	Mac and Cheese, lasagna, pasta w/
ENTIRE ITEM BLANK	7	Spaghetti or other pasta w/ meat
ENTIRE ITEM BLANK	7	Spaghetti or other pasta w/o meat
ENTIRE ITEM BLANK	7	Low-fat Pizza
ENTIRE ITEM BLANK	7	Pizza
ENTIRE ITEM BLANK	7	Tamales with or without meat
ENTIRE ITEM BLANK	7	Chilaquiles
ENTIRE ITEM BLANK	7	Soft quesadilla
ENTIRE ITEM BLANK	7	Crispy quesadilla and chili relle
ENTIRE ITEM BLANK	7	Soft taco and enchilada baked
ENTIRE ITEM BLANK	7	Faluta and crispy rolled taco
ENTIRE ITEM BLANK	7	Regular burrito and enchilada
ENTIRE ITEM BLANK	7	Taco and tostada
ENTIRE ITEM BLANK	7	Low fat lunch meats
ENTIRE ITEM BLANK	7	Regular lunchmeat
ENTIRE ITEM BLANK	7	Hot dogs, sausage
ENTIRE ITEM BLANK	7	Creamy soups
ENTIRE ITEM BLANK	7	Bean soups
ENTIRE ITEM BLANK	7	Vegetable soups
ENTIRE ITEM BLANK	7	Menudo and tortilla soup
ENTIRE ITEM BLANK	7	Other soups
TOO MANY BLANK ITEMS	10	SWEETS SECTION
ENTIRE ITEM BLANK	10	Low fat dairy desserts
ENTIRE ITEM BLANK	10	Donuts, cakes, pastries
ENTIRE ITEM BLANK	10	Cookies, regular
ENTIRE ITEM BLANK	10	Pumpkin and sweet potato pie
ENTIRE ITEM BLANK	10	Pies, fried pastries, pastelitos
ENTIRE ITEM BLANK	10	Chocolate candy
ENTIRE ITEM BLANK	10	Hard candy, sugars
TOO MANY BLANK ITEMS		WHOLE FFQ

Section 10
Dietary Assessment

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