SECTION 6

DIETARY MODIFICATION (DM)

INTRODUCTION

The objective of the Dietary Modification (DM) component of the Clinical Trial (CT) is to determine the effect of a low-fat dietary pattern that includes five or more daily servings of fruits and vegetables and six or more daily servings of grains on reducing the incidence of breast cancer, colorectal cancer, and coronary heart disease.

The proposed study will at the same time provide information on the effect of a low-fat dietary pattern on serum cholesterol, blood pressure, and body weight. If a low-fat diet does reduce the incidence of any one of the clinical outcomes of breast cancer, colorectal cancer, or coronary disease, the public health implications will be enormously important.

The participants in the DM component of the CT will be randomized into one of two arms: Comparison (Control) or Dietary Change (Intervention). The preferred terminology is Comparison or Dietary Change when interacting with participants. The terms Control (Comparison) and Intervention (Dietary Change) are interspersed throughout the WHI Manuals, recognizing that the documents are limited to staff and investigator use.

6.1 Assessment of DM Eligibility Issues (Required)

The following topics should be considered before a participant is randomized into the DM.

6.1.1 Food Frequency Questionnaire (Required)

All participants complete *Form 60 - Food Frequency Questionnaire* (*FFQ)* to screen out potential DM participants who are already consuming dietary intakes of less than 32% calories from fat.

Women are ineligible for DM if their baseline *FFQ* nutrient analysis is (1) less than 32% energy from fat, or (2) less than 600 kcalories, or (3) more than 5,000 kcalories.

6.1.2 Low Fiber (Required)

During the initial screening, the low-fiber/low-residue question on *Form 2/3 - Eligibility Screen* is meant to identify participants who are following physician prescribed dietary restrictions that may be incompatible with the increased fruits, vegetables and grains of the DM Intervention program.

If a participant responds "yes" to the question on *Form 2/3 - Eligibility Screen* that she is following a physician prescribed low-fiber diet, she would be temporarily ineligible for DM. Clinical Centers (CC) may determine when to rescreen using the procedures described in *Section 4.5.4 - Rescreening Ineligible Participants*. However, before starting the rescreening process, a Nutritionist should assess the frequency, severity, and duration of the episodes where a low-fiber diet is prescribed, and use clinical judgment to determine how this would impact on the woman's ability to follow the DM Intervention program. If the nutritionist finds that the woman would not be a good DM candidate based on these considerations, use the staff assessment question on *Form 6 - Final Eligibility Assessment* to make the woman ineligible.

6.1.3 BMI (Required)

Participants who have a BMI < 18 are not eligible for DM unless the Nutritionist overrides the exclusion on *Form 6 - Final Eligibility Assessment.* If a participant is joining HRT+DM, the Clinic Practitioner's decision to override the BMI criterion (or not override the criterion) for HRT does not affect the Nutritionist's override decision for DM.

6.1.4 Number of Meals Prepared Away From Home (Required)

Participants who eat 10 or more meals each week prepared away from home are not eligible for DM unless the CC Nutritionist overrides this exclusion. For a definition of a meal prepared away from home, refer to the Item Instructions for meals away from home question on *Form 2/3 - Eligibility Screen*, Item Instructions.

Before overriding the meals away from home exclusion criterion, the Nutritionist should refer to *Form 6 - Final Eligibility Assessment*, Item Instructions and consider the following:

- **Study goals.** The Nutritionist should assess a participant's ability to comply with the rigorous dietary changes required by the DM Intervention. A woman who eats 10 or more meals prepared away from home each week may have difficulty reducing her fat intake to the level required for the study.
- **Lifestyle.** The Nutritionist should assess if a participant's lifestyle is compatible with the demands of the DM Intervention. Frequent meals prepared away from home may indicate a lifestyle that is too complicated or busy to accommodate the time commitment required for successful participation and performance.

6.1.5 Availability During Next Year (Required)

Women who are interested in DM participation must be available for the first six months of DM Intervention (i.e., Sessions 1-12). Currently, there are no provisions for women to "drop-in" to DM Intervention group sessions at other CCs. Therefore, CCs should try to identify potential DM participants who travel away from their home for extended periods of time, as soon as possible in the screening process.

To assure that a randomized DM Intervention participant will be available for the first six months of DM Intervention meetings, *Form 2/3 - Eligibility Screen,* gathers information about a participant's availability for one year from the time she completes the form. If a woman responds "no" to being available for the next year, she is considered "not interested in DM at this time." A participant may reinitiate the screening process when she is available.

6.1.6 DM Eligibility Checklist (Required)

At the SV3 before randomization, the certified Lead Nutritionist or a staff person certified to administer the *DM Eligibility Checklist* assesses the participant's willingness and ability to complete the activities of the DM Intervention using the *DM Eligibility Checklist* (see *Figures 6.1a and 6.1b*). This review takes about 30 minutes and requires judgment by the staff who administer the Checklist.

The *DM Eligibility Checklist* provides a discussion guideline for assessing key eligibility issues related to the following topics:

- DM Adherence
- DM Design
- DM Expectations
- DM Randomization

The topics listed on the *DM Eligibility Checklist* are the minimum points to cover. The points may be addressed in any order; however, WHI experience to date suggests that the order shown in *Figures 6.1a and 6.1.b* works well.

The participant must satisfactorily complete the *DM Eligibility Checklist* review process, including the completion of an acceptable 4DFR, before she is eligible for DM. DM eligibility is assessed at several points during the *DM Eligibility Checklist* review process. If the participant becomes ineligible during the *DM Eligibility Checklist* review process, the review is stopped and staff document the participant's eligibility status on one of the following three forms: *Form 11 - Consent Status, Form 6 - Final Eligibility Assessment,* or *Form 62 -4DFR*. The form used depends on the reason for ineligibility as described in *Sections 6.1.6.1 - Review DM Adherence Related Issues, 6.1.6.3 - Review DM Expectations, and 6.1.6.4 - Review DM Randomization.*

6.1.6.1 Review DM Adherence Related Issues (Required)

The following adherence related areas are to be considered when determining eligibility for the DM: (1) weight loss as a motivator for joining DM, (2) history of weight cycling, (3) unusual eating patterns, and (4) the ability to complete 4DFRs in order that adherence can be monitored.

Begin the interview by reviewing the participant's motivation for joining the DM. Refer to *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask the participant.

Weight Loss as Motivator for Joining DM

Carefully assess and evaluate the appropriateness of a woman who is interested in losing weight or actively and intentionally losing weight as evidenced by (1) using weight loss medications (prescription or over-the-counter), (2) considering the use of weight loss medications (prescription or over-the-counter), (3) on a weight loss program, (4) considering a weight loss program, and (5) stating an interest in losing weight.

A woman stating that weight loss is a motivator for joining DM is not a good candidate for DM. She may have unrealistic expectations for DM that could cause disappointment and later result in her dropping from the study. Clarify that the DM program is not a weight loss program. Remind the participant that DM group sessions will not include information on weight loss methods. Ask the participant open-ended questions to assess her feelings about weight loss. Ask the participant how she would feel if she didn't lose weight or if she gained weight.

In addition, some women may be following a weight loss regimen that conflicts with the DM Intervention goals. Look for potential dietary conflicts when reviewing the *4DFR* for unusual eating patterns.

Further, a woman interested in losing weight may be hoping to be randomized to the Dietary Change group and will likely be disappointed if she's randomized to the Comparison group. Look for women who are unwilling to be randomized to either DM group when reviewing DM randomization.

History of Weight Cycling

A woman exhibiting a history of weight cycling may not be an appropriate candidate for the DM. Repetitive weight loss and weight gain during adulthood may make it more difficult for the participant to make permanent lifestyle changes required by the DM Intervention. The nutritionist should evaluate if the woman's weight history will negatively impact her performance in the DM if she is randomized to the Dietary Change group. Refer to *Form 34 — Personal Habits Questionnaire*, Question 4.

Determine Eligibility

- If the participant's primary motivation for joining the study is weight loss and she declines further screening to participate in DM, stop the *DM Eligibility Checklist* review process. Thank her for her interest. Complete *Form 11 - Consent Status*. Mark all reasons that apply.
- If the Group Nutritionist or Dietary Assessment staff feel that the participant's primary motivation for joining the study is weight loss or her weight history will negatively impact her performance, stop the *DM Eligibility Checklist* review process. Explain that she is ineligible for the study. Thank her for her interest. 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 "focus on weight loss" or "weight history" as applicable.
- If the participant is not focused on weight loss as a motivation for joining the WHI or does not have a weight history that contraindicates randomization, continue with the *DM Eligibility Checklist* review process.

Review the *4DFR* for Unusual Eating Patterns

Visually scan each page of the *4DFR* for unusual eating patterns. This is a judgment decision. The purpose of this review is to identify participants whose eating patterns appear incompatible with the DM Intervention goals. Look for participants who appear to have compulsive eating patterns, skip meals or avoid entire food groups, particularly fruits, vegetables, or grains. In addition, look for participants who have unique or very limited intakes of foods (e.g., liquid diets, routine consumption of diet beverages, bars etc. or fasting regimens). If a participant eats a limited variety of foods, ask open-ended questions to assess whether the four days recorded are typical and whether she is willing and able to include more variety in her diet. *See Figure 6.1-b DM Eligibility Checklist* with *Questions* for examples of open-ended questions.

Determine Eligibility

- If the participant feels that she is not willing or able to choose foods that are compatible with the DM Intervention goals and declines further screening to participate in DM, stop the *DM Eligibility Checklist* review process. Thank her for her interest. Complete *Form 11 - Consent Status*. Mark all reasons that apply.
- If the Group Nutritionist or Dietary Assessment staff feel that the participant has eating patterns or food choices that would **not** be compatible with the DM Intervention goals, stop the *DM Eligibility Checklist* review process. Explain that she is ineligible for the study. Thank her for her interest. 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 "unusual eating patterns."

- If the Group Nutritionist or Dietary Assessment staff feel that the participant has eating patterns or food choices that are compatible with the DM Intervention goals, continue the *DM Eligibility Checklist* review process.

Review the *4DFR* for Completeness

Evaluate the 4DFR for sufficient vision, reading and writing skills to determine a woman's future ability to self-monitor (i.e., record and calculate fat, fruit/vegetable, and grain scores), complete forms and complete make-up assignments.

The *4DFR* is considered to be "not satisfactorily completed" if any of the following items are inadequate:

- **A minimum of three days are required.** The *4DFR* with three days is acceptable. However, if fewer than three days are recorded, randomization should be delayed until the participant completes an acceptable *4DFR* (see *Section 10.1.6 - Common Problems and Solutions*).
- **Food record is legible.** Determine the participant's willingness and ability to provide legible records of the food she eats. Look for whether the participant can write well enough to keep self-monitoring tools if she is randomized into the Dietary Change group.
- **Food descriptions are complete.** Determine the participant's willingness and ability to completely describe the food she eats. Look for whether the participant can describe foods with enough detail to keep self-monitoring tools if she is randomized into the Dietary Change group. Select one or two different food items (e.g., main dishes, side dishes, desserts) on each page. Briefly review how the participant described the foods. Use the examples provided in the *4DFR* (pages 6, 8, and 10) as a guideline. Refer to *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask the participant.
- **Serving sizes are reasonably estimated.** Determine the participant's willingness and ability to reasonably estimate portion sizes. Briefly review the portion sizes listed in the record. Look for unreasonable estimates (e.g., a 7" diameter orange or a 1 oz. chicken leg). Refer to *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask the participant.

The CC Lead or Group Nutritionist should be involved in deciding whether a woman is an appropriate candidate for DM if she cannot read or write English (or Spanish) well. Dietary Change participants must be able to read and write English (or Spanish) well enough to complete the self-monitoring and home activities that are part of the intervention. Dietary Change group sessions use a discussion format and, therefore, rely more heavily on verbal skills than reading and writing skills. Dietary Change makeup sessions, on the other hand, rely more heavily on reading and writing skills because the participant is expected to read session materials and complete session worksheets before meeting with the nutritionist to review the missed session. Refer to *Vol. 2 - Procedures, Section 20.2.7 - Women with Special Needs.*

Determine Eligibility

- If a participant has not satisfactorily completed the *4DFR*, stop the *DM Eligibility Checklist* review process. Explain that she is ineligible for the study. Thank her for her interest. Complete the appropriate questions in the *4DFR* data entry box (shaded section on back page) using *Vol. 3 - Forms, 4DFR* General and Item Instructions. Mark "no" to the *4DFR* satisfactorily completed question. Forward the *4DFR* to data entry.
- If a participant has satisfactorily completed the *4DFR*, complete the appropriate questions in the *4DFR* data entry box (shaded section on back page) using *Vol. 3 - Forms, 4DFR* General and Item Instructions. Mark "yes" to the *4DFR* satisfactorily completed question. Continue the *DM Eligibility Checklist* review process.

Assess Willingness and Ability to Self-Monitor

Explain that self-monitoring is a critical part of the study. Review the frequency of self-monitoring for the Dietary Change group. Ask open-ended questions to assess the participant's willingness to record the foods she eats for each group session for the duration of the study. See *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask participants.

Determine Eligibility

- If the participant feels that she is not willing or able to self-monitor and declines further screening to participate in DM, stop the *DM Eligibility Checklist* review process. Explain that she is ineligible for the study. Thank her for her interest. Complete *Form 11 - Consent Status*. Mark all reasons that apply.
- If the Group Nutritionist or Dietary Assessment staff feel that the participant is unwilling or unable to self-monitor, stop the *DM Eligibility Checklist* review process. Explain to the participant that she is ineligible for the study. Thank her for her interest. 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 "unwilling or unable to self-monitor."
- If the Group Nutritionist or Dietary Assessment staff feel that the participant is willing and able to self-monitor, continue the *DM Eligibility Checklist* review process.

6.1.6.2 Review DM Design (Required)

Briefly review the DM design. The purpose of this review is to assess the participant's understanding that the DM has two groups (Comparison and Dietary Change) and that both groups are equally important for the success of the study.

Define both DM groups. Briefly explain that the DM study has two different groups. The Comparison group will eat as they usually do. The Dietary Change group will meet with a Nutritionist and other participants to learn how to eat less fat and more fruits, vegetables, and grains.

Reinforce the importance of both groups. Briefly explain that both groups are important for the success of the study. The study needs to have a group of people who do not change the way they eat in order to see if changing diet makes any difference. There could be no comparison without these two groups. See *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask participants.

6.1.6.3 Review DM Expectations (Required)

Briefly review the expectations of the two groups (Comparison and Dietary Change). The purpose of this review is to assess the participant's ability and willingness to meet the requirements of either group. Include the following information:

Review General DM Expectations

- **Review semi-annual contact.** Let the participant know that she will be contacted by a CC staff person (by phone, mail, or in-person depending on your CC procedures) every six months to check on general health and update any changes in address or phone numbers.
- **Review annual follow-up visit.** Let the participant know that she will be asked to come back to the CC once a year for a follow-up visit. The procedures done at this visit are similar to the baseline screening procedures (height, weight, blood draws, completion of forms, etc.).
- **Review dietary assessment requirements.** Let the participant know that she may be asked to occasionally provide information on the foods that she eats (*FFQ*, potential *4DFR* and/or 24-Hour Recall).

Review Comparison Group Expectations

Rather than repeating information given at previous screening visits, ask the participant to describe her understanding of the Comparison group expectations. If the participant is unclear about the expectations, clarify with the following information:

- **Eat as you normally do.** Briefly explain that a participant in the Comparison group will not be asked to make any changes in her eating patterns. She will continue to eat the way she normally eats. She will not meet with a Nutritionist. She will be followed for health outcomes in the same way as the Dietary Change group women.

Ask the participant open-ended questions to assess her understanding, willingness, and ability to meet DM Comparison group expectations. See *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions.

Review Dietary Change Group Expectations

Rather than repeating information given at previous screening visits, ask the participant to describe her understanding of the Dietary Change group expectations. If the participant is unclear about the expectations, clarify with the following information:

- **Review dietary changes.** Briefly explain that a participant in the Dietary Change group will be taught how to lower the fat in her diet and increase her servings of fruits, vegetables, and grains. Explain that the dietary program is not meant to be a weight loss program. The changes she will be asked to make are lifestyle changes that she will be expected to maintain for 8-12 years. Ask open-ended questions to assess her willingness and ability to make dietary changes. In addition, ask open-ended questions to assess how her family will react to her involvement in the dietary change program.

- **Review expectations of group sessions.** Briefly explain that during the first year, group meetings are held once a week for six weeks, once every two weeks for six weeks, and once a month for nine months. After the first year, the group sessions are four times a year until the study ends. Each group session lasts about two hours.

- **Determine participant's availability to attend group sessions.** Pay close attention to a participant's response to the following areas:

  a. Does the woman have a flexible schedule (i.e., more than one day of the week, or time of the day, that she is available to attend group sessions)?

  b. Will the woman be available to attend all group sessions, especially during the first year when group sessions are more frequent?

  c. Does the woman travel for extended periods of time (business or retirement trips)?

  d. Does the woman have reliable transportation to the CC? Will weather (or darkness) impact the woman's transportation? Does the woman live a distance from the CC and is she willing to come for all group sessions despite living far from the clinic?

- **Determine participant's willingness to attend group sessions.** Explain that group sessions are very important to help the participant learn how to change. She must be willing to attend all sessions. If she misses a session, she will be expected to make it up. Ask open-ended questions to assess the participant's willingness to attend sessions and to make-up missed sessions.

Ask the participant open-ended questions to assess her understanding, willingness, and ability to meet DM Dietary Change group expectations. See *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask participants.

Determine Eligibility

- If the participant is unwilling or unable to meet DM expectations for the Comparison or the Dietary Change group and declines further screening to participate in DM, stop the *DM Eligibility Checklist* review process. Thank her for her interest. Complete *Form 11 - Consent Status*. Mark all reasons that apply.

- If the Group Nutritionist or Dietary Assessment staff feel that the participant is unwilling or unable to meet the DM expectations, stop the *DM Eligibility Checklist* review process. Explain that the participant is ineligible for DM. Thank her for her interest. 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 "unwilling (or unable) to meet DM expectations."

- If the participant is willing and able to meet the expectations of both groups, continue with the *DM Eligibility Checklist* review process.

6.1.6.4 Review DM Randomization (Required)

Determine Participant's Willingness to be Randomized in Either Group (Comparison or Dietary Change)

Ask the woman an open-ended question to assess her willingness to be in either group. For example, ask the participant how she feels about not knowing the group she will be assigned to. See *Figure 6.1-b - DM Eligibility Checklist with Questions* for examples of open-ended questions to ask participants.

Determine Eligibility

- If the participant is unwilling to be randomized into either group and declines further screening to participate in DM, stop the *DM Eligibility Checklist* review process. Thank her for her interest. Complete *Form 11 - Consent Status*. Mark all reasons that apply.
- If the Group Nutritionist or Dietary Assessment staff feel that the participant is not willing to be randomized into either group, stop the *DM Eligibility Checklist* review process. Explain that she is ineligible for the study. Thank her for her interest. 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 "unwilling to be randomized."
- If the participant is willing to be randomized to either group, forward the *4DFR* to data entry. Inform the CC staff responsible for randomization that the participant is ready to be randomized.

6.2 Randomize DM Participant (Required)

Participants Eligible for DM

Participants who satisfactorily complete the *DM Eligibility Checklist* review process should be randomized using the procedures outlined in *Section 4 - Screening* and *Section 4.6.3.2 - DM Randomization*. The CC should have local procedures in place to maintain blinding of the Dietary Assessment staff to the participant's randomization assignment.

At randomization, if the participant's *4DFR* is identified as part of the *4DFR* subsample, follow the procedures in *Section 10 - Dietary Assessment.* If the *4DFR* is not identified in the *4DFR* subsample, no further documentation of the *4DFR* is required. File the completed *4DFR* at the CC.

Participants Ineligible for DM

Participants who do not satisfactorily complete the *DM Eligibility Checklist* review process should not be randomized. File the *4DFRs* for an ineligible participant in her file at the CC.

Figure 6.1a
DM Eligibility Checklist

Review DM Adherence Related Issues

_____ Review motivation for joining DM. Clarify that DM is not a weight loss program

_____ Review history of weight cycling

_____ Review *4DFR* for unusual eating patterns, estimate daily servings of fruit/veg and grains

_____ Review the *4DFR* to assess satisfactory completion:

- A minimum of three days is required (four days is ideal)
- Food record is legible
- Food descriptions complete and serving sizes reasonably estimated

_____ Assess willingness and ability to self-monitor

Review DM Design

_____ Review the general DM design; include the following:

- Definition of the two DM groups (Comparison and Dietary Change groups)
- Reinforce the importance of both groups to the study

Review DM Expectations

_____ Review general DM expectations; include the following:

- Semi-annual contact (via phone, mail, or in person)
- Annual follow-up visits with procedures similar to baseline (height, weight, blood pressure, blood draws, etc.)
- Dietary assessment requirements: occasional record-keeping of foods you eat (occasional *FFQ*, potential *4DFR* and/or 24-Hour Recall)

_____ Review **Comparison group** expectations; include the following:

- Eat what you normally do, no changes required

_____ Review **Dietary Change group** expectations; include the following:

- Change eating patterns to greatly reduce fat and increase fruits/vegetables and grains
- Review group session schedule and length of group sessions
- Determine availability to attend group sessions
  - — Flexibility when available to attend groups
  - — Availability during first year of DM Intervention
  - — Extended periods of travel (business or retirement)
  - — Transportation available and distance to travel to CC
- Determine willingness to attend sessions
  - — Willingness to make-up missed group sessions

Review DM Randomization

_____ Determine the participant's willingness to be randomized into either group

Figure 6.1b
DM Eligibility Checklist with Questions

Review DM Adherence Related Issues

_____ Review motivation for joining DM. Clarify that DM is not a weight loss program

What interests you in the DM study? What is your motivation for joining the WHI?

Do you understand that the Dietary program is not a weight loss program? How do you feel about that?

_____ Review history of weight cycling

How often are you dieting?

Are you currently dieting or thinking about dieting? How much weight are you trying to lose?

Have you tried to lose weight before? What methods have you used to lose weight? Were you successful in losing weight? How much weight did you lose? Were you successful in maintaining the weight loss?

_____ Review *4DFR* for unusual eating patterns, estimate daily servings of fruit/veg and grains

How does the amount and type of food you ate compare to what you usually eat?

It looks like you ate about ___servings of F/V, how does that compare to what you usually eat? If low ask: *What would it be like for you to eat more fruits and vegetables? Are there any fruits and vegetables you don't eat? Which ones? Can you tell me why you don't eat these?*

It looks like you ate about ___ servings of grains, how does that compare to what you usually eat? If low ask: *What would it be like for you to eat more grains? Are there any grains you don't eat? Which ones? Can you tell me why you don't eat these?*

_____ Review the *4DFR* to assess satisfactory completion:

- A minimum of three days is required (four days is ideal)
- Food record is legible
- Food descriptions complete and serving sizes reasonably estimated

Can you tell me more about how this [food name] was prepared?

How did you estimate the amount of this [food name] you ate?

When did you record the foods you ate?

_____ Assess willingness and ability to self-monitor

Tell me about how keeping a food record might have influenced what you ate.

How did you feel about keeping a food record?

What would it be like for you to keep track of the foods you eat on a regular basis? For a long time?

What kinds of things might come up that would keep you from keeping track of what you eat?

What concerns, if any, do you have about recording what you eat on a regular basis?

Review DM Design

_____ Review the general DM design; include the following:

- Definition of the two DM groups (Comparison and Dietary Change groups)
- Reinforce the importance of both groups to the study

Why do you think the Comparison group is important for the study?

Review DM Expectations

_____ Review general DM expectations; include the following:

- Semi-annual contact (via phone, mail, or in person)
- Annual follow-up visits with procedures similar to baseline (height, weight, blood pressure, blood draws, etc.)
- Dietary assessment requirements: occasional record-keeping of foods you eat (occasional *FFQ*, potential *4DFR* and/or 24-Hour Recall)

_____ Review **Comparison group** expectations; include the following:

- Eat what you normally do, no changes required

What is your expectation of what you would be asked to do if randomized to the Comparison group?

_____ Review **Dietary Change group** expectations; include the following:

- Change eating patterns to greatly reduce fat and increase fruits/vegetables and grains

What is your expectation of what you would be asked to do if you were randomized to the Dietary Change group?

How would you feel about changing your eating patterns to eat less fat?

How would you feel about increasing your intake of fruits and vegetables?

How would you feel about increasing your intake of grains?

What might interfere with you changing your eating habits?

How would your family react to you changing your eating habits?

- Review group session schedule and length of group sessions
- Determine availability to attend group sessions

— Flexibility when available to attend groups

How will a "fixed" meeting date fit into your current schedule?

How much control do you have over your daily schedule?

— Availability during first year of DM Intervention

Are you anticipating a change in your availability to attend sessions during the next year?(e.g. change in work schedule, new job, retirement, babysitting responsibilities)?

— Extended periods of travel (business or retirement)

How often do you travel for business or pleasure? When you travel how long do you usually stay?

— Transportation available and distance to travel to CC

What has been your experience getting to the CC for your screening visits?

What types of situations could make it difficult for you to get to the CC (e.g. weather, night driving, reliable transportation, etc.)?

Do you have any concerns about commuting to the CC for group sessions?

- Determine willingness to attend sessions

— Willingness to make-up missed group sessions

What kinds of things might come up that would keep you from attending a group session?

What would it be like for you to work a make-up session into you schedule, if you miss group sessions?

How would you feel about doing session activities (like shopping, worksheets, keeping track of what you eat, etc.) in addition to the time you spend in the group session?

Review DM Randomization

_____ Determine the participant's willingness to be randomized into either group

How do you feel about not knowing which group you will be randomized into?

How would you feel if you were randomized to the Comparison group?

How would you feel if you were randomized into the Dietary Change group?

6.3 Handling Randomized DM Participants (Required)

Make sure randomized DM participants leave with all the materials handed out by the CC at randomization (see *Section 4.3.5.2 - Participant Hand-Outs*).

6.3.1 Participants Assigned to the DM Comparison Group (Required)

Participants randomized to the DM Comparison arm meet with a non-blinded staff person to review the requirements of the Comparison group and its importance in the DM Trial. The general strategy for women randomized into the Comparison group is one of minimum interference with their customary diets while collecting nutritional and health outcome data appropriate for comparison with the Dietary Change group.

Health and Dietary Information

Give DM Comparison group participants a copy of the USDA/DHHS Dietary Guidelines for Americans (3rd edition) in addition to the other materials handed out at randomization. Restrict dietary responses to provide only information on the various food groups and the Recommended Dietary Allowances (RDAs). DM Comparison group participants must not be given any additional nutrition information, counseling, or resources such as health pamphlets with nutritional advice, the American Dietetic Association Consumer Information phone numbers, etc. For a list of health information brochures that can be used with DM Comparison participants as retention incentives, see *Section 2.3.2.6 - Other Equipment and Supplies.*

Refer participants who specifically ask for information, or a referral to their primary care provider. Remind DM Comparison participants that they will receive an annual WHI newsletter.

6.3.2 Participants Assigned to the DM Dietary Change Group (Required)

Participants randomized to the DM Dietary Change arm meet with a Nutritionist (or other designated non-blinded staff) to be assigned to a DM Intervention group. For more information about DM Intervention group formation, scheduling considerations and handling women waiting for group assignment, refer to *Section 6.8 -DM Intervention Group (Required).*

6.4 DM Intervention Goals and Design (Required)

6.4.1 Goals of DM Intervention (Required)

The goals of the DM Intervention are to:

- Reduce dietary fat to 20% of energy intake.
- Decrease intake of saturated fat to less than 7% of total energy intake.
- Increase intake of fruits and vegetables to five or more servings per day.
- Increase intake of grains and grain products to six or more servings per day.

6.4.2 Conceptual Design (Required)

The conceptual design of the WHI DM Intervention includes nutritional and behavioral themes. The three major content areas within these themes include: eating patterns, dietary change skills, and behavioral skills.

6.4.2.1 Nutritional Themes (Required)

The WHI DM Intervention is based on two nutritional themes: 1) eating patterns and 2) dietary change skills.

Eating Patterns

The specific eating patterns targeted in the DM Intervention are: 1) a reduction in fat from meat, dairy products, fats and oils, baked goods, and snacks, and 2) an increase in the use of fruits, vegetables (including beans and legumes), grains, and grain products.

These changes focus on reduction in total fat rather than type of fat which simplifies the message, increases the participant's potential success, and streamlines self-monitoring requirements. The original Women's Health Trial (WHT) found that participants automatically lowered their average intakes of saturated fat to 7% when total fat was decreased to 20% or less of baseline calories.

Dietary Change Skills

The specific information and skills required for dietary change and targeted in the DM Intervention include: 1) food selection and analysis, 2) food purchasing, 3) food preparation, 4) social dining, and 5) identification of high-risk eating situations.

6.4.2.2 Behavior Themes (Required)

The WHI DM Intervention is based on several psychosocial and behavioral themes, which are grouped into six categories: 1) reinforcements and motivators, 2) self-management, 3) skills training, 4) social support, 5) relapse prevention, and 6) self-reliance and self-efficacy.

Reinforcements and Motivators

The process of successful long-term behavior change begins with a guided self-analysis of the woman's initial motivations for participating. During the first few DM Intervention sessions, nutritionists encourage each woman to understand these motivations as a way of strengthening her resolve to change her diet. The most common motivators identified by the women in the original WHT were: 1) helping in a scientific research project; 2) personal health; 3) having a close relative or friend with breast cancer; 4) fear of cancer; and 5) learning more about nutrition.

The DM Intervention emphasizes additional motivators later in the behavior change process. These motivators include: 1) improved self-confidence and self-efficacy; 2) a sense of empowerment and self-control; 3) greater or improved social support; and 4) healthier living. The DM Intervention counters barriers to change at a very early stage. These barriers often include time and financial costs, increased awkwardness in social and eating situations, guilt about non-adherence, and decreased enjoyment when eating

recommended foods. The costs of the DM Intervention are discussed with participants throughout the sessions, and methods of minimizing cost barriers are identified continually.

Self-Management

Proven behavioral modification and self-control techniques are used throughout the DM Intervention sessions. Participants learn these techniques through a series of steps:

1. Self-monitoring of targeted behaviors.
2. Defining specific behaviors to be changed.
3. Setting quantifiable intervention goals.
4. Breaking complex behaviors down into smaller steps.
5. Specifying an action plan.
6. Obtaining evaluation and feedback on behavior changes from support network.

   Reinforcing progress and encouraging self-praise.

Skills Training

Most people need new skills to complete the process of behavior change. The original WHT identified several skills needed to modify dietary fat. Each of these skills is linked with an appropriate nutritional topic in the DM Intervention. These skills are taught and reinforced throughout the first year and include:

1. Problem-solving and analytic skills, to allow participants to handle new situations with knowledge and confidence.
2. Assertiveness and communication skills, to allow participants to actively seek out necessary foods, ingredients, and workable situations.
3. Stress-management skills, to help participants use non-eating strategies to cope with stressful situations and feelings of stress and fatigue.

   Cognitive skills, such as cognitive restructuring and imagery, to assist participants in identifying potentially dangerous self-talk and then replacing it with more healthful thoughts and feelings.

Social Support

Social support is critical for maintaining behavior change. The DM Intervention provides social support in three ways:

1. The Group Nutritionist serves as a main source of support and encouragement. Group Nutritionists are trained in listening and empathy skills. Participants learn that they can discuss any nutritional aspect of the study with their Group Nutritionist.
2. The group itself serves as a supportive environment. The tone of the group, set initially by the Group Nutritionist and maintained by the participants, has to be open, honest, sharing, and understanding. In the DM Intervention, problem-solving is a group effort and participants are encouraged to bring their most difficult situations to the group. This sharing is affirming to the participant and helps to solve the problem.
3. Family and other significant people in a participant's life provide a third source of support. Long-term dietary change is more easily maintained when it "fits" with normative family behavior. Changing a woman's eating habits often results in modifications of the family's eating habits as well. Thus, women are asked to involve their "significant others" in the change process. Problems regarding the "others'" acceptance of the low-fat eating plan are addressed as part of the DM Intervention. Most solutions will require a combination of these three sources of social support: 1) the participant asking for help, 2) receiving support from "significant others," and 3) learning to cook low-fat meals that are acceptable to "significant others."

Relapse Prevention

Maintaining behavior change requires a series of steps, known as relapse prevention strategies, to avoid the high relapse rates associated with appetite behaviors. Relapse prevention techniques are introduced during the first six months of DM Intervention. Participants identify high-risk situations such as social gatherings, emotions and changes in routines. They develop coping strategies to help them handle these high-risk situations and learn how their thoughts influence the actions they take. The women learn to think about a "high-fat" dietary behavior as a momentary lapse. They are taught to substitute "low-fat" dietary behaviors to prevent a relapse back to their original high-fat consumption pattern. Slipping back gradually to old high-fat patterns is defined specifically as low-fat dietary change relapse. Techniques for managing momentary lapses and relapses have been tested in other situations and are applied in the DM Intervention near the end of the first year. Relapse prevention is a major focus in year 2 and beyond.

Self-Reliance and Self-Efficacy

In a long-term intervention such as WHI, participants must be able to rely on their own choices and behaviors instead of a strict adherence to a prescribed dietary plan. Self-efficacy is the participant's belief that she can actually change and maintain dietary behaviors leading to a low-fat eating plan. The DM Intervention provides deliberate opportunities for participants to increase self-reliance and self-efficacy. For example, women are taught skills necessary for feeling more competent and assured in uncomfortable situations. They also learn ways to improve social support as a means of promoting confidence with new ways of eating. Group Nutritionists encourage participants to discover their own "inner power" by regularly reinforcing personal accomplishments, no matter how small. This process of empowerment and emphasis on self-control is necessary to enable women to maintain dietary changes over the long term.

6.4.3 Incorporation of Conceptual Design into DM Intervention (Required)

6.4.3.1 Daily Fat Gram Goal (Required)

Each DM Intervention participant receives a daily fat gram goal based on an algorithm that takes height into account. She makes her own food choices within the fat gram goal. There is no dietary prescription provided. The low-fat message is simplified by focusing on reductions in total fat intake. For example, one participant might choose non-fat milk while another one chooses low-fat milk and both participants are able to meet their own fat gram goal.

The CCs should not provide DM Intervention participants with the baseline grams of fat reported on the WHI *FFQ*. This instrument was intended to measure the percentage of kcalories consumed as fat, not the absolute grams of fat.

A participant who wants to determine her baseline fat intake before she starts changing her eating behaviors, may use the Food Diary assigned at Session 1 to record her usual/baseline intake instead of post-Session 1 intake. This option should be reserved only for those participants who inquire about baseline fat grams. It should not be promoted by the Group Nutritionist as the desired self-monitoring activity. At Session 2 the participant learns how to count fat grams using the Fat Counter. She can calculate her baseline fat grams from her first Food Diary at this time, however, this delays fat intake reduction by one week. Previous WHT experience indicates that participants who reduce their fat intakes early have better overall performance (attendance and fat scores).

6.4.3.2 Integration of Nutritional and Behavioral Concepts (Required)

Appropriate nutritional and behavioral concepts are integrated into each of the DM Intervention sessions and carefully ordered to produce the maximum effect. The nutritional topics in Sessions 1-8 cover the eating pattern changes that have the greatest impact on the major sources of fat in the U.S. diet (fats and oils, dairy foods, red meats, snacks and baked goods). In addition, Sessions 4-6 cover the critical dietary change skills needed for major fat changes (label reading, shopping, recipe modification, dining out). The earlier sessions introduce the concept of increasing fruits and vegetables. In later sessions (Sessions 11-14) the nutritional

topics are more specialized and include topics such as handling vacations or holidays and increasing grain and fish consumption. Nutritional topics that deal with maintenance are included later in Sessions 15-17 (i.e., changes in routine eating patterns, gradual drift in eating patterns, etc.).

Nutritional and behavioral strategies are integrated into each session for several reasons. The DM Intervention materials focus on dietary behaviors, not nutrients, as a means of decreasing fat intake and increasing fruit, vegetable and grain intake. Participants and Group Nutritionists in the original WHT were uncomfortable in group sessions where only behavioral topics were presented, so complementary nutritional and behavioral topics were included in each subsequent session in Women's Health Trial: Feasibility Study in Minority Populations (WHT:FSMP). Implementing the WHI DM Intervention eating plan means that each Group Nutritionist and participant must view dietary changes as a series of activities that will ultimately become part of everyday life. Integrating nutritional and behavioral strategies in each session also helps participants integrate them in daily life. The focus on nutritional topics is highest in the early sessions during the time of intensive dietary change. The emphasis on behavioral strategies increases during later sessions to maintain the early dietary changes.

6.4.3.3 Sequencing of Behavioral Concepts (Required)

The behavioral session topics are grouped around strategies that facilitate behavior change. The first two behavioral topics, covered during Sessions 1-3, are motivations for low-fat dietary change (i.e., family and personal health or contributing to science) and self-management (self-monitoring and goal setting). The identification and reinforcement of motivators are included in the first session to develop and maintain participants' interest in dietary change. Self-management steps form the core of necessary behavior skills. Social influences and support are included in the first nine sessions because of the critical relationship between social influences on eating and successful health behavior change. Problem-solving, cognitive restructuring, time management and coping with stress are introduced during Sessions 10-15 after the initial large decreases in fat consumption have occurred. These topics help the women incorporate the new low fat behaviors into everyday living. Finally, relapse prevention and motivation are included in the last sessions (Sessions 16-18) of the first year to assist with long-term maintenance.

An overview of the first year of DM Intervention is provided in *Table 6.3 – Summary of DM Intervention Session* (at the back of this section).

6.5 Pre-existing Diets and DM Intervention Participants (Required)

Women with pre-existing therapeutic diets may be randomized to the Dietary Change arm of the WHI. The WHI DM Intervention is modeled after the original Vanguard WHT (average 20% fat/day) and is compatible with many therapeutic meal plans. For guidelines and suggestions to help Group Nutritionists incorporate pre-existing diets into the WHI DM Intervention, refer to *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual, Section 1.1 - Guidelines for WHI DM Group Nutritionists.*

6.5.1 Participants with Diabetes (Required)

The CCs should take the steps listed below to adequately accommodate participants who have Type II diabetes in DM Intervention groups. (*Note:* Women with Type I, or insulin-requiring diabetes are not eligible for DM. Women using insulin for Type II diabetes are eligible.)

Before randomization:

- Dietary Assessment staff evaluates whether the participant can adjust to the dietary changes recommended in the DM Intervention.

After randomization, if randomized to Dietary Change arm:

- Group Nutritionist (or other designated staff) reminds participant that changing her eating habits may also change her blood glucose levels.
- Group Nutritionist (or other designated staff) refers participant to her diabetes health care team for potential adjustments to medications.
- Group Nutritionist determines the presence of participants who have diabetes prior to or at the first group session.

Refer to *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual* for more information on working with participants who have diabetes.

6.6 Nutrition Policy Issues (Required)

For information about nutrition policy issues such as definitions of and servings for fruits, vegetables and grains, general use of supplements and food handling guidelines, refer to *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual, Section 1.1 - Guidelines for WHI DM Group Nutritionists.*

6.6.1 Calcium Supplements (Required)

Group Nutritionists should not recommend calcium supplements for any WHI participants. This interferes with one of the study hypotheses in the Calcium/Vitamin D (CaD) component of the CT. DM Intervention participants may be counseled on selecting foods that are good sources of calcium. However, to recommend beyond this could be construed as treatment and be considered a co-intervention as mentioned above.

6.6.2 Donated Food Samples (Required)

Group Nutritionists can accept donated food samples provided that it is made clear to the donor (preferably in writing) that acceptance of the donation does not imply National Institutes of Health (NIH) or WHI endorsement of the product or company. It is equally important that the women receiving the food samples be made aware of this policy of non-endorsement (verbally or in writing). Specific policies and procedures are being developed.

6.7 Facility, Equipment and Supply Requirements for DM Intervention (Required)

The furniture, equipment and supplies required or recommended for DM Intervention group sessions are listed in *Section 2.3.1.2 - Supplies Provided by the CCC* and *Section 2.3.2.2 - DM Intervention.*

6.7.1 Facilities (Required)

The room(s) used for the DM Intervention group sessions are required to be large enough for groups of at least 15 participants. These rooms may occasionally be used for potlucks, cooking demonstrations and larger social functions where family members and friends are encouraged to attend.

Clinical Centers may be required to obtain group session room space outside the main clinic area as more DM Intervention groups form. Frequently churches, community centers and local libraries have rooms that they are willing to lease. When looking for outside facilities, consider the following requirements: availability of space long-term, size of room, location (easy to find, close to bus line), cooking facilities, water availability and parking.

6.8 DM Intervention Groups (Required)

6.8.1 Description of DM Intervention Groups (Required)

DM Intervention groups are permanent groups. The Clinical Coordinating Center (CCC) requires the group consist of 8-15 members and to be led by a designated Group Nutritionist.

6.8.2 Forming DM Intervention Groups (Required)

After randomization to DM Intervention, the participant meets with a Nutritionist or other non-blinded CC staff to be assigned to a DM Intervention group. The Nutritionist makes a list of potential group meeting times defined by day of week, time and location. The Lead Nutritionist (or other designated staff) uses this list to assign DM Intervention women to an available group. The Appointment Coordinator (or other designated staff) asks randomized DM Intervention participants to sign-up for a DM Intervention group. The Lead Nutritionist should be notified when 8-15 women are assigned to a group.

Participants who cannot attend any of the available groups are placed on a waiting list. The Appointment Coordinator (or other designated non-blinded staff) asks the DM Intervention participant to provide the following information for tracking participants waiting for a group assignment: name, phone number, and preferred meeting times. The CCC requires the Lead Nutritionist to use a DM Intervention group tracking sheet such as the *Table 6.4 – Sample DM Intervention Group Tracking Sheet* (at the back of this *Section 6*) or a similar CC-designed sheet when she/he schedules a new DM Intervention group (see *Section* 6.8.2.3 – *Handling DM Intervention Participants Waiting for a Group.*).

6.8.2.1 Scheduling Considerations

The Lead Nutritionist considers the following areas when forming and scheduling DM Intervention groups:

- Group size and number: The ideal group size is 12 participants but groups may contain from 8-15 women. The size of each group ultimately determines the total number of DM Intervention groups required at the CC.
- Participant requirements: Schedule groups when participants can attend (i.e., evenings and weekends, if needed) and prioritize to accommodate women who have been on the group assignment waiting list for more than eight weeks.
- DM Intervention staff availability: Consider the number, days, and times of groups taught by each Group Nutritionist. Avoid scheduling morning and evening groups for one Group Nutritionist on the same day. Also avoid scheduling groups back to back for the same Group Nutritionist. Part-time Group Nutritionist staff can lessen scheduling difficulties.
- Classroom availability: Consider using a public place in the local community such as libraries, churches, etc., if group meeting space is limited at CC.
- Maximum efficiency: Consider beginning two or three groups at the same time. This allows easy access to make-up groups when participants miss a group session. It also helps save time and labor by combining shopping and food preparation activities for several groups.
- Monthly sessions: When scheduling monthly sessions, avoid clumping by staggering groups throughout the month. Plan ahead for holidays (most are on Mondays) and prime summer vacation times.
- Lack of interruption: Whenever possible, schedule DM Intervention group sessions to allow six weekly meetings without interruption. Occasionally, the Group Nutritionist may need to skip a week in scheduling a group sessions to avoid meeting on a holiday or to accommodate central training requirements. Whenever possible, reschedule the group session within a week of its usual meeting date.
- Holidays: Try to avoid starting a DM Intervention group in December. The December holidays (Christmas, Hanukkah, etc.) are a difficult time for women to attend groups meetings and to begin

changing their eating habits. If a new DM Intervention group is formed during December, skip no more than one week of groups sessions or consider delaying the starting date of the DM Intervention group rather than skipping two weeks of groups sessions during the first six weeks. Be aware of other specific holiday periods in your area and try to schedule around them whenever possible.

6.8.2.2 Assignment of Group Nutritionist to DM Intervention Group (Required)

The Lead Nutritionist assigns a Group Nutritionist to facilitate the group, using some of the considerations listed above. The designated Group Nutritionist calls the participants assigned to her group and arranges a date for the first group meeting. After the Group Nutritionist verifies the new groups start date and list of participants, she gives her list to data entry (or other designated staff) to generate a *Form 63 - Session Data Sheet* for the first group session. Refer to *Vol. 5 - Data System, Section 8 - DM Intervention Group - Data System* for more details about DM Intervention group data entry.

Note: The Lead Nutritionist is required to lead the first DM Intervention group formed at the CC. She/he must facilitate all sessions for training and quality assurance reasons (see *Section 19 - Quality Assurance*).

6.8.2.3 Handling DM Intervention Participants Waiting for a Group (Required)

Clinical Centers need to begin DM Intervention groups whenever they have an adequate number (8-15) of DM Intervention participants available. The goal is to have DM Intervention women in groups by three months post-randomization (12 weeks). After a new DM Intervention group begins, the Lead Nutritionist selects a time slot for the next group to start. She/he selects times that accommodate participants who have been on the group assignment waiting list for more than eight weeks, as well as other considerations listed above (see *Section 6.8.2.1 – Scheduling Considerations*).

All DM Intervention participants who have not started DM Intervention (i.e., completed Session 1 or more) are required to be contacted at least once a month by phone or mail. If DM Intervention groups are formed more frequently than once a month, a participant does not need to be called more than once a month. The Lead Nutritionist (or other designated staff) contacts the DM Intervention participants on the DM group waiting list to:

- Maintain interest in the program (this is particularly important if groups are formed less frequently than once a month).
- Determine if a participant's availability for groups has changed (record new times).
- Determine if a participant can attend a new group that is forming.

The staff member calling uses a DM Intervention group tracking sheet (see *Table 6.3 – Sample DM Intervention Group Tracking Sheet* or similar CC-designed sheet) to record the dates when the participant is contacted by phone. If a CC is unable to reach the woman by telephone, after at least three attempts at different times of the day, she is contacted by mail. The CCC strongly recommends that the CC's group tracking sheet contain the following information: name, preferred group times, phone number, date reached (phone or mail), and comments column to record group assignment and changes in group scheduling needs. Depending on the CC's needs, the group tracking sheet might also contain some of the following information: date of randomization, date of goal to be in a group (12 weeks post-randomization), and best times to call the woman. The CCC requires the CC to record the reason a DM Intervention participant is not assigned to a group. The Lead Nutritionist uses this DM Intervention group tracking system when she/he schedules a new DM Intervention group. Refer to *Vol. 5 - Data Systems, Section 8 - DM Intervention Group Data System* for information about reports that track DM Intervention startup and unassigned DM members.

In the initial three to six months of the Dietary Trial, slow recruitment rates may interfere with the establishing groups in a timely manner. During this time period, the DM Intervention participants interest may be maintained by using the procedures recommended in *Section 6.8.3 – Maintaining Interest in Women Waiting for DM Intervention*. It is very important to get women into groups as soon as possible after randomization. The Group Nutritionist has the option to proceed with a DM Intervention group assignment and provide a participant with catch-up sessions on an individual basis, rather than allow a woman to wait 12 or more weeks for assignment to a DM Intervention group. The Lead or Group Nutritionist uses her own

best judgment to make this decision. However the following criteria must be met before a participant who receives individual catch-up sessions is placed in an ongoing DM Intervention group:

- The participant will be unavailable to start another DM Intervention group in a reasonable amount of time (i.e., three months).
- There is an ongoing DM Intervention group that has only covered Sessions 1-3 (ideally not more than Session 2). The Group Nutritionist schedules an individual visit with the participant, prior to her attendance in the DM group and completes *Form 64 - Individual Data Sheet* for each session covered. No more than three sessions can be made up in an individual visit.
- The group members in the ongoing group have no reservations about having a new group member.
- The group enrollment in the ongoing group will not exceed 15 group members with the addition of the new participant.

If a woman has been randomized in DM Intervention but is unable to join an Intervention group, refer to *Section 6.10.6.3.1 – Awaiting Start-Up of DM Intervention* for procedures.

6.8.2.4 Final Group Formation at the End of Recruitment

The principle to use when planning final Dietary Change group formation is to arrange for as many participants as possible to receive as much of the DM Intervention as possible. Participants should be assigned to active groups, rather than creating a separate "straggler" group(s) which will never actually meet. This approach will best provide the mechanism to deliver the intervention to all active Dietary Change participants (by intervention as designed or Interrupted DM Intervention Participation). Nutritionists will also find it a more streamlined procedure.

Use the following hierarchy when planning final Dietary Change groups:

- First option: Form groups per usual procedure (to preserve the concept of group social support for new groups and minimize changes to existing groups). Screen women for availability to attend sessions of the final groups.
- Second option: Assign women to recently formed groups and use makeup sessions to catch these women up to the group's session schedule. This option will work for women willing and able to attend sessions, though unable/unwilling to attend the last groups forming. Nutritionists should attempt to assign women to groups that are as near the beginning of intervention as possible (e.g., within the first six sessions). The final assignment decision should be based on balancing a participant's ability to catch up, existing group dynamics, and staffing considerations.
- Third option: For those participants who are unable/unwilling to attend group sessions with either existing or the last groups forming, use Interrupted DM Intervention Participation procedures to deliver as much intervention as possible in as efficient a manner as possible. Refer to *Section 6.10.6.3 (including all subsections) – Interrupted DM Intervention Participation Procedures.*

6.8.3 Maintaining Interest in Women Waiting for DM Intervention (Required)

If a randomized DM Intervention woman has been waiting <u>at least one month</u> for her first group meeting, send the participant the written post randomization material: "Your New Eating Style." The material can be given to the woman in person or sent to her in the mail. Refer to *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual, Section 4 - Post-Randomization Intervention Material* for a copy of this introductory material.

The purpose of the introductory material is to provide some guidance and motivational information for women randomized to the Dietary Change group who are waiting for their first DM Intervention group session.

The CC may use other types of activities (instead of, or in addition to, the booklet "Your New Eating Style") to maintain interest and motivation (i.e., introductory sessions including food tasting and get acquainted

activities, etc.). However, a CC that wants to use a different activity to maintain interest during the "down time" between randomization and the start of DM Intervention groups is required to submit their plans/ideas in writing to the CCC for approval at least one month prior to the planned activity.

If a DM Intervention participant cannot attend the scheduled introductory activity, the CCC requires the CC to arrange for the participant to receive another form of communication. For example, the CC could mail the woman the supplementary materials from the CC introductory group activity, or provide her with the introductory booklet: "Your New Eating Style." A nutritionist should follow this mailing with a telephone call.

6.8.4 Combining DM Intervention Groups in First Year (Required)

During the first year, DM Intervention groups should be maintained with the same group of women assigned at randomization and with the same Group Nutritionist. Groups should not be combined during the first year of DM Intervention.

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6.9 DM Intervention (Required)

6.9.1 Group Nutritionist and Participant Manuals (Required)

Group Nutritionists trained and certified by the CCC deliver the DM Intervention. The DM Intervention uses a group teaching format and integrates nutritional and behavioral content within each session.

Vol. 4 - Dietary Modification Intervention consists of two parts, the *Group Nutritionist Manual* and the *Participant Manual*. The CCC provides each CC with five copies of *Vol. 4.* Three copies are for Group Nutritionist use (CCs with remote sites receive four copies for Group Nutritionists) and the other two copies are for general CC use.

6.9.1.1 Group Nutritionist Manual (Required)

The *Group Nutritionist Manual* includes the materials needed to facilitate the first year of DM Intervention Sessions (1-18, and Individual Session). The materials for each session include: session objectives, materials needed, suggestions for food tasting, *Participant Manual* page references and a suggested outline and procedures for the session.

In addition, the *Group Nutritionist Manual* contains information about handling pre-existing diets, nutritional policy issues, group facilitation, suggested readings and low-fat cookbooks, and a copy of the post-randomization DM Intervention material: "Your New Eating Style."

6.9.1.2 Participant Manual (Required)

Each DM Intervention participant receives a *Participant Manual* containing worksheets used during the group sessions and specific nutritional and behavioral information. The session information is written as self-help material and is designed to help women who miss class keep up with their group. The women are not required to read the materials if they come to class.

In addition, each participant receives a Fat Counter, Food Diaries, Fat Scans, recipes and supplementary handouts. The CCC provides Spanish versions of all participant materials for women who speak or read Spanish.

6.9.2 DM Intervention Schedule (Required)

During the first year, the participant attends group sessions once a week for six weeks, once every two weeks for six weeks, and once a month for nine months, for a total of 18 group sessions. Each participant also has one Individual Session with her Group Nutritionist. Beginning in the second year, there are four required maintenance sessions scheduled for each group per year.

6.9.3 Individual Session (Required)

The Group Nutritionist schedules an Individual Session with each group member between Sessions 9 and 10. The interval between these two sessions is normally one month (four weeks). However, this interval, between Session 9 and 10, may be extended (per Group Nutritionist discretion) to six weeks if needed to complete all Individual Sessions between Session 9 and 10.

The Individual Session lasts approximately 45 minutes and follows the outline and procedures detailed in "Individual Session," *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual*. The Group Nutritionist completes *Form 64 - Individual Data Sheet* for each Individual Session. *Note:* The Individual Session is different from other individual visits that would be scheduled for such activities as make-up or additional assistance (see *Section 6.10.5 – Make-Up Activities for Women Who Miss Sessions* and *Section 6.11 – Participant Progress*).

The Group Nutritionist will not have nutrient data available to look at nutritional adequacy issues. However, self-monitoring tools (Fat Scans and Food Diaries) can be used to assess the overall nutritional balance of a participant's food choices and identify areas that need to be changed. The Group Nutritionist should use the Individual Session as an opportunity to:

- Give each participant individual support and feedback.
- Discuss dietary changes.
- Evaluate variety and balance of current eating patterns.
- Identify potential compliance problems and plan for long-term maintenance.

Scores: Collecting and Recording

The total number of Fat Scans assigned between Sessions 9 and 10 is determined by the length of the interval between the sessions. The Group Nutritionist assigns the number of Fat Scans necessary to maintain a biweekly self-monitoring schedule. The number of Fat Scans assigned at Session 9 and the Individual Session depends on the placement of the Individual Session between Sessions 9 and 10. The Group Nutritionist assigns the appropriate number of Fat Scans at Session 9 and the Individual Session using *Table 6.1-b – Number of Fat Scans to Assign Dependent on Placement of Individual Session (6-Week Interval)*.

The Group Nutritionist collects the scores from Fat Scans assigned at Session 9 at the Individual Session and records them on *Form 64 - Individual Data Sheet*. Scores from Fat Scans assigned at the Individual Session are collected at Session 10 and recorded on *Form 63 - Session Data Sheet* (or *Form 64*, if doing make-up). If a participant does not complete the assigned score(s), the Group Nutritionist collects the score(s) at a later date using the procedures outlined in *Section 6.9.5.3 – Self-Monitoring Procedures*.

Home Activity: Collecting and Recording

The Group Nutritionist collects the Home Activity assigned at Session 9 at the Individual Session and records its completion of *Form 64 - Individual Data Sheet*. Home Activity assigned at the Individual Session is collected at Session 10 and recorded on *Form 63 - Session Data Sheet* (or *Form 64*, if doing make-up).

Table 6.1a
Number of Fat Scans to Assign Dependent on Placement of Individual Session (4-Week Interval)

4-Week Interval Between Session 9 and Session 10				
Number of weeks between **Session 9** and **Individual Session**	Number of Fat Scans Assigned at **Session 9**	Number of weeks between **Individual Session** and **Session 10**	Number of Fat Scans Assigned at **Individual Session**	**Total Number** of Fat Scans
0 →	**0**	4 →	**2**	**2**
1 →	**1**	3 →	**1**	**2**
2 →	**1**	2 →	**1**	**2**
3 →	**1**	1 →	**1**	**2**
4 →	**2**	0 →	**0**	**2**

Table 6.1b

Number of Fat Scans to Assign Dependent on Placement of Individual Session (6-Week Interval)

6-Week Interval Between Session 9 and Session 10				
Number of weeks between **Session 9** and **Individual Session**	Number of Fat Scans Assigned at **Session 9**	Number of weeks between **Individual Session** and **Session 10**	Number of Fat Scans Assigned at **Individual Session**	**Total Number** of Fat Scans
0 →	**0**	6 →	**3***	**3**
1 →	**1**	5 →	**2**	**3**
2 →	**1**	4 →	**2**	**3**
3 →	**1**	3 →	**1**	**3**
4 →	**2**	2 →	**1**	**3**
5 →	**2**	1 →	**1**	**3**
6 →	**3***	0 →	**0**	**3**

Note(*): If a participant turns in more than two fat scores (or fruit/vegetable or grain scores) at one session, the Group Nutritionist must average the scores before they are key entered into the WHILMA database. For example, if a participant turns in three fat scores (e.g., 30 g, 34 g, 27 g) at one session, the Group Nutritionist would record the average of the scores (e.g., 30) on *Form 63* (or *Form 64* if doing make-up) for the session.

6.9.4 Group Sessions (Required)

6.9.4.1 Content and Length (Required)

DM Intervention sessions are designed to take 1-1/2 to 2 hours. The schedule, session objectives and nutritional and behavioral topics for the first year of DM Intervention sessions are shown in *Table 6.2 – Summary of DM Intervention Sessions*.

6.9.4.2 Delivery of Group Sessions (Required)

The DM Intervention uses a variety of educational techniques to increase the participant's level of interest and retention of information. It is recommended that the use of lecture be limited and that the majority of class time be spent on interactive activities. Session activities give participants an opportunity to practice skills during group sessions. This lets participants anticipate problems and develop solutions before they leave the supportive group environment.

To maintain the sequence of key behavioral topics and ensure that all DM Intervention participants receive similar information, the Group Nutritionist is required to present the sessions in the same order as written (i.e., Session 5 must be presented before Session 6). DM Intervention sessions are designed to build on each other (see *Section 6.4.3 – Incorporation of Conceptual Design into DM Intervention*).

Group Nutritionists can modify the foods served or examples used in DM Intervention sessions to accommodate group interests and food preferences. For example, if the session on cognition (Session 11 - Self-Talk) is covered during the winter months, the examples used for food tasting and group discussion could focus on holiday situations and foods instead of lunches as written.

6.9.4.3 Format of Group Session (Required)

Each DM Intervention session consists of five parts: review of previous home activity, new material, summary, assignment of new home activity and food tasting. The following briefly summarizes the purpose of each of these sections and the Group Nutritionist's role in the process.

Review of Previous Home Activity

The Group Nutritionist is required to begin each DM Intervention session with a review of the previous home activity assignment. This review allows the participant to evaluate the goals she set and discuss behavioral and dietary successes and challenges that occurred during the previous period. In addition, it gives the participant an opportunity to provide support and guidance to other group members. The Group Nutritionist's primary role is to facilitate group discussion. She/he should use the group discussion to emphasize positive behaviors and provide reinforcement and direction for selection of appropriate strategies.

New Material

The major part of the group session presents new information or ideas to the group and lets them practice the skills or concepts within the supportive group environment. This section also provides the structure for each individual to gather information and select a specific topic-related goal to work on before the next session. The Group Nutritionist's primary role is to present the new information, guide group discussion using facilitation skills, and help the group members help each other. The Group Nutritionist should encourage equal participation among group members, encourage positive support and feedback, keep the group on topic, summarize the group at appropriate points and ask for feedback. The Group Nutritionist should facilitate horizontal interaction (participant to participant) versus vertical interaction (participant to Group Nutritionist).

Summary

Near the end of each DM Intervention session there is a brief summary required. The purpose of this section is to provide an opportunity for formative evaluation by assessing the participant's understanding of the ideas and skills presented during the session. It allows the Group Nutritionist to evaluate the group's ability to accomplish the objectives outlined for the session and provides an opportunity to reinforce learning. The Group Nutritionist's primary role is to briefly summarize the key points and then ask open-ended questions that allow the participants to process the information they have received during the session. The Group Nutritionist should also use the participants' responses during the discussion to clarify any misunderstood concepts.

Home Activity Assignment

At the end of each session participants receive an assignment to complete at home. The purpose of this assignment is to allow the participants to identify specific goals and action plans they will use between DM Intervention sessions. The home activity assignment provides an opportunity for the participants to use the nutritional and behavioral information they received during class and to measure their progress. The Group Nutritionist's role is to ensure that all participants understand the importance of this assignment and outline the areas where the participants should be setting their goals. For details on handling Home Activity Worksheets see *Section 6.10.4.3 – Home Activity Worksheets (Required).*

Food Tasting

Each group session includes food tasting. The provision of food tasting allows the participants to sample new foods, modified traditional favorites and foods prepared with new cooking techniques. The Group Nutritionist's role is to see that the food is prepared using safe food handling techniques and presented in a way to encourage participant use. The Lead Nutritionist uses nutrition support staff (if available) to assist Group Nutritionists with the preparation of foods and classroom materials. The Lead Nutritionist coordinates shopping, preparation, storage and service of food items as dictated by availability of staff, space and equipment. The Lead Nutritionist modifies food-tasting suggestions, if necessary, to accommodate cooking resources and/or regional food preferences; however, foods sampled in a session should reflect the session's message. The Lead Nutritionist ensures that intervention staff always use safe food handling procedures. For more information on food handling guidelines, see *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual, Section 1.3 - Food Handling Guidelines.*

6.9.5 Self-Monitoring (Required)

Self-monitoring is an essential part of the DM Intervention. The self-monitoring tools allow the participant to monitor her intake of fat, fruit/vegetable and grain servings, and to calculate the following scores:

- Fat score (average grams of fat consumed per day)
- Fruit/vegetable score (average fruit/vegetable servings consumed per day)
- Grain score (average grain servings consumed per day)

6.9.5.1 Aims of Self-Monitoring

The aims of self-monitoring are to:

- Increase the participant's awareness of her food intake.
- Teach the participant how to make wise food choices while decreasing fat and increasing fruits, vegetables and grains.
- Assist the participant in monitoring her progress during the DM Intervention.
- Provide the Group Nutritionist with information about a participant's dietary intake.
- Provide methods to monitor dietary change data over time.

6.9.5.2 Self Monitoring Tools (Required)

The DM Intervention uses two different self-monitoring tools: the Fat Counter with the Food Diary and the Fat Scan. Participants use the Fat Counter with the Food Diary during the first two months of group sessions (Sessions 2-6) and then replace them with the shorter Fat Scan at Session 7.

Fat Counter and Food Diary

The WHI Fat Counter was expanded from the Fat Counter used in the WHT:FSMP. It contains approximately 1,000 foods listed in two sections, one which is alphabetical and one which is by food group. The Fat Counter gives fat grams per serving for each food item and also lists servings of fruit/vegetables and grains in color-coded columns. The fat gram values in the Fat Counter are from the Minnesota Nutrient Data System (NDS) which the CCC uses to analyze all WHI dietary data. NDS Version 2.6. was used to calculate the fat gram values in the WHI Fat Counter. The DM Intervention participants begin using the Fat Counter at Session 2. A participant uses the Food Diary to record everything she eats or drinks for a minimum of three days (including one weekend day) each week. She uses the Fat Counter to look up the grams of fat in each food. She adds the grams of fat for each day and divides by the total number of days recorded to calculate her fat score.

The Food Diary contains an optional "fat-o-meter" (see Food Diary) that requires minimal math skills. A participant may use this method to track of the grams of fat she consumes and calculate a fat score. The meter is a scale with numbered dots that can be marked off as fat grams accumulate.

Fat Scan

The Fat Scan is a shorter and quicker method of monitoring fat intake that also allows monitoring of fruit/vegetable and grain consumption. The Fat Scan contains approximately 260 foods listed by food group. The food groups include: 1) breads, cereals and grain products; 2) dairy products; 3) fats, oils, nuts and sauces; 4) fruits, salads and vegetables; 5) meat, poultry and fish; 6) mixed dishes, and 7) sweets and desserts. The fat grams in the Fat Scan are from the same database (i.e., Minnesota NDS) used in the Fat Counter. The Fat Scan gives fat grams per serving for each item and color codes fruit/vegetable and grain sources for easy identification. A participant does not keep a separate Food Diary when using the Fat Scan. As a participant consumes food, she circles the items in the Fat Scan. At the end of the day she adds the circled numbers (fat grams) to calculate her fat intake and counts the servings of fruits/vegetables and grains. She records her food intake for three days and calculates her scores by averaging the daily totals. Participants use the Fat Scan beginning at Session 7 and continue to use them at every session during the first year.

6.9.5.3 Self-Monitoring Procedures (Required)

The Group Nutritionist encourages all participants to use the self-monitoring tools provided (Food Diary and Fat Scan) and turn them in after completion. Ask the participant to complete at least one 3-day self-monitoring tool for each session.

Collecting and Recording Scores

At the end of each session, collect the self-monitoring tools. Record the self-monitoring scores, assigned at the previous session, on *Form 63 - Session Data Sheet*. If the participant does not bring a completed self-monitoring tool to the session, leave the "score" column blank on *Form 63* (or *Form 64*, if doing make-up). Encourage the participant to complete the self-monitoring tools. If the participant completes the self-monitoring tools after the session, go back to *Form 63* (or *Form 64*, if doing make-up) for that session and record the scores. In addition to recording the scores, record the number of days the participant recorded her food intake. See Vol. 3 Forms instructions for *Form 63 - Session Data Sheet* and *Form 64 - Individual Data Sheet*.

Reviewing Self-Monitoring Tools

Review the completed Food Diaries or Fat Scans, prior to the next session, for accuracy of calculations and maintenance of healthy low-fat eating behaviors. Return the self-monitoring tool to the participant at the next session with corrections and comments which praise progress and note problems. Provide a clear message to participants that the Group Nutritionist uses the participant's self-monitoring scores to track their progress and provide additional assistance as needed.

Note: The Group Nutritionist encourages DM Intervention participants to self-monitor on a regular basis and uses the information to track progress. The Group Nutritionist monitors individual progress using the procedures outlined in *Section 6.10 (including all subsections) – DM Intervention Participation* and *Section 6.11 (including all subsections) – Intensive Intervention Protocol (IIP).* The Group Nutritionist monitors group progress using the procedures outlined in *Volume 7 - QA, Section 5 – Data Monitoring*. DM reports available in WHILMA help the Group Nutritionist track individual and group progress. Refer to *Vol. 5, Section 8.2 – DM Intervention Group Reports* and *Vol. 5, Appendix D – WHILMA Reports* for information about DM reports.

The CCC monitors self-monitoring data. Quality assurance performance goals for self-monitoring are outlined in *Volume 7 – QA, Section 6 – Performance Monitoring*.

Use of Whole Numbers or Fractions

Participants use whole numbers or fractions/decimals per individual preference, in the self-monitoring tools. The Group Nutritionist instructs the participants who choose to record only whole numbers to use the following rounding rule: round up to the next whole number if the fraction/decimal is greater or equal to 0.5; and round down to the previous whole number if the fraction/decimal is less than 0.5.

The Group Nutritionist records the scores on the data collection forms (*Form 63 - Session Data Sheet* and *Form 64 - Individual Data Sheet*) as follows:

- If the participant reports scores as whole numbers, the Group Nutritionist records the scores as whole numbers.
- If the participant reports scores as decimals, the Group Nutritionist records the scores as decimals. The computer automatically completes the decimal rounding.
- If the participant reports scores as fractions, the Group Nutritionist records the scores as decimals. The computer automatically completes the decimal rounding.

Handling Incorrect Fat Scores

If the Group Nutritionist discovers an error in a participant's fat, fruit/vegetable or grain score(s), she/he records the correct score on *Form 63 - Session Data Sheet* or *Form 64 - Individual Data Sheet*. Refer to *Section* and *Vol. 3 - Forms* for more details about use of *Form 63* and *Form 64*. If the Group Nutritionist

discovers an error after either of these forms have been data entered, she/he notifies the CC data entry staff that the score(s) requires correction.

6.9.5.4 Self-Monitoring Issues

During the study, there might be a percent of participants who do not self-monitor. Some typical reasons that have been given in other studies include boredom or fatigue, lack of perceived benefit from ongoing record keeping, inability to make self-monitoring part of daily routine, and math/literacy problems.

DM Intervention participants may have some difficulty maintaining self-monitoring. Group Nutritionists may need to spend extra time helping participants learn how to keep records and use the various self-monitoring tools. It is also critical that participants understand the importance of self-monitoring as it relates to achieving their goal and to the study. However by using the following activities, some form of self-monitoring can be maintained throughout the study:

- Provide a clear message about self-monitoring expectations during screening visits.
- Provide clear self-monitoring instructions early in the DM Intervention process (Session 2).
- Provide a variety of self-monitoring tools (Fat Counter and Food Diary in early sessions, Fat Scan in later sessions and alternative tools for participants who are unable or unwilling to use the Food Diaries or Fat Scans.)
- Require a minimum of three days.
- Provide a math-easy option (“fat-o-meter”).

Although some self-monitoring should continue throughout the study, the amount can probably be reduced at the beginning of the year 2. Starting with year 2, the requirement for self-monitoring is reduced to a minimum of three days per month compared to the three days every two weeks in year 1. The Group Nutritionist should encourage DM Intervention participants who wish to self-monitor more frequently to do so. The Group Nutritionist may recommend a more frequent self-monitoring schedule when a participant is having trouble attaining goals.

If participants have difficulty self-monitoring, the Group Nutritionist may want to consider using some of the following suggestions to promote self-monitoring:

- Use-alternative self-monitoring tools.
- Use self-monitoring tools without looking up fat grams or calculating fat scores (i.e., keeping a Food Diary without looking up fat grams).
- Use self-monitoring tools for only one or two days instead of three or more days.
- Individualize self-monitoring requirements as the study progresses.

The possibility of making other easy-to-use self-monitoring tools available, such as a checklist system, will be considered.

6.9.5.5 Alternative Self-Monitoring Tools:

Alternative self-monitoring tools were developed to enhance adherence to dietary and self-monitoring goals and to encourage self-monitoring for women experiencing problems with the usual tools. Participants should be given ample opportunity to learn to use the usual tools prior to introducing the alternatives. Wait until maintenance sessions to introduce these tools to participants, however, if needed they may be introduced as early as session 12.

The alternative tools address issues that interfere with self-monitoring.

- A simpler and more portable format.
- A graphic format.

- A behavioral and less mathematical manner of monitoring.
- A need for "change," particularly for women who have reached years two and three in maintenance.

Score generating self-monitoring tools likely give participants a better picture of their adherence to dietary goals than do behavioral tools. Therefore, behavioral tools are ideally offered to participants unable or unwilling to use score generating tools or who express interest in using a behavioral tool in addition to a score generating tool.

Keeping Track of Goals

A participant uses the Keeping Track of Goals to record her fat, fruit/vegetable and grain intake. The participant checks a box for each fruit/vegetable and grain eaten and records fat grams for meals and snacks for up to 6 days per form. It is appropriate to use during maintenance with participants who are familiar with fat gram values, working women who need to keep diaries at home and work and for those who eat the same foods regularly.

Quick Scan

The Quick Scan is similar to the Fat Scan, except that it is only two pages. The Quick Scan lists commonly eaten foods and includes space to add foods. The Quick Scan may be tailored to suit regional preferences by adding or substituting foods on a master copy. Like the Fat Scan, the foods are listed by food groups and list Fat, Fruit/Vegetables and Grain servings. The Quick Scan has space to record three days intake and participants average the three days to calculate their scores.

Picture Tracker

The Picture Tracker was designed to provide a graphic tool for participants who are visually impaired or who find record keeping tedious and prefer a quick visual tool. It is offered to participants who are not turning in any records. Participants count servings of Fruits/Vegetables and Grains. Participants are asked to list low-fat and high-fat foods, but they do not record fat grams. Only one day's food intake is recorded per record.

Eating Pattern Changes

The Eating Pattern Changes questionnaire tracks behavior changes in eating. The behaviors tracked include key fat reduction strategies (e.g. reducing fat from snacks, desserts, meats, dairy, added fats and using assertiveness skills). In addition, participants record goals to help them achieve their dietary goals .

This tool is appropriate for women who have never monitored or who dislike the current method of monitoring or who are having trouble with math and those who may be at risk for adherence. This tool encourages participants to self-assess behaviors and to identify the goals they need to achieve. The Eating Pattern Changes questionnaire may help motivate participants to eventually return to using the Fat Scan and Food Diary, because it emphasizes the positive changes participants are making in their diet.

6.10 DM Intervention Participation (Required)

Attendance at all DM Intervention sessions is important. Attendance during the first six months (Sessions 1-12) is particularly critical because the information given to participants during these sessions is the foundation of the DM Intervention.

At the Screening Visit 3 (SV3), before randomization, a certified Lead Nutritionist, Dietary Assessment staff, or Group Nutritionist is required to use the *DM Eligibility Checklist* to assess a participant's ability to complete the activities of the DM Intervention. For more information about this review process and DM eligibility status, see *Section 6.2 – SV3 Assessment of DM Eligibility* and *Section 6.2.1 – DM Eligibility Checklist.*

6.10.1 Travel and Group Participation (Required)

During the first six months, the DM Intervention covers the basic nutritional and behavioral skills required to change eating patterns. It also provides time for the Group Nutritionist and the group members to develop rapport and group bonding.

Currently, there are no provisions for "drop-ins" to DM Intervention group sessions at other CCs. Therefore, the CCs should try to identify prior to randomization, participants who travel away from their home for extended periods of time. (Refer to *Form 2/3 - Eligibility Screen.*) The Group Nutritionist must make every attempt to encourage active participation of women randomized to DM Intervention. For more detailed information about determining levels of DM Intervention participation, see *Section 6.10.6 – Determining and Maintaining Levels of DM Intervention Participation (Required).*.

6.10.2 Family and Friends Attendance at Group Sessions

Group Nutritionists may encourage participants in the DM Intervention groups to bring family members and/or friends, dependent on the size of the meeting room and the feelings of other group members. However, Control participants in DM or any participants who are randomized to other components of WHI (OS and HRT) cannot attend DM Intervention sessions. This could confound the results of the study.

6.10.3 Methods to Encourage Participation (Required)

To encourage regular attendance, each CC emphasizes the significance of attendance during both pre- and post-randomization visits.

6.10.3.1 Pre-Randomization Methods (Required)

- Discuss and review the demands of the DM Intervention class schedule at all screening visits.
- Verify the participant's availability to attend for the first six months of DM Intervention sessions (Sessions 1-12). *Form 2/3 - Eligibility Screen* gathers information on a participant's availability. Refer to *Section 6.1.5 – Availability During Next Year* for more detailed information about DM eligibility.

6.10.3.2 Post-Randomization Methods

- Schedule DM Intervention sessions at times that are convenient for participants (i.e., avoid holidays whenever possible, locate group meetings in local neighborhood churches, libraries, etc.).
- Verify the participant's ability to attend at least the first six sessions before class assignment is made.
- Encourage the participant to take responsibility for attendance, including notification of CC staff if she is unable to attend a scheduled session.

- Involve the participant in maintaining the group's attendance by using a participant phone tree or buddy system established early in the DM Intervention (optional).
- Display graphs of group attendance at DM Intervention sessions (optional).
- Increase the participant's motivation and interest by providing feedback on the participant's self-monitoring tools.
- Phone DM Intervention participants or mail them reminder postcards (at least 1-1/2 weeks prior to scheduled session) during the monthly and maintenance sessions.

6.10.4 Monitoring Participation (Required)

The Group Nutritionist uses the following forms and tools to keep track of participant's progress and DM participation:

- *Form 63 - Session Data Sheet*
- *Form 64 - Individual Data Sheet*
- Home Activity Worksheets
- Group Nutritionist Progress Notes

6.10.4.1 Session Data Sheet (*Form 63*) (Required)

Form 63 - Session Data Sheet documents the following:

- Group session attendance.
- Completion of home activity.
- Fat, fruit/vegetable and grain scores.
- Make-up activities (date of Group Nutritionist phone call and reason for absence).

At each session, the Group Nutritionist documents attendance and other data described above using *Form 63*. She/he assures that the data entry of *Form 63* is completed before the group's next DM Intervention session. If the Group Nutritionist is unable to reach absent participants before the form is sent to Data Entry, the following data fields are left blank: date of phone call and reason for absence. *Form 63* can be updated when the data become available. See *Vol. 3 - Forms, Form 63* Instructions for details.

6.10.4.2 Individual Data Sheet (*Form 64*) (Required)

Form 64 - Individual Data Sheet documents various types of individual contact and includes data similar to that found on *Form 63 - Session Data Sheet*. The Group Nutritionist must use *Form 64* to document required individual DM Intervention contacts. Required individual DM Intervention contacts include:

- Missed session makeup.
- Individual Session (required between Sessions 9 and 10).
- Intensive Intervention Protocol (IIP) contacts.

The Group Nutritionist may use *Form 64* at CC discretion to document optional individual DM Intervention contacts. Optional DM Intervention contacts include any non-required individual DM Intervention contacts. Optional contacts are marked "Other" on *Form 64*.

The Group Nutritionist (or other designated CC staff) completes data entry of *Form 64 - Individual Data Sheet* within one week of the individual contact, whenever possible. See *Vol. 3 - Forms, Form 64* Instructions for details on the use of *Form 64 - Individual Data Sheet*

6.10.4.3 Home Activity Worksheets (Required)

The Group Nutritionist monitors completion of Home Activity Worksheets and records this information on the *Form 63 - Session Data Sheet* or *Form 64 - Individual Data Sheet* as described above. The Group Nutritionist may monitor completion of the Home Activity Worksheet by collecting and reviewing the worksheets after each session or she/he may choose to evaluate completion of the Home Activity Worksheets based on participant responses during the Review of Home Activity discussion that occurs at the beginning of each session. If the Group Nutritionist chooses the latter option, she/he will not have the opportunity to make written comments on the worksheets, which may be valuable for some participants. In addition, the Group Nutritionist should allow adequate time in the group discussion to evaluate completion of Home Activity Worksheets by all participants if the worksheets are not collected.

6.10.4.4 Group Nutritionist Progress Notes (Required)

The Group Nutritionist keeps progress notes on each individual in every DM Intervention group she/he facilitates. These notes help her/him to personalize the DM Intervention sessions and provide background information for the Individual Session. Progress notes may include information about food preferences or intolerances, family support, special situations such as illnesses or work schedules and other personal commitments. The CCC does not require the use of a special form to record progress notes. The notes should be dated and kept in a notebook or file for each DM Intervention group. Depending on the requirements of each CC's institution, the Group Nutritionist progress notes may need to be kept in a locked cabinet or as part of the medical record.

6.10.5 Make-Up Activities for Women Who Miss Sessions (Required)

This section describes the procedures a Group Nutritionist is required to use when a participant misses a DM Intervention group session(s).

6.10.5.1 Procedures for Communicating with Women Who Miss Sessions (Required)

Group Nutritionists use standardized procedures for contacting non-attendees between sessions to maintain participation, identify problems and arrange for make-up of missed sessions. Immediate contact after a missed session makes the woman aware of the importance of attendance and strengthens her commitment to the study.

The make-up procedures described in the section are minimal requirements. Clinical Centers are encouraged to develop additional methods that will promote group attendance. For example, the CCs could decide to schedule an individual meeting for a participant who has missed one or two sessions during the biweekly or monthly group sessions. Group Nutritionists must complete *Form 64 - Individual Data Sheet* whenever make-up activities involve individual participation, whether it is in person, by phone or by mail.

Participant Misses Session Without Notification

Whenever a participant misses a session without notifying the Group Nutritionist in advance, the Group Nutritionist communicates with the participant using the following procedures:

- Calls the woman by telephone within one week. A minimum of three attempts at different times of the day are made to reach the participant.
- Sends a follow-up letter if the participant cannot be reached by phone and asks her to call the clinic as soon as possible.
- Makes a follow-up call if the participant fails to respond to the letter within one week.

When the Group Nutritionist reaches the participant for make-up, she/he uses the following procedures:

- Records the participant's reason for the absence and the date the participant was reached to schedule a make-up activity on *Form 63 - Session Data Sheet.*

- Schedules a participant make-up activity (see *Section 6.10.5.2 - Description of Make-Up Plans for Women Who Miss Sessions*).
- Mails the missed session material to the participant if she doesn't already have the materials and cannot attend another group's session. Mail make-up activities cannot be easily used during the first six weeks because of the lack of sufficient time between DM Intervention sessions.

Participant Misses Session With Notification

Whenever a participant misses a session but notifies the Group Nutritionist in advance, the Group Nutritionist can either give her the missed session materials early or mail them to her, if she doesn't already have them. The Group Nutritionist records the participant's reason for absence and the date the participant was reached to schedule a make-up activity on *Form 63 - Session Data Sheet* as follows:

- If the Group Nutritionist arranges make-up of the missed session when the participant notifies her of the absence, the Group Nutritionist records the date the woman notified her as the call date on *Form 63 - Session Data Sheet*.
- If the Group Nutritionist does not arrange make-up of the missed session when the participant notifies her of the absence, the Group Nutritionist records the date she reaches the participant to schedule the make-up as the call date on *Form 63 - Session Data Sheet*.

6.10.5.2 Description of Make-Up Plans for Women Who Miss Sessions (Required)

Whenever a participant is absent she is required to make up the session. The make-up plan depends on the number of DM Intervention sessions the woman has missed, the Group Nutritionist's workload and the participant's availability. It also depends on whether the session(s) missed is one or more of the first six DM Intervention sessions.

Participant Misses 1-2 Sessions At Any Time

If a woman misses one or two sessions at any time during the study, the Group Nutritionist uses <u>one</u> of the methods described below:

- Allows the woman to attend another DM Intervention group that is covering the missed session(s) material.
- Mails the woman the missed session(s) material (if she doesn't already have it) and asks her to complete the worksheets, furnish self-monitoring data and attend an individual meeting with the Group Nutritionist. The meeting may occur at any time before or after the next group session. The Group Nutritionist uses the meeting to review the session material, respond to participant questions, discuss ongoing challenges and collect self-monitoring data.
- If the woman cannot come in for an individual meeting before or after the next group session, the Group Nutritionist arranges a time to call the participant. The Group Nutritionist uses the phone call to review the session materials, including completion of the Home Activity Worksheet assignments, and verbally collects self-monitoring data. The Group Nutritionist also uses the phone call to respond to participant questions and discuss ongoing challenges.

Note: The telephone make-up method should be used only when it is not possible to see a participant in an individual meeting.

Participant Misses Three or More of First Six Sessions

If a woman misses three or more of the first six weekly sessions, the Group Nutritionist uses <u>one</u> of the following methods:

- Encourages the woman to begin again with a new group in order to complete the basic skills needed to change her eating patterns.
- Arranges an individual meeting with the participant if it is not possible or acceptable for the woman to begin a new group. The individual meeting can be used to review a maximum of three DM Intervention sessions.

Participant Misses Three Consecutive Sessions After the First Six Weeks

If a woman misses three consecutive sessions after the first six weeks, the Group Nutritionist uses the following procedure:

- Schedules an individual meeting with the participant. The Group Nutritionist reviews all the worksheets from the missed sessions, responds to the participant's questions and discusses ongoing challenges. In addition, the Group Nutritionist collects all available self-monitoring data that is missing from the previous DM Intervention sessions. A maximum of three missed sessions can be covered during one individual visit.

6.10.5.3 Data Collection for Women Who Miss Sessions (Required)

The Group Nutritionist records session data for make-up activities on the *Form 63 - Session Data Sheet* or *Form 64 - Individual Data Sheet,* as described below. Refer to *Vol. 3 - Forms* for detailed instructions on the completion of these two forms.

Participant Attends Another Group

If a participant attends another group's session(s), the Group Nutritionist uses the following procedures:

- Attaches the participant's barcode label to the *Form 63 - Session Data Sheet* of the group she attends.
- Records the participant's session data (attendance, scores, score source and home activity completion) on *Form 63* of the group she attends.

Participant Meets Individually with Group Nutritionist

If a participant meets individually with the Group Nutritionist (in person or by telephone), the Group Nutritionist uses the following procedures:

- Records the participant's session data on a *Form 64.*
- Completes a *Form 64* for each session covered during the individual visit. For example, if the Group Nutritionist meets individually with a participant to make-up three missed sessions, she/he would complete three separate *Form 64* forms.

6.10.6 Determining and Maintaining Levels of DM Intervention Participation (Required)

6.10.6.1 Participation Goals

The goals of DM Intervention participation are to:

- Start DM Intervention (regular group session attendance/completion) as soon as possible.
- Keep women participating in the DM Intervention at the highest level possible.
- Resume participation as quickly as possible, if DM Intervention is interrupted.
- "Stop DM Intervention" (Form 7) only if necessary.

DM Dietary Change participants are an important part of the Dietary Modification Clinical Trial whether they are active participants of a Dietary Change group or "Awaiting DM Intervention Start-Up". Once a participant has been randomized into DM, her data (or lack of data) will be included in study analyses, regardless of her participation and/or performance. This "once randomized, then analyzed" concept is the reason for the emphasis on getting Dietary Change participants into groups as soon as possible and keeping them in groups whenever possible. However, there may be occasions when a woman is unavailable or unwilling to participate in a group. To handle these special situations, the Group Nutritionist should use the procedures described in *Section 6.10.8 – Interrupted DM Intervention Participant Procedures* and shown in *Figure 6.2 - Interrupted DM Intervention Participation Flow.*

6.10.6.2 Definition of Non-Participation and Active Participation

Participation in the DM Intervention can be defined as Non-Participation or Active-Participation. The Group Nutritionist makes every attempt to encourage Active Participation.

6.10.6.2.1 Non-Participation

A Dietary Change participant is classified as a non-participant if she refuses all contact (in-person, by phone, or by mail) with the Group Nutritionist and other CC nutrition staff, and all special retention activities have failed. Refer to *Vol. 2, Section 17.2.3* (including all subsections) *– Special Activities for DM Intervention Retention Challenges* and *17.4 - Changes in Participant Status*.

6.10.6.2.2 Active-Participation

A Dietary Change participant is classified as an active participant if she is completing any of the activities described below.

Full participation:

- The participant is attending Dietary Change group sessions (and/or completing session makeup activities).

Low participation:

- The participant is unable or unwilling to attend Dietary Change group sessions or complete session makeup activities, but agrees to have contact with the Group Nutritionist or other CC nutrition staff as described in *Section 6.10.8 – Interrupted DM Intervention Participation Procedures.*

6.10.7 Triage System for DM Intervention

The Triage System for DM Intervention assists Nutritionists in case management and setting priorities. The system divides active Dietary Change participants into one of four adherence categories based on participant session completion and self-monitoring effort. Level 1 reflects high adherence and Level 4 reflects low adherence. The Triage System for DM Intervention provides a mechanism for prioritizing nutritionist effort according to participant level of effort.

6.10.7.1 Participant Level of Effort

Participant level of effort can be generally be described as follows:

- The Level 1 participant completes sessions, self-monitors, and meets fat gram goal.
- The Level 2 participant completes sessions, self-monitors, but does not meet fat gram goal.
- The Level 3 participant completes sessions, but does not provide fat scores.
- The Level 4 participant does not complete sessions (and seldom, if ever, provides fat scores).

Refer to Table 6.2 - *Triage System for DM Intervention* for a complete summary of the specific session completion and self-monitoring criteria defining each level.

Table 6.2
Triage System for DM Intervention

Adherence Level	General Description of Participant Effort	Criteria
Level 1 (High)	Completes sessions, self-monitors, and meets fat gram goal.	During the previous 12 months, the participant: • completed ≥ 50% of sessions, • provided a fat score at ≥ 50% of sessions, • the average of the provided scores was at or below fat gram goal.
Level 2 (Medium)	Completes sessions, self-monitors, but does not meet fat gram goal.	During the previous 12 months, the participant: • completed ≥ 50% of sessions, • provided a fat score at ≥ 50% of sessions, • the average of the provided scores was above fat gram goal.
Level 3 (Medium)	Completes sessions, but does not provide fat scores.	During the previous 12 months, the participant: • completed ≥ 50% of sessions, • provided a fat score at < 50% of sessions.
Level 4 (Low)	Does not complete sessions (these participants seldom, if ever, self-monitor).	During the previous 12 months, the participant: • completed < 50% of sessions.

6.10.7.2 Nutritionist Level of Effort

Nutritionists triage efforts beginning with participants in Level 1 and ending with participants in Level 4. Nutritionists generally spend the most time applying high intensity effort to participants in Level 2 and Level 3, and relatively less time applying low intensity effort to participants in Level 1 and Level 4. The actual amount of time devoted to efforts within each level depends on DM adherence and CC resources. Clinical Centers with high staff resources and high DM adherence may have the opportunity to apply high intensity efforts to all adherence levels. Clinical Centers with low staff resources and low DM adherence rely on the Triage System for DM Intervention to prioritize nutritionist efforts.

Refer to *Section 6.10.8 – Interrupted DM Intervention Participation Procedures* for information about using the Triage System for DM Intervention to guide low intensity efforts with Level 4 participants, i.e., active participants who are unable or unwilling to attend Dietary Change group sessions or complete makeup activities, but agree to have contact with the Group Nutritionist or other CC nutrition staff.

Refer *Section 6.11 – Intensive Intervention Protocol (IIP)* for information about using the Triage System for DM Intervention to guide high intensity efforts of the Intensive Intervention Protocol.

6.10.8 Interrupted DM Intervention Participation Procedures

Participants with low DM Intervention participation have Level 4 adherence per the Triage System for DM Intervention. These are participants who are unable or unwilling to attend Dietary Change group sessions or complete makeup activities, but agree to have contact with the Group Nutritionist or other CC nutrition staff. Refer to *Sections 6.10.6.2.2. – Active Participation* and *6.10.7.1 – Participant Level of Effort.*

Nutritionists triage efforts by using low intensity Interrupted DM Intervention Participation Procedures with Level 4 participants. Refer to *Figure 6.2 - Interrupted DM Intervention Participation Flow*.

If CC resources support focusing higher intensity effort on Level 4 participants, the nutritionist uses procedures outlined in *Section 6.11 – Intensive Intervention Protocol*.

6.10.8.1 Awaiting Start-up of DM Intervention

During Recruitment

After a participant is randomized into the DM Intervention, the goal is to have her attending/completing sessions by three months (12 weeks) post-randomization, whenever possible. If a Dietary Change participant has not started Session 1 in a group by five months (20 weeks) post-randomization due to insufficient DM group formation at the CC, and not due to the participant's unavailability or unwillingness, the Lead Nutritionist should reassess the CC's group formation schedule.

Dietary Change participants who have not started DM Intervention (i.e., not completed Session 1 or more) should remain on the waiting list and should be contacted monthly using procedures described in *Section 6.8.2.3 – Handling DM Intervention Participants Waiting for a Group (Required)* until they start DM Intervention sessions. If a Dietary Change participant who has been on the waiting list for a long time expresses frustration or feels pressured by the required monthly contacts, keep her on the waiting list but negotiate a less frequent contact (e.g., quarterly). Avoid completing a *Form 7-Participation Status* to "stop" DM Intervention for participants on the waiting list, even if they remain on the waiting list for a long time.

The advantage of keeping a Dietary Change participant on the waiting list rather than completing a *Form 7-Participation Status* to "stop" DM Intervention, is that it:

- Allows the CC to track the individual participant and ensure that she is not lost in the shuffle of recruitment/screening activities.
- Maintains the Lead Nutritionist's awareness of the length of time a Dietary Change participant has been waiting to start Session 1.
- Maintains a stronger link between the CC and the Dietary Change participant, thus increasing the potential of actively involving the participant at a later date.

A Clinical Center's guiding principle should be to maintain contact with Dietary Change participants and negotiate the greatest amount of DM participation possible without having participants stop DM Intervention.

If a Dietary Change participant on the waiting list refuses all contact (in-person, by phone or by mail) with the Group Nutritionist and other CC nutrition staff, and all special retention activities have failed, refer to *Section 6.10.6.2.1 – Non-Participation.*

End of Recruitment

As the study reaches the end of recruitment and Lead Nutritionists plan final Dietary Change group formation, they may find they have participants who have not started DM Intervention and are unable/unwilling to attend sessions with either existing or currently forming final groups.

A Dietary Change participant who has not started DM Intervention and is unable/unwilling to attend sessions with either existing or currently forming final groups should be contacted to assess the situation and to determine willingness to continue active participation. Refer to *Section 6.10.8.2 – Assessing the Situation for Interrupted DM Intervention Participation.* If the participant is willing to continue active participation, assign her to an existing or currently forming final group. The group assignment decision should be based on maximizing the participant's exposure to and participation in the intervention and staffing considerations. Work with the participant to develop and implement a plan for delivering as much intervention as possible in as efficient a manner as possible. Refer to *Sections 6.10.8.3 – 6.10.8.6.*

Refer to *Section 6.8.2.4 - Final Group Formation at the End of Recruitment* for information about intervention start-up and final group formation options at the end of recruitment.

6.10.8.2 Assessing the Situation for Interrupted DM Intervention Participation

The Group Nutritionist assesses the situation when a Dietary Change participant who has started DM Intervention (i.e., completed Session 1 or more) completes less than 50% of sessions during the previous 12 months. The Group Nutritionist uses the *IIP Triage & Tracking* (WHIP0444) report to identify these participants. Refer to *Vol. 5 – Data System, Section 8.2 – DM Intervention Group Reports* and *Vol. 7, Section 5, Table 5.2 – CC Schedule for Data Monitoring – Required.* At this time, the Group Nutritionist contacts the participant and assesses the situation. The key points to include when assessing the reasons for

not completing sessions include the participant's perception of the problem as well as her preference for a plan. Refer to *Figure 6.3 – Interrupted DM Intervention Participation Worksheet.*

End of Recruitment

The Group Nutritionist assesses the situation when a Dietary Change participant has not started DM Intervention and is unable/unwilling to attend either existing or currently forming final groups. The key points to include in the assessment are the same as those outlined above for a participant who has started DM Intervention. Refer to *Section 6.10.8.1 – Awaiting Startup of Dietary Change* for additional information about handling participants who have not started intervention at the end of recruitment.

6.10.8.3 Developing and Implementing a Plan for Interrupted DM Intervention Participation

If after assessing the situation, the participant is willing to continue active participation, the Group Nutritionist and participant develop a plan and timeline to keep the participant involved and/or to resume regular group participation. The ultimate goal is to have Dietary Change women with interrupted participation resume regular group attendance. The key points to include when developing a plan to maintain active participation and/or contact are listed below. Refer to *Figure 6.3 - Interrupted DM Intervention Participation Worksheet.*

- Keep the participant assigned to an active Dietary Change group.
- Based on the participant's level of effort, determine: contact type, contact frequency, contact content, and date to reassess plan.

The Group Nutritionist encourages the woman to attend group sessions during her interrupted participation whenever possible. The woman may attend session(s) with her assigned group or with another group as a guest. Refer to *Section 6.10.5.3 – Data Collection for Women Who Miss Sessions.*

End of Recruitment

The Group Nutritionist develops a plan for maximizing exposure to and participation in the DM Intervention when an active Dietary Change participant has not started DM Intervention and is unable/unwilling to attend sessions with either existing or currently forming final groups. The plan includes all aspects described above for a participant who has started intervention, plus the following additional key points:

- Remove the participant from the waiting list by assigning her to an active Dietary Change group.
- Make every effort to have the participant complete at least Session 1.

Refer to *Section 6.10.8.1 – Awaiting Startup of DM Intervention* for additional information about handling participants who have not started intervention at the end of recruitment.

6.10.8.4 Documenting and Tracking Interrupted DM Intervention Participation Plan and Contacts

Interrupted DM Intervention Participation Worksheet (Figure 6.3)

Use the *Interrupted DM Intervention Participation Worksheet (Figure 6.3),* a similarly designed CC-developed worksheet, or the participant progress notes to document the following key points of the plan:

- Contact: type, frequency and content.
- Date to reassess plan and revise if appropriate.

Form 24 – Adherence and Retention Worksheet

Form 24 – Adherence and Retention Worksheet is recommended for use when clinical center staff have made a contact to conduct special retention activities with participants. Refer to *Vol. 3 – Forms, Instructions for Form 24 – Adherence and Retention Worksheet.*

The Group Nutritionist is strongly encouraged to use *Form 24 – Adherence and Retention Worksheet* to document all Interrupted DM Intervention Participation contacts. Per this recommendation, *Form 24 – Adherence and Retention Worksheet* would be completed for the following contacts:

- When Interrupted DM Intervention Participation procedures are initiated (i.e., when the Group Nutritionist contacts the participant to assess the situation and develop a plan).
- When the participant is contacted per the Interrupted DM Intervention Participation plan.

Using *Form 24 – Adherence and Retention Worksheet* allows the Group Nutritionist to track Dietary Change participants receiving retention contacts (i.e., Interrupted DM Intervention Participation). The *IIP Triage & Tracking* (WHIP 0444) report lists the re-contact date from the *Form 24* most recently completed for DM Intervention Participation (Qx. 6.3). Refer to *Vol. 5 –Data System, Section 8.2 – DM Intervention Group Reports*. The *Member Adherence and Retention Activity Tracking* (WHIP 1238) report shows additional information from *Form 24*. Refer to *Section 17.2.1 – Identifying Retention Challenges and Tracking Special Activities* and *Vol. 5 – Data System, Appendix B3.4 – Adherence and Retention Worksheet*.

Progress Notes

The Group Nutritionist is strongly encouraged to place a note in the participant progress notes to cross reference the completion of any *Form 24 – Adherence and Retention Worksheet*, if this form is used to document participant contacts. This cross referencing will help other Group Nutritionists (e.g., replacement or relief staff) track Interrupted DM Intervention Participation activities.

6.10.8.5 Reassessing the Interrupted DM Intervention Participation Plan

The Group Nutritionist reassesses the situation at the time outlined in the Interrupted DM Intervention Participation plan.

Participant resumes group session attendance/completion

If a woman resumes regular group session attendance after a period of Interrupted DM Intervention Participation, the Group Nutritionist uses the following guidelines (listed in order of priority) for triaging participant and staff effort:

- Encourage the participant to focus on maintaining the newly resumed session attendance and self-monitoring.
- Encourage the participant to self-monitor, if not resumed.
- During Year 1, complete missed sessions if the participant is willing and local staffing configurations support this level of effort. Encourage participants to do makeup sessions by guest attendance whenever possible. Complete individual makeup only if group makeup is unavailable and the participant is willing to complete the session individually.
- During Maintenance, do not complete missed sessions that cannot be completed by guest group attendance.

Participant does not resume group session attendance/completion

If a woman does not resume group session attendance/completion at the agreed upon time, use the same procedures as described above in *Sections 6.10.8.2 – Assessing the Situation for Interrupted DM Intervention Participation* and *6.10.8.3 – Developing and Implementing a Plan for Interrupted DM Intervention Participation* to reassess the participant's situation and plan for continued contact. Document and track any revisions to the plan using the procedures described in *Section 6.10.8.4 – Documenting and Tracking Interrupted DM Intervention Participation Plan and Contacts.*

6.10.8.6 Handling Participants Who Refuse Contact with the Group Nutritionist and Other CC Nutrition Staff

The Group Nutritionist uses the procedures described in *Section 6.10.6.2.1 – Non-Participation* if a Dietary Change participant refuses contact (in person, by phone, or by mail) with the Group Nutritionist and other CC nutrition staff.

Figure 6.2
Interrupted DM Intervention Participation Flow

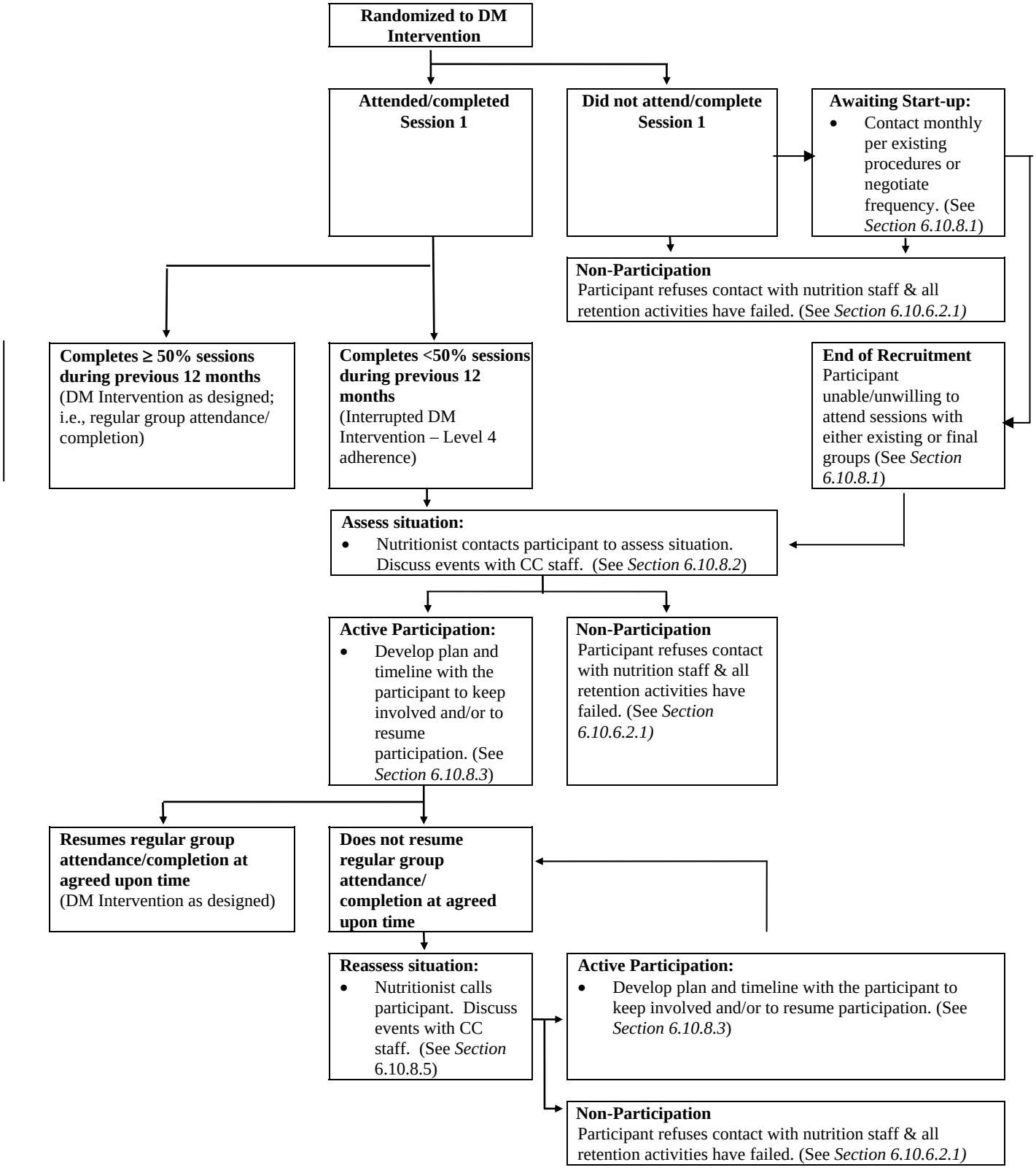

Figure 6.3
Interrupted DM Intervention Participation Worksheet

Participant Name/ID: _____	**Group Nutritionist: _____**
Participant Phone: _____	**Group Number: _____**

Date: _____

Assessment:

Participant has completed less than 50% of sessions during previous 12 months (Level 4 adherence).

_____
_____
_____
_____
_____
_____
_____

Goal:

Maintain contact during interrupted intervention and resume group session attendance.

_____
_____

Plan:

- Keep participant assigned to an active Dietary change Group.
- Contact Type: _____
- Contact Frequency: _____
- Contact Content: _____
- Date to reassess plan (see Form 24): _____
- _____
- _____

6.11 Intensive Intervention Protocol (IIP) (Required)

The Intensive Intervention Protocol (IIP) is a protocol composed of three individual contacts using a brief motivational interviewing approach. The goal of the IIP is to increase the C- I difference by helping participants discover their own motivation to consider dietary changes. The timeline for completing the initial round of IIP contacts is December 31, 2000.

6.11.1 IIP Sample (Who To Contact)

All DM Intervention participants (Year 1 and Maintenance) are eligible for IIP. The IIP sample for each Clinical Center is based on the Triage System for DM Intervention. This system categorizes participants into one of four adherence levels based on a participant's session completion and self-monitoring efforts. Refer to *Section 6.10.7 – Triage System for DM Intervention*.

Nutritionists should focus first on participants triaged to Levels 2 and 3. This focus provides Nutritionists an opportunity to tailor adherence efforts to participants' efforts and abilities. The participants in Levels 2 and 3 represent a cohort of participants who are currently participating in the WHI Intervention but are not meeting their fat gram goal or not self-monitoring. IIP contacts may be expanded to other participants after completing the IIP contacts with participants in Levels 2 and 3.

The Nutritionist has discretion when deciding whether or not to conduct IIP contacts with individual participants. Per clinical judgement, the Nutritionist may decide not to conduct IIP contacts with participants who are in crisis situations (e.g., serious personal or family illness, death of spouse, etc.). However, it is critically important to keep in mind that every time a decision is made not to do an IIP contact with a participant, WHI misses an opportunity to improve the C-I.

6.11.2 Number, Type, and Frequency of Contacts

The following section presents information about the usual number, type and frequency of IIP contacts.

Number of Contacts.

The IIP will most often be a series of three contacts. Occasionally a participant will receive more or fewer than three contacts based on Nutritionist discretion.

Type of Contact.

IIP contacts will most often be a mixture of in-person and telephone contacts as follows:

- Contact to schedule IIP Contact #1- usually by telephone. Refer to *Scheduling IIP Contact #1 – Sample Script – Figure 6.4*.
- IIP Contact #1 - usually in-person.
- IIP Contacts #2+ - usually by telephone.

This format provides a mix of rapport building (in-person) and efficient (telephone) contacts. However, if the IIP Contact #1 cannot be done in person, it would be preferable for the Nutritionist to conduct the contact by telephone than to not complete the contact at all.

Frequency of Contact.

Most IIP contacts will be spaced about one month apart. The Nutritionist will most often initiate and complete the series of IIP contacts within 3 months. Completing the series in this timeframe will facilitate sample management. Refer to *Vol. 2, Section 6.11.6. - IIP Sample Management*.

Figure 6.4

Scheduling IIP Contact #1 - - Sample Script

Hello Mrs. _____. This is ____ from WHI. Do you have a few minutes? I'm calling today because I'm interested in hearing about how WHI is going for you and also to share some information about the Dietary program.

As you know from your group sessions, we are finding that the study participants, as a whole, are not decreasing their fat intake enough to answer the questions asked by the research. We're also finding that many women are getting burned out and tired. Some women who made a lot of changes at first are finding it very difficult to keep them up.

Because of this, we've added something new to the Dietary Change program. We are contacting participants to set-up individual meetings (with a nutritionist). We're hoping that by talking with women, like yourself, we can get a better picture of what is really happening. We need know how WHI is going - - what you are experiencing. Our hope is to find ways to help our participants and the study move closer to the goal.

We need your help to do this. Can we schedule an in-person meeting to talk about how WHI is going for you? How would ___ work for you?

6.11.3 Framework of the Contact

The Nutritionist uses a brief motivational interviewing approach to conduct the IIP contacts. The approach is a participant-centered method for increasing participants' motivation to consider dietary changes and to negotiate the best course of action.

During the contact, the Nutritionist does not assume an authoritarian role. She/he attempts to draw on and enhance the participant's internal motivation to make eating behavior changes based on the participant's own decisions and choices. The focus shifts from giving information, advice and behavior change prescriptions to helping the participant explore concerns, ambivalence, reasons for change, and ideas and strategies for change. The Nutritionist utilizes a variety of negotiation strategies based on the participant's readiness to consider change.

The IIP Roadmap provides the structure to guide the Nutritionist through an IIP contact. Refer to *Figure 6.5 - IIP Simple Roadmap* and *Figure 6.6 - IIP Detailed Roadmap*. The Simple Roadmap provides an overview of the components, while the detailed version of the IIP Roadmap provides suggested script and questions for each of the components. The components of the IIP Roadmap include:

- Set the Stage
- Provide Feedback
- Assess Readiness to Make WHI Dietary Changes
- Offer Support (Optional Additional Strategies)
- Close

Although the steps in the IIP Roadmap are listed in the order shown above, the contact does not need to flow in this exact order. For example, a Nutritionist may opt to assess a participant's readiness to make dietary changes before providing feedback.

The theoretical background, goals, key elements, areas to avoid, key questions/statements, strategies and tools for each component are provided in the IIP training manual. Refer to *Vol. 2, Appendix G.5 – Motivation Enhancement Training August 1999, WHI Intensive Intervention Protocol*.

The Nutritionist provides participants with individualized feedback about self-monitoring and session completion efforts by using information from *the Individual Progress Report* (*WHIP 0428*), or by creating graphs using the WHILMA Custom Data Extract System. Refer to *Vol. 5 – Data System.*

Figure 6.5

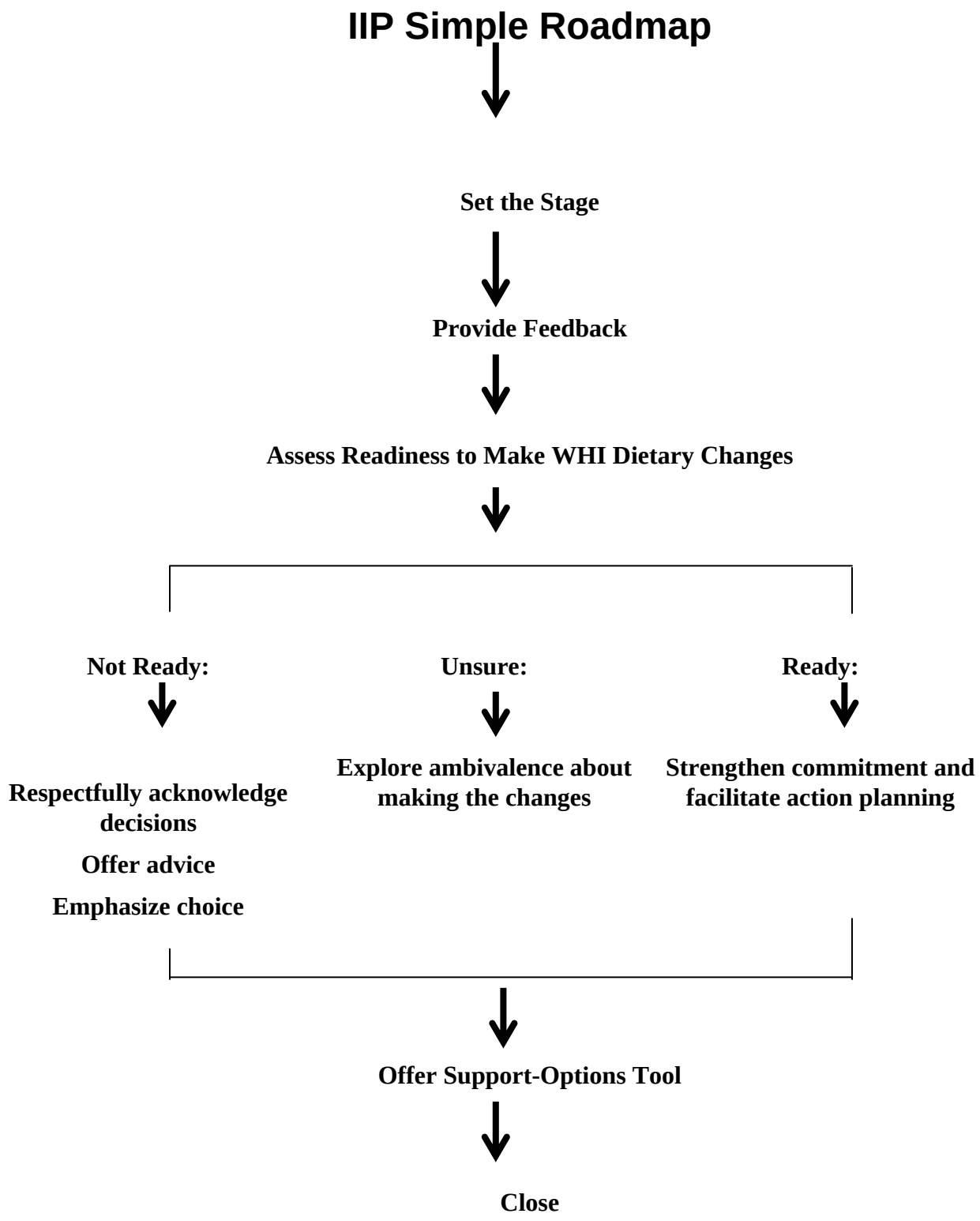

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Figure 6.6

WHI IIP Detailed Roadmap

Set the Stage

- **Establish Rapport.**
- **Make Opening Statement**. Let the participant know who you are (if needed), why you are there, and how much time you have.
- **Ask permission to discuss participation in the study.**

We have about _____ minutes to meet today. I thought we might talk about your participation in WHI and how the study is going for you. I have some information and feedback that I'd like to share but mostly I want to understand how you are doing with the study. Would that be all right?

Provide Feedback

- **Provide feedback in a neutral manner; compare with norms and standards.**
- **Elicit participant's interpretation.**

"As you probably know from the quarterly sessions, one of things we are finding is that the study participants, as a whole, are not decreasing their fat intake enough to answer the questions asked by the research. (Show graph if appropriate) We're also finding that many women are getting burned out and tired. Some women who made a lot of changes at first are finding it very difficult to keep them up. We expected some of that but have concerns about how much trouble some participants are having. We're hoping that by talking with women like you we can get a better picture of what is really happening, and we hope to find some ways to help our participants and the study move closer to the goal."

"*What are your thoughts and feeling about this?"*

"What do you think about this?"

"I also have your latest Individual Progress report here and the graph that shows how your group is doing compared to all other groups at our center and the study as a whole over time. What do you think of this information?" "Do these data make sense to you?"

For participants who have been self-monitoring:
"Your average daily fat gram intake is ___. Does this seem right to you? How closely do the days you self-monitor represent what you typically eat?"

For participants who have not been self-monitoring:
"I don't have your current food records so I am wondering, when you think about your typical day, how would you say your fat gram intake compares with your fat gram goal? How has it changed?"

"In general, how is WHI going for you."
"Given all the complexities, how does your participation in WHI fit into your life?"

- **Listen and summarize. Emphasize self-motivational statements.**

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Figure 6.6 (continued)

Assess Readiness to make WHI Dietary Changes

"I really appreciate you sharing your thoughts and feelings with me. I do believe it will help the study. In order to best make use of our time today I'd like to ask you a question."

- **Show ruler:**

"On a scale of 0-12, Where would you say your motivation / energy / enthusiasm / interest is for following the dietary recommendations that WHI has asked you to follow?" (0 = not at all interested; 12 = very interested and motivated to follow all the recommendations)

- **Explore participant's selection:**

Straight question: *"Why did you pick a _____?"*

Backward questions: *"Why did you pick a 4 and not a 1?"*

Forwards question: *"What would need to be different in your life to move from a 2 to an 8?"*

- **Listen and summarize. Emphasize self-motivational statements.**

If not ready:	**If unsure:**	**If ready:**
Respectfully acknowledge decisions. **Key Questions:** *"I wonder what would have to be different for you to consider making any changes?"* **Listen and summarize.** **Offer advice and emphasize choice:** ***"****I understand and respect your decisions about WHI right now. Of course, I encourage you to think about making the dietary changes when the time is right for you. A diet low in fat and high in fruits, vegetables and grains may reduce your risk of diseases such as cancer and heart disease. Also, your participation in the study is important to the results. It is your choice and I'm confident that if you chose to make any changes you can find a way to be successful in the long term."*	**Explore ambivalence about making the changes** **Key Questions**: *"What are the advantages/disadvantages of making dietary changes?"* *"What do you like/dislike about the WHI dietary changes*?" **Listen and summarize.** *"Where does that leave you?"* *"What do you see as the next step?"*	**Strengthen commitment.** **Facilitate action planning.** **Key Questions**: *"What are your reasons for wanting to make or maintain these changes?"* *"What are you thinking about doing?"* *"What have been your successes with this in the past?"* *"What works for you when making changes?"* **Listen and summarize.** **Help participant set a reasonable plan of action.**

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Figure 6.6 (continued)

Offer Support (Optional Additional Strategies)

For participants who are unsure or ready*:* "Here are some strategies that some participants have found helpful when thinking about the possibility of change. (show How Can We Support You option tool) Are you interested in exploring any of them? Or is there something else that might be more helpful?"

For participants who are not ready: "I understand that you are not interested in making any changes right now. We still have about 20 minutes today and I'd like to use that time in a way that is best for you. Here are some discussion items that some participants have found helpful when thinking about their participation in WHI. Are any of these of interest to you or is there something else you would like to discuss this time?"

Assess current eating behavior.

Tell me about a typical day in regard to food.
What do you see as ideal eating habits? Where would you like to be?

Explore options for dietary change (WHI Dietary Goals options tool).

Here are the WHI dietary goals. What do you think about them?
Which of these goals might you be interested in working on right now?

Explore study activities (WHI Study Activities options tool).

Here are some of the WHI activities. What do you think about them?
What has changed for you since the beginning?

Explore self-monitoring.

What are your thoughts about self-monitoring?
What are the advantages/disadvantages of self-monitoring?

Explore barriers to change

What do you see as your greatest barriers to change?
What kinds of strategies have you used to overcome barriers?

Dreaming.

Let's suppose that it is 10 years from now. WHI is over. With the help of all the participants we were able to prove that making dietary changes reduced the risk of cancer and heart disease What is your life like?

Closing

- **Summarize the session, including thoughts and concerns.**
- **Support self-efficacy.**
- **Thank the participant.**
- **Arrange follow-up contact**

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6.11.4 Documenting IIP Contacts

The Nutritionist uses *Form 64 – Individual Data Sheet (ver. 4)* and progress notes to document IIP contacts.

Form 64.

Form 64 – Individual Data Sheet (ver. 4) is the data collection form that documents who, when, how, and how much IIP a participant receives. The Nutritionist must complete a *Form 64* for each IIP contact. Questions 5, 9 and 10 pertain to IIP data collection.

The goals of *Form 64 - Individual Data Sheet (ver. 4),* Qx. 5 – Description of contact are:

- To document who receives the Intensive Intervention Protocol (IIP) (Qx. 5, boxes 26-29);
- To document who does not receive IIP (Qx 5, boxes 24-25), and;
- If a participant does not receive IIP, to identify whether this is due to:
  - Nutritionist discretion (Qx. 5, box 24 -Not appropriate for IIP), or
  - Participant request (Qx. 5 box 25 -Participant declined IIP).

Below are examples of how to complete *Form 64,* Qx. 5 in various situations. For complete details and instructions, refer to *Vol. 3 – Forms, Instructions for Form 64 – Individual Data Sheet (ver. 4).*

- *Not appropriate for IIP*: The Nutritionist marks *Form 64* - Qx. 5, box 24 "Not appropriate for IIP" when her/his clinical judgement indicates that a participant should not be approached for IIP. This decision may occur because a participant has a crisis situation (e.g., serious personal or family illness, the death of spouse, etc.). If the Nutritionist wants to try to initiate IIP at a later date, she/he may complete Qx. 9 "Date to re-contact". Note: Qx. 5, box 24 "Not appropriate for IIP" should only be used if a participant does not receive any IIP. Therefore, once a participant has received IIP Contact #1, Qx. 5, box 24 should not be used.
- *Participant declined IIP: The* Nutritionist marks *Form 64* - Qx. 5, box 25 "Participant declined IIP" if a participant declines IIP Contact #1 when approached. If the Nutritionist wants to try to initiate IIP at a later date, she/he may complete Qx. 9 "Date to re-contact". Note: Qx. 5, box 25 "Participant declined IIP" should only be used if a participant does not receive any IIP. Therefore, once a participant has received IIP Contact #1, Qx. 5, box 25 should not be used.
- *IIP Contact 1-4+: For* all other IIP contacts (i.e., IIP Contact #s: 1, 2, 3, or 4+), the Nutritionist selects the appropriate box on *Form 64* – Qx. 5 to document the IIP contact. In addition, she/he records the date for the next scheduled IIP contact (Qx. 9), if appropriate.
- *IIP Complete:* The Nutritionist marks Qx. 10 "IIP Complete" on *Form 64* when clinical judgement indicates that the IIP series is complete (i.e., no more IIP contacts will be done before December 31, 2000). The Nutritionist most often marks "IIP Complete" after IIP Contact #3. However, the Nutritionist has the discretion to mark "IIP Complete" following IIP Contact #s 1 - 4+.

Progress Notes.

In addition to *Form 64 – Individual Data Sheet (ver. 4),* Nutritionists will want to keep notes about each IIP contact. The purpose of these IIP progress notes is to help the Nutritionist manage contact information that is not data-entered, but is important for conducting future IIP contacts [e.g. the participant's interpretation of the feedback discussed; how the participant responded to readiness question(s); self-motivational statements]. Keeping notes is required; the method used to keep the notes is the Nutritionist's option. [Refer to *Figure 6.7 – IIP Progress Notes* (*Example*)]

Figure 6.7

IIP Progress Notes (Example)

Participant Name/ID:_____ Group Nutritionist: _____

Participant Phone: _____ Group Number: _____

Date: _____ **Contact #: _____**

Feedback Discussion	**Self-Motivational Statements**
Feedback provided: Ppt's interpretation:	Problem Recognition: Concern:
Readiness Assessment	
Readiness question(s) asked: Ppt's response: ___ on a scale of ____ to ____	Intention to Change:
Intervention Approach	
Check one: ___ Not Ready ___ Unsure ___ Ready	Optimism:
Support Offered/Options Explored	**Action Plan (if ready)**

Next Steps/Follow-up Contact:

6.11.5 Tracking IIP Contacts

The *IIP Triage & Tracking* (WHIP 0444) report is a WHILMA-based report that the Nutritionist uses to manage local implementation of IIP. The report includes all active Dietary Change participants assigned to a DM group. For each participant listed, the report shows several key IIP tracking variables (e.g., Nutritionist, DM Group, Triage Level, % Fat Goal Overall, most recent IIP Contact and Date, Date to Re-contact and IIP Complete).

The Lead Nutritionist (or designee) uses the *IIP Triage & Tracking* (WHIP 0444) report to manage the IIP sample for the clinical center. The report will:

- Categorize all active Dietary Change participants by triage level.
- Identify the IIP sample (participants triaged to Levels 2 and 3).
- Track description and date of most recent IIP contact for each participant.
- Track IIP re-contact dates.
- Track participants who have completed IIP.

The report lists participants in order by Nutritionist, DM Group, Triage Level, and last name. The Triage Level and % Fat Goal Overall are based on a 12-month assessment period (12 months prior to the report run date). For example, if a Nutritionist runs the report on 11/1/99 (if DM Snapshot updated on 11/1/99), the report would be based on the twelve month assessment period between 11/2/98 and 11/1/99. Because the report is based on data from the last 12 months, it is critical for a CC to maintain timely DM Intervention data entry.

It is recommended that Nutritionists run the *IIP Triage & Tracking* (WHIP 0444) report quarterly from the CC local database (see *Section 6.11.6 - IIP Sample Management).* For complete details about running the *IIP Triage & Tracking* (WHIP 0444) report, refer to *Vol. 5, Section 8.2 – DM Reports*

6.11.6 IIP Sample Management

The Lead Nutritionist develops and implements an IIP Sample Management Plan.

Development of Plan:

It is the responsibility of the Lead Nutritionist to develop an IIP Sample Management Plan. The purpose of this plan is to provide guidance for the CC in completing the first series of IIP contacts by the studywide timeline - December 31, 2000. In developing a plan, the Lead Nutritionist includes the following considerations:

- Time blocks available for contacts (divide into manageable blocks of time; suggest 3-month blocks).
- Total IIP sample estimate.
- Percent of IIP sample to see per time block.
- Projected number of participants to see per time block.
- Projected number of contacts to make per time block. (Assume that each participant will receive a series of 3 contacts approximately 1 month apart).

The table below provides an example using an estimated IIP sample of 200 participants.

Time blocks available (3-month).		Oct-Dec 1999	Jan-Mar 2000	Apr-June 2000	July-Sept 2000	Oct-Dec 2000
Estimate total IIP sample (Levels 2&3)	200					
Percent of IIP sample to see per time block.		10%	35%	30%	25%	0%
Project # of participants to see per time block.	IIP sample estimate multiplied by % to see per time block.	200 x .10 = 20	200 x .35 = 70	200 x .30 = 60	200 x .25 = 50	
Project # of contacts per time block (assume a series of 3 contacts/participant).	Number of participants to see per time block multiplied by 3.	20 x 3 = 60	70 x 3 = 210	60 x 3 = 180	50 x 3 = 150	

When making a plan, the Lead Nutritionist also needs to consider some of the following:

- Number of nutritionists (or other trained staff) available to conduct contacts (e.g., workload distribution, part-time staff, vacations, etc.).
- Travel time and maximum efficiency for off-site locations. For example:
  - If going to an off site location, prioritize all participants in IIP sample who live or attend groups in the specific area. This may mean that the Nutritionist(s) conducting the IIP contacts may see participants who are not members of groups they facilitate.
- Availability of participants during extended holiday periods and/or winter travel.

Implementation of Plan:

Time Block #1:

1. October 1999: Run the *IIP Triage & Tracking* (WHIP 0444) report to identify the current (i.e., as of the report run date) total IIP sample for your CC.
2. Determine the number of participants to begin IIP during the first time block by multiplying the total IIP sample by the percent to be seen during the first time block.

   For example: If the total IIP sample is 200 and your plan is to begin 10% during this time block, then you need to begin IIP with at least 20 participants (200 x .10 = 20) during this time block.
3. Select participants who will begin IIP during this time block.
4. Conduct contacts. Conduct all IIP Contact #1s for the selected participants during the first month of the time block. Complete IIP for these participants within this time block by conducting all IIP Contacts #2, #3, and #4+ during the remainder of the time block.

   For example: If you plan to begin IIP with 20 participants during the time block, then you will make approximately 60 contacts (20 participants x approximately 3 contacts/participant) to complete IIP for these participants during the time block.

Time Block #2+:

1. Run the IIP *Triage & Tracking* (WHIP 0444) report early during the last month of each time block to identify the updated IIP sample for the next time block.

   For example: If the second time block is January-March, then run the *IIP Triage & Tracking* (WHIP 0444) report in early December. This will allow adequate time to complete data entry for the Fall Maintenance session (which should be finished by the end of November) and time to call and schedule IIP contacts for January through March.

2. Determine the number of participants to begin IIP during the time block by multiplying the updated total IIP sample by the percent assigned to the time block.

   For example: If the updated total IIP sample is 180 and your plan is to begin 35% during this time block, then you need to begin IIP with at least 63 participants (180 x .35 = 63) during this time block.

3. Select participants who will begin IIP during this time block. Select participants who have not had any IIP contacts.

   For example: The 63 participants to begin IIP during the January – March time block would be selected from the list of participants who do not have any IIP contacts showing on the *IIP Triage and Tracking* (WHIP0444) report.

4. Conduct contacts. Conduct all IIP Contact #1s for the selected participants during the first month of the time block. Complete IIP for these participants within this time block by conducting all IIP Contacts #2, #3, and #4+ during the remainder of the time block.

5. Repeat steps 1-4 for each time block.

The implementation plan described above assumes a non-staggered approach for initiating IIP Contact #1 during each time block (i.e., all IIP Contact #1s for the time block happen during the first month of the time block). Conducting all IIP Contact #1s during the first month of the time block means that most of the participants selected to begin IIP during the time block will also complete IIP within the time block.

Clinical Centers have the option to use a staggered approach for initiating IIP Contact #1 (i.e., the IIP Contact #1s for the time period are spread out during the first, second, and third month of the time period). Staggering the IIP Contact #1s throughout the time block means that most of the participants selected to begin IIP during the time block will not complete IIP until the next time block. Clinical Centers using a staggered approach for initiating IIP Contact #1s will need to see a larger percent of their total IIP sample during the earlier time blocks to allow time to conduct a larger percent of IIP Contacts 2+ in later time blocks. The staggered approach for initiating IIP Contact #1 also requires more complex tracking because each time block (except the first) will include participants beginning IIP during that time block plus participants from the previous time block who have not yet completed IIP.

Prioritizing IIP Contacts:

The Nutritionist considers participant requirements and availability when making decisions about which IIP-eligible participants to see first. For example:

- Prioritize participants who are leaving the area for extended periods (e.g., snowbirds, long vacation trips).
- Accommodate participants who need evenings or weekend contact times.
- Conduct IIP contacts by telephone, when participants are unable or unwilling to come to the CC (e.g., due to weather, transportation, health, etc.).

Scheduling Tips for IIP Contact #1:

Other areas that a Nutritionist needs to consider when contacting participants to schedule IIP Contact #1:

- Call easy to reach participants first.
- If a participant is not available and there is no answer, leave a brief message.
- If you reach a participant and she indicates that it is not a good time, schedule a 'call back.' Then make every effort to contact the participant at the agreed upon date and time.
- For IIP Contact #1, develop a tickler file (by contact date) to facilitate reminder calls or postcards.

6.11.7 IIP Evaluation

The FFQ will be used to evaluate the IIP. It is important to remember that the efficacy of the IIP protocol was tested in the IIP pilot study. Therefore, the IIP evaluation has the following objectives, in order of importance:

- Provide feedback on the effect of the IIP on the C-I difference for the purpose of intervention planning for the trial.
- Monitor completeness of the protocol implementation at the clinic level.

It is critical that the IIP intervention remains independent from its evaluation and that neither staff nor participants directly connect this new protocol with the monitoring instrument. Therefore, to minimize the potential for introducing intervention associated bias in FFQ responses, IIP contacts should not generally be scheduled in relation to the participant's annual visit. Some exceptions exist, such as for participants who live long distances from the clinical center or for whom travel to the clinical center is difficult. The data analyses program will be able to determine, for any Dietary Change participant completing an FFQ, whether (and when) she received the IIP intervention.

6.12 Maintenance of DM Intervention Participants (Required)

Throughout the first year, the delivery of the DM Intervention is consistent in all CCs. Maintenance of dietary change begins in year 2. The maintenance package consists of the following activities: group sessions, newsletters, peer-led groups and social activities.

6.12.1 Group Sessions (Required)

Maintenance of dietary change begins in year 2 and involves four required group sessions each year. The maintenance sessions provide opportunities to update nutritional information and review and practice skills for maintaining dietary change. The CCC in collaboration with the CCs, develops materials for the four required yearly maintenance group sessions. Clinical Centers are encouraged to provide suggestions or plans for maintenance phase topics. Some variation in the delivery of the DM Intervention is allowed beginning in the second year; however, the range of variation is limited. The CCs must submit any plans for DM Intervention activities to the CCC for approval at least one month prior to their implementation in the clinic.

If the number of women attending DM Intervention groups is small (fewer than eight), groups may be combined for the maintenance sessions at the CC's discretion. The CCC will develop procedures to handle combining DM Intervention groups after the first year of DM Intervention.

6.12.2 Newsletter

Beginning in the year 2, the DM Intervention participants receive a quarterly newsletter (winter, spring, summer, fall). The CCC sends copies of each newsletter to the CCs for distribution to DM Intervention participants. Participants should receive the newsletters at regularly spaced intervals throughout the year. Each newsletter includes:

- Tips on low-fat food preparation and recipes
- Behavioral topics
- Ways to enhance maintenance

The CCs are encouraged to include additional local information about restaurants, regional recipes and a question-and-answer column with responses to commonly asked questions from group participants.

6.12.3 Peer-Led Groups

During year 2 and beyond, the Group Nutritionist uses peer-led groups for DM Intervention participants who want added social support. These groups meet more frequently than quarterly under the guidance of "peer-group leaders," who are identified and trained in the local CCs. The CCs support the "peer-group leaders" by supplying resource lists of speakers, reference materials, photocopying, financial reimbursement for phone calls to study participants and mileage to the CC for supplies.

The CCC provides information to the Group Nutritionists to assist with the identification of peer-group leaders and the establishment of peer-led groups at the second Group Nutritionist training workshop. A peer-led group protocol for identification and training of local peer-led group leaders will be included in *Vol. 4 - Dietary Modification Intervention Group Nutritionist Manual, Section 2 - Group Facilitation.*

DM Intervention peer group meeting attendance is documented and key-entered using *Form 66 - DM Intervention Peer Group Meeting*. See *Vol. 3 - Forms* and *Vol. 5 - Data System, Section 8 - DM Intervention Group Data System* (to be added).

6.12.4 Social Activities for DM Intervention Participants

In addition to the planned quarterly group sessions, the CCs may have one or two annual large-group social functions (i.e., guest speakers, potlucks, food demonstrations). The purpose of these social activities is to promote social support among group members, spouses and members in other DM Intervention groups.

6.12.5 Make-Up Activities After First Year (Required)

Group Nutritionists must use the standardized make-up procedures outlined in *Section 6.10.5 – Make-Up Activities for Women Who Miss Sessions.* To determine other levels of DM participation available, refer to *Section 6.10.6 - Determining and Maintaining Levels of DM Intervention Participation (Required).*

6.13 Guidelines for Participants with Self-Reporting Scores Consistently < 15 grams/day (Optional)

The Group Nutritionist may use the following guidelines to educate DM participants who express concerns about the safety of a low fat diet or those few individuals whose self-reported fat scores are below 15 gm/day on a consistent basis. The GN may complete a dietary assessment if she/he has concerns about the adequacy or balance of a participant's eating pattern. This assessment may take up to 30 minutes to complete.

6.13.1 Identify Participants

To evaluate consistency, rather than single episodes of fat intake below 15 grams daily, the Nutritional Adequacy Working group recommends that nutritionists look at fat score trends or averages (of fat scores) over time. Suggested time frames are:

- Session 3-9 (3 sessions in a row)
- Sessions 10-18 (3 sessions in a row, or 3 months)
- Maintenance Years 2+ (2 sessions in a row, or 6 months)

The Group Nutritionist may use *Form 63* (Session Data Sheet) and/or the *Individual Progress Report* (*WHIP 0428*) to monitor and identify participants who report fat scores that are consistently less than 15 grams.

6.13.2 Contacting Participants

The Group Nutritionist may use any type of contact that will be time efficient and simplify the assessment process for both the participant and the nutritionist. An assessment may be done by phone or a visit may be arranged before or after a regularly scheduled group meeting. The assessment may take up to 30 minutes to complete.

Before talking to the participant, it is strongly recommended that the Group Nutritionist review the participant's previous self-monitoring information to identify potential discussion areas.

6.13.3 Assessing Very Low-Fat Eating Patterns

The Group Nutritionist may either use the *Outline for Group Nutritionist (Figure 6.4)* to facilitate an interactive discussion, or she/he may use the *Group Nutritionist Assessment Worksheet (Figure 6.5)* to conduct an optional interactive assessment interview.

The key areas to include when conducting an interview to assess very low fat eating patterns are listed below. Refer to *Figure 6.4 Outline for Group Nutritionist.*

- Review self-monitoring information
- Assess eating patterns
- Assess other potential areas
- Help participants identify challenges
- Clarify misunderstandings, if necessary
- Negotiate a plan to provide a better balance in eating patterns

When reviewing the self-monitoring information, the Nutritional Adequacy Working group has the following recommendations:

- Look for balance and variety in food choices. Check for a reasonable balance in saturated and unsaturated food choices. Identify participants who are consistently selecting foods that are high in saturated fats (e.g., red meats, high-fat dairy foods and desserts) while excluding foods that are sources of essential fats (polyunsaturated oils, whole grains, beans/legumes, etc.). Be aware of signs of restrained eating patterns.

- Look for other eating patterns that could influence food intake and hydration (e.g., alcohol or caffeine use, water intake, use of supplements or diuretics, etc.).

- Assess whether self-monitoring information represents typical eating pattern. For example:
  - Did the participant record only their best/lowest days?
  - Did the participant eat out more frequently than indicated on the days recorded?
- Look for potential recording errors or omissions. It is important not to assume that a fat score below 15 grams indicates a very low fat intake. Make sure the participant understands how to self-monitor and is accurate in reporting. For example:
  - Are foods left out?
  - Are portion sizes estimated correctly?
  - Are fat scores calculated correctly?
  - Are any "oil-based supplements" used, but not recorded?
- If the participant reports symptoms, (e.g., dry skin, brittle nails, etc.) check for potential misattribution. For example, rapid weight loss, environmental changes, and even inadequate water intake may contribute to dry skin.

There are two optional participant handouts available for the Group Nutritionist to use during the counseling session. The first, *Potential Ideas to Provide Better Balance in Eating Patterns* (see *E.5.14*) may be used by the Group Nutritionist and participant at the end of their discussion to identify a dietary change(s) that the participant is willing to make to improve the balance in their eating pattern. The second, *Fact Sheet-Learning about Fat* (see *E.5.15*) may be provided at the end of the discussion to help address participant questions about the safety and adequacy of the WHI low-fat eating pattern.

6.13.4 Recording Contact(s)

The Group Nutritionist should use *Form 64 (Individual Data Sheet)* to document a contact with a participant who has received optional counseling for nutritional adequacy. The "Other" category on *Form 64* should be checked off.

Figure 6.8
Outline for Group Nutritionist
Areas to Review When Assessing A Very Low-Fat Eating Pattern

I. Self-Monitoring Information
- A. Fat intake
  - 1. Average total fat grams
    - a) Weekly or monthly averages?
    - b) Comparison to fat gram goal?
- B. Self-monitoring tool used (Food Diary, Fat Scan, Keeping Track of Goals, etc.)
  - 1. Number of days?
  - 2. Food choices/selections available?
    - a) How representative of regular eating patterns?
    - b) Frequency of meals eaten away from home?
    - c) Information on frequency of use/serving size?
  - 3. Assess ability to self-monitor
    - a) Understanding
    - b) Accuracy
- C. No information about food choices or no self-monitoring information available.
  - 1. Complete a Diet History "typical day" for assessment.

II. Eating Pattern Assessment
- A. Food Groups Contributing Fat
  - 1. Assess Saturated Fat Food Sources
    - a) Protein-red meats
    - b) Dairy Foods
    - c) Grains-snacks, desserts, baked goods
    - d) Fats-butter, commercial fried foods
  - 2. Assess Unsaturated Fat Food Sources
    - a) Protein-fish, tofu
    - b) Beans and legumes
    - c) Grains-whole grains
    - d) Vegetables
    - e) Fats-nuts/seeds, peanut butter, vegetable oils (particularly Canal™, olive, safflower, sunflower or corn), mayonnaise, salad dressings
- B. Other Eating Patterns
  - 1. Restrained eating patterns.
  - 2. Water intake (average)
  - 3. Alcohol intake (average)
  - 4. Use of supplements
    - a) Probe for fat-containing supplements
    (e.g. flaxseed oil, fish oil capsules, cod liver oil, etc.)
    - b) Inform participant to include these in her fat score calculations.

III. Other Potential Areas to Assess
- A. Weight Status
  - 1. Stability of weight during last 3-6 months
  - 2. Reasons, if unstable
    - a) Weight loss program (self-imposed or commercial)
    - b) Health reasons
    - c) Major life event/stress (death in family)
    - d) Unexplained weight loss
- B. Physical Symptoms
  - 1. What are they?
  - 2. How persistent (duration of symptoms)
  - 3. Possible reasons for symptoms (other than WHI low-fat diet)
    - a) Physical (stress, age, menopause, health related problem, etc.)
    - b) Medication(s)
    - c) Environmental (changes in products, weather, etc.)

Figure 6.8 (continued)

IV. Help Participant Identify Challenges
- A. Unbalanced Food Choices
  - 1. More sources of saturated fats than unsaturated fats.
    - a) One or more food groups missing (e.g., few vegetables, no oil)
    - b) Frequently budgeting fat grams for high-fat desserts, baked goods or red meat
    - c) Over use of fat-free foods
  - 2. Lack of variety within specific food groups
    - a) Protein (red meat vs. poultry vs. fish, vs. meatless)
    - b) Vegetables (dark green leafy, yellow, etc.)
    - c) Grains (refined vs. whole grains and baked goods vs. starches)
    - d) Fats (minimal use of vegetable oils, nuts or seeds
    - e) More commercial fat-free foods (cookies, cake, crackers) vs. naturally fat-free foods (fruits, vegetables, grains)
- B. Physical or Environmental Challenges
  - 1. Physical Challenges
    - a) Difficulty chewing or swallowing.
    - b) Pain in mouth, teeth or gums.
  - 2. Environmental Challenges
    - a) Poor appetite
    - b) Medications interfere with appetite
    - c) On a special diet
    - d) Dislikes cooking
    - e) Usually eats alone
    - f) Limited finances
    - g) Fasts for periods of time

V. Identify Potential Strategies
- A. Clarify Misunderstandings
  - 1. Low-fat diet is safe, but not a zero fat diet.
  - 2. Fat-free equals calorie free and no limits
  - 3. Why you need the type of fat contributed by certain foods
- B. Negotiate Ways to Balance Eating Patterns
  - 1. Increased fat gram intake (up to goal)
  - 2. Food choices to decrease saturated food sources
  - 3. Food choices to increase unsaturated food sources (polys, monos)
  - 4. Alternating food choices made when budgeting fat – fat budgeting compromise
  - 5. Other strategies (eating alone, dislike for cooking, chewing/swallowing problems)

Figure 6.9
Group Nutritionist Assessment Worksheet
(Very Low-Fat Eating Pattern)

Note: Be sure to consider the age and ethnic background of the participant when asking about food choices and eating patterns.

NOTES

Self-Monitoring Information:

Avg. Fat Score: _____ **WHI Fat Gram Goal: _____**

Form used:_____ (diary, scan, quick scan, computer, etc.)

- Assessment based on: _____ (# of days)
- Representative of 'regular eating patterns'? ___ Yes ___ No

If 'No', why not: _____

_____

- Frequency of Meals Prepared or Eaten Away from Home:_____
(weekly average: % or average #)

Typical Day (Optional)

Morning meal/snacks:

_____
_____
_____
_____
_____
_____

Afternoon meal/snacks:

_____
_____
_____
_____
_____
_____
_____

Evening meal/snacks:

_____
_____
_____
_____
_____
_____
_____
_____

Figure 6.9 (Continued)

NOTES
Eating Pattern Assessment – Food Groups Contributing Fat
Assess balance between saturated and unsaturated food choices. Look at: 1) variety of foods eaten within each group, 2) frequency eaten, 3) average serving size. Use space below to note food choices.

Assess Saturated Fat Food Sources:

Protein (red meats): _____

_____

_____

Dairy foods: _____

_____

_____

Grains (snacks, desserts, baked goods): _____

_____

_____

_____

_____

Fats (butter, com'l. fried food): _____

_____

_____

_____

_____

Assess Unsaturated Fat Food Sources:

Protein (fish, tofu): _____

_____

_____

Beans and legumes: _____

_____

_____

Whole grains: _____

_____

_____

_____

_____

Fruits/Vegetables (olives, avocado, etc.): _____

_____

_____

_____

Fats (nuts/seeds, peanut butter, vegetable oils, salad dressings, and mayonnaise): _____

_____

_____

_____

Figure 6.9 (Continued)

NOTES

Eating Pattern Assessment - Other Eating Patterns:

Water use: Avg./week or day: _____ (lack = less than two 8 oz. glasses/day)

Alcohol use: Avg. /week or day:_____

Liquid supplements (Boost, Ensure, Slimfast, Medifast, etc.). ___ Yes ___ No

If yes, approximate amount/week or day: _____

Vitamins/mineral supplements. (Probe for fat-containing supplements: fish oil capsules, flaxseed oil, etc.)

___ Yes ___ No

If Yes, specify (type and amounts): _____

_____

_____

_____

Other Potential Areas to Assess – Weight Status

Stable (no change in past 3-6 months)

Weight GAIN > 5 lbs. in past 3 months

Weight LOSS > 5 lbs. in past 3 months

Possible reasons for weight changes:

Intentional weight loss (self-imposed or program)

Health-related

Major life event/stress

Other:_____ - (e.g., unexplained)

Comments: _____

_____

_____

Figure 6.9 (Continued)

NOTES

Other Potential Areas to Assess – Physical Symptoms of Concern

Weight loss
Changes in skin
Hair loss
Changes in fingernails
Other:_____

- Duration of symptoms:_____(approx. length of time)

Possible Reasons for Symptoms (other than WHI low-fat diet):

Age
Major life event
Stress
Menopause
Health-related problems
Rapid weight loss
Lack of water intake
Other non-WHI diet
Medications
Changes in environment (weather, air conditioning, heating)
Changes in products (detergents, cosmetics, bath products)
Other:_____

Comments: _____

_____

Figure 6.9 (Continued)

NOTES

Help Participant Identify Challenges – Unbalanced Food Choices

More Sources of Saturated vs. Unsaturated Fats.

One or more food group missing (e.g., few vegetables, no vegetable oils, etc.)

Frequent budgeting of fat grams for high-fat desserts, baked goods or red meat

Over use of fat-free commercial products (refined grains/sugar vs. whole grains; trans fats)

Lack of Variety Within Specific Food Groups:

Protein (more red meat than poultry and/or fish; meatless meals)

Vegetables (dark green leafy, yellow/orange, cruciferous, etc.)

Grains (refined vs. whole grains; baked goods/sweets vs. complex carbohydrates)

Fats (no use of vegetable oils, nuts or seeds, etc.)

More commercial fat-free foods (cookies, cakes/pastries, crackers) vs. naturally fat-free foods (fruits, vegetables and whole grains)

Physical or Environmental Challenges:

Physical:

Has difficulty chewing or swallowing

Has pain in mouth, teeth, or gums

Unable to prepare own meals/food

Other:_____

Environmental:

Has a poor appetite or on medications that interfere with appetite

On a special diet

Dislikes cooking

Usually eats alone

Limited finances

Has a pattern of fasting 1 or more days each month

Other:_____

Comments: _____

_____

_____

Figure 6.9 (Continued)

NOTES

Identify Potential Strategies

Clarify Misunderstandings (Potential areas where participant may need clarification):

Low-fat diet is safe, but not a zero fat diet.

Fat-free foods contain calories.

Importance of certain types of fat

Other: _____

Negotiate Ways to Balance Eating Patterns:

Plan of Action:

Table 6.3
Summary of DM Intervention Sessions

Session Number	Session Objectives	Nutritional Topics	Behavioral Topics
	Weekly		
1	Review goals and objectives of the WHI DM Intervention. Discuss the benefits and responsibilities of being a participant. Identify the amount of fat in foods. Identify lower-fat food choices, especially fruits, vegetables and grains.	Awareness of fat in foods. Awareness of fruits, vegetables and grains.	Awareness of costs/benefits to study participants. Social support in group and home setting. Communication skills.
2	Discuss ways to reduce added fats. Use Fat Counter to calculate fat score. Use self-monitoring to evaluate dietary changes.	Awareness of current fat intake. Method to record fat intake.	Self-monitoring of dietary behavior.
3	Identify high-fat dairy foods currently used. Discuss skills for selection and use of low-fat dairy foods. Identify reasons for goal setting as a component of behavior change. Set goals using "Guidelines for Goal Setting."	High-fat dairy foods. Low-fat substitutes. Low-fat calcium sources.	Definition of problem behavior. Setting goals for behavior change.
4	Read and interpret nutrition labels and marketing techniques. Identify how other people influence their eating patterns.	Nutrition label reading. Shopping skills. Food availability.	Social influences on eating. Self-control skills.
5	Identify high-fat entrees. Discuss skills for selection and preparation of low-fat entrees. Practice modification of entree recipes. Identify strategies to accommodate friends and family in the low-fat eating plan.	Low-fat entree substitutes. Vegetarian entrees. Entree recipe modification.	Support from home eating partners. Problem solving skills. Communication skills.

Session Number	Session Objectives	Nutritional Topics	Behavioral Topics
6	Discuss skills and strategies for eating in social situations. Learn the skill of fat budgeting. List strategies for low-fat restaurant eating. Practice menu selection using local restaurant menus.	Fat budgeting skills. Low-fat dining options. Evaluation of restaurant menus.	Problem-solving skills. Communication skills.
	Every Two Weeks		
7	Learn how to use shorter self-monitoring tool (Fat Scan). Learn how to use fruits and vegetables and grains as low-fat snacks. Identify family and friends' influences on snacking patterns. Learn ways to say "no" to high-fat snacks.	Short self-monitoring tool (Fat Scan). High-risk foods. Fruit and vegetable snack alternatives.	Self-monitoring Social influences on snacking. Resistance skills.
8	Select low-fat dessert alternatives. Discuss ways sweets are used as a reward. Identify social support strategies to deal with sweets and desserts. Identify people who can help and ask for support.	High-risk food situations. Fruit dessert suggestions.	Asking for social support. Foods as reinforcers.
9	Share low-fat eating experiences with other DM Intervention participants. Identify ways eating partners can support each other.	Low-fat recipe exchange. New food preparation ideas.	Promotion of group cohesiveness.
(I)	Individual Session: Provide individual support and feedback. Discuss dietary changes made to date. Evaluate variety and balance of current eating habits. Identify potential problems and plan for long-term maintenance.	Nutritional evaluation. Current eating habits.	Evaluation of current behavior. Reinforcing change. Planning for future change.
	Monthly		
10	Review group progress. Identify potential situations that interfere with low-fat eating. Learn how to use the skill of problem solving.	Areas that interfere with low-fat eating.	Barriers to change. Self-management strategies.
11	Explain how self-talk influences actions. Identify negative thought patterns by listening to self-talk. Replace negative self-talk with positive thoughts. Identify low-fat lunch ideas.	Low-fat lunch ideas. Vegetables for lunch.	Cognitive restructuring.

Session Number	Session Objectives	Nutritional Topics	Behavioral Topics
12	Identify the challenges that vacations and holidays present to low-fat eating. Review strategies to handle vacations and holidays. Identify lower fat alternatives to modify home-baked goods.	Vacation/holiday foods Recipe modification of baked goods.	High-risk situations. Self-management strategies.
13	Discuss time-saving strategies to reduce time spent in food management activities. Plan three days of menus and make a shopping list. Identify ways to increase fish consumption.	Meal planning skills. Fish preparation ideas.	Organizational and planning strategies and skills.
14	Identify sources of complex carbohydrates. Identify and describe ways to increase complex carbohydrate intake. Discuss techniques for introducing new cuisine to family and friends.	Sources of complex carbohydrates. Tasting meatless recipes.	Communication skills. Social support.
15	Identify sources of stress that interfere with ability to change. Demonstrate strategies to cope with stress. Practice relaxation exercise. Identify methods and recipes for quick meal preparation.	Preparation of quick meals.	Stress management. Relaxation.
16	Explore the events and emotions that may trigger slips. Identify strategies to recover from a slip. Practice strategies to prevent setbacks. Taste new low-fat alternatives for "out-of-routine" situations.	High-risk foods. Low-fat alternatives for "out-of-routine" situations.	Relapse prevention.
17	Identify factors that help maintain dietary changes. Learn how loss of motivation can lead to "drift" in eating patterns. Identify self-monitoring ideas to maintain dietary changes. Learn ways to add flavor without fat.	Dietary variety. Fats and oils.	Reinforcement of current changes. Self-management. Self-help groups.
18	Review strategies that help maintain a low-fat plan. Review the progress made in WHI. Identify sources of continued support for low-fat eating.	Recipe exchange featuring new food products.	Review. Celebration. Group support.

Table 6.4
Sample DM Intervention Group Tracking Sheet

(Participants Waiting for a Group)

	Preferred Meeting Times				Dates Reached by Phone						Comments
Name of Person	**Phone Number**	**Days**	**Times (morning, afternoon, evening)**		**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Group assignment; Reason not assigned to a group; Changes in preferred group times**
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											

Potential codes to use for reasons not assigned to a DM Intervention group:

1 Personal illness
2 Family demands
3 Work demands
4 Out-of-town
5 Transportation
6 Other (Specify)

6.14 Targeted Message Campaign (TMC) (Required)

The Targeted Message Campaign (TMC) is an initiative to support and improve DM Intervention participation and adherence. The intent of the campaign is to help DM Dietary Change participants rediscover their motivation for participating in the WHI and to identify strategies for personal success. The campaign is founded on the motivational enhancement (ME) approach initiated with the Intensive Intervention Protocol (IIP).

The campaign materials were developed from scientific literature that supports the importance of intrinsic motivations in bringing about successful behavior change. Components of the campaign include:

- Kickoff Newsletter: Introduces the campaign and invites participants to join a fun studywide event, the Eat and Tell Challenge.
- Mailing 1 (M1): Invites participants to think about areas that are important for personal success in WHI.
- TMC Phone Call: Helps participants explore areas for personal success to identify an underlying theme.
- Mailing 2 (M2): Invites participants to consider theme-targeted activity options that support stage of readiness and motivation.

TMC activities begin in the Fall of 2000 and continue through December 31, 2001.

6.14.1 TMC Slogan, Objectives, and Themes

The TMC campaign slogan, *"It's Gotta Be You - Strength from WHIth-in,"* promotes a sense of self-reflection and internal motivation, embraces WHI cohesiveness, and supports a sense of belonging to an important group effort.

The ME approach is integrated within all TMC components to accomplish the campaign objectives as follows:

- Encourage participants to eat more fruits and vegetables while continuing to decrease dietary fat.
- Build a sense of spirit, camaraderie, and commitment to a bigger whole.
- Increase a sense of surprise, colorfulness, creativity, fun, and anticipation of possibilities.

Central to the campaign are five main themes that represent what is important for personal success in the WHI Dietary Change program. The themes are based on WHI Nutritionist input regarding common beliefs that motivate participants to commit to change and common barriers that challenge participants' ability to commit to change. The five themes are: 1) Feel the Difference, 2) Taste is Everything, 3) It's Got to Be Easy, 4) Look at Yourself, and 5) Family and Friends Count. *Figure 6.10 – Themes Overview* describes each of the campaign themes.

Figure 6.10
Themes – Overview

Color	ORANGE	GREEN	IVORY	YELLOW	BLUE
Theme (Key)	**Feel the Difference**	**Taste is Everything**	**It's Got to Be Easy**	**Look at Yourself**	**Family and Friends Count**
What's important to my personal success in WHI	To feel healthy and good about what I'm doing.	To have food taste good.	To make low-fat eating as easy as possible.	To be aware of my choices.	To give and get support from family and friends.
Focus	Feelings (physical & emotional)	Tasty choices	Easy choices	Thoughts & awareness	Family & friends

6.14.2 TMC Sample (Who is Eligible)

All DM Dietary Change participants are eligible for the TMC except those who have the following status:

a) 'Stop DM intervention and no mail follow-up' status, or
b) 'Absolutely no contact follow-up' status, or
c) Deceased.

Participants meeting the above criteria are automatically excluded from the TMC. Nutritionists may remove (or delay involvement) of eligible participants from the TMC, per their discretion based on knowledge of individual participants. Delaying participation can honor particular situations, such as illness or travel, thereby increasing the opportunity to improve DM Intervention participation and adherence. Nutritionists are encouraged to limit discretionary removal of eligible participants from the TMC because each time the decision is made to remove an eligible participant from the TMC there is a missed opportunity to improve DM Intervention participation and adherence. For additional information about modifying the TMC sample, refer *to Section 6.14.3.2 – Mailing 1 (M1) – Sent by the CCC* and the TMC WHILMA Upgrade Notes (available in the Outlook Public Folders October 2000).

6.14.3 TMC Components

The campaign includes the following sequential components: Kickoff Newsletter, Mailing 1 (M1), TMC Phone Call, and Mailing 2 (M2). Additional details about the timeline for implementing the TMC are provided in *Table 6.5* below.

Table 6.5

Components and Timeline for WHI DM Targeted Message Campaign

2000		2001									
Nov	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**
Kickoff Newsletter • Direct Mailing by CCC											
Eat & Tell Challenge Postcard returned to CCC											
		Mailing 1 (M1) ▪ Direct mailing by CCC ▪ On average, 60 mailings per CC each month									
			TMC Phone Call ▪ Telephone contact about 1 month after M1 ▪ Call conducted by CC Nutritionists (60/month) ▪ ME approach								
				Mailing 2 (M2) ▪ Mailing by CC about 1 week after call (60/month) ▪ Content based on information collected at call							

6.14.3.1 Kickoff Newsletter – Sent by CCC

The Fall/Winter 2000 issue of the Making WHIse Choices Newsletter kicks off the campaign and increases participant awareness and excitement about being a part of the WHI Dietary Change program. All Dietary Change participants receive the newsletter except those removed, per nutritionist discretion.

The newsletter invites participants to participate in a studywide event - the **Eat and Tell Challenge**. For this challenge, participants count the number of fruit and vegetable servings they ate during one day, write down the number on a pre-paid addressed postcard, and mail the postcard to the CCC. The collective goal is to consume 85,000 fruit and vegetable servings. Results of this activity are published in the Summer/Fall 2001 Making WHIse Choices Newsletter.

6.14.3.2 Mailing 1 (M1) - Sent by the CCC

Mailing 1 (M1) includes an introductory letter and a set of 20 colorful cards formatted as a table tent. The purpose of M1 is to have participants look through the cards and think about areas that are important for personal success in the WHI Dietary Change program. The cards represent the five campaign themes and set the stage for the TMC Phone Call. *Figure 6.11 – Mailing 1 – Cards by Theme* outlines which cards represent each theme.

The *TMC Tracking* screen in WHILMA provides the mechanism for Nutritionists to identify which participants receive M1 and when they begin the TMC process by receiving M1. The CCC uses the participant list from this screen to identify participants who receive M1 for a specific month. For more information about using the *TMC Tracking* screen, refer to *Section 6.14.6 – WHILMA Resources for TMC Management.*

Figure 6.11
Mailing 1 – Cards by Theme

Theme (Key)	Feel the Difference	Taste is Everything	It's Got to Be Easy	Look at Yourself	Family and Friends Count
M1 Cards	Life's Little Pleasures & You (pg. 3)	Love 'Em and Eat 'Em (pg. 5)	Easy Does It!…a WHI fable (pg. 4)	Produce Results…and see how you're doing (pg. 6)	A Chain Reaction…it starts with you (pg. 7)
	How's It Going? (pg. 12)	Jazz Up Your Salads (pg. 9)	Make It Easy (pg. 8)	Seeing is Believing (pg. 10)	Better Together (pg. 11)
	Your Recipe for Success (pg. 16)	Color Me Delicious (pg. 14)	Rumor Has It (pg. 13)	Strength in Numbers…. WHI's believe it or not (pg. 19)	The WHI Melting Pot (pg. 15)
	Only You Know for Sure (pg. 21)	Taste Magic (pg. 18)	Easy Ways to Add Fruits and Vegetables (pg. 17)	That's the Way It Is (pg. 22)	Reach Out… the art of asking (pg. 20)

6.14.3.3 TMC Phone Call - Conducted by CC staff

Approximately six weeks after M1 is sent, the Nutritionist conducts a brief phone call (15 minutes) with the participant using an ME approach. The purpose of this call is to help the participant identify and explore the theme that is important for her personal success in WHI and to lay the groundwork for Mailing 2 (M2).

Framework of the TMC Phone Call

Nutritionists use a motivational enhancement (ME) approach when conducting the TMC Phone Call. Motivational enhancement is a participant-centered approach that focuses on participants' motivations, ambivalence and ability to make choices. This approach is characterized by interpersonal style as well as use of particular skills.

Key elements of a ME interpersonal style include:

1. **Understanding**
   - Empathetic and careful listening in a non-judgmental, warm and supportive manner.
   - Seeing things from the participant's perspective and respecting whatever decision she makes about health behavior change.
2. **Participant-Centered**
   - Encouraging the participant to be active in making decisions about her behavior change.
   - Eliciting motivation for change from the participant.
3. **Collaborative**
   - Working together to determine the best course of action for change.
   - Sharing of ideas, goals and responsibility.
4. **Individualized**
   - Tailoring intervention approaches to match the participant's needs and readiness to change.
   - Moving at the participant's pace.
5. **Emphasizing Freedom of Choice**
   - Acknowledging that the decision if, when, and how to change is the participant's.
   - Avoiding "restrictive" messages (e.g., "you have to," "you must," "you can't").

Key skills used within a ME approach include:

- Asking open-ended questions.
- Reflective listening.
- Summarizing.
- Creating discrepancies to encourage further exploration on the part of the participant regarding her chosen theme.

Purpose of the TMC Phone Call is to:

1. Help the participant identify which of the five themes, introduced in Mailing 1 (M1), is most important to her participation/success in WHI.
2. Explore the reasons why the participant chose the theme.
3. Set the stage for Mailing 2 (M2).

Combining these elements of interpersonal style and particular skills allows the Nutritionist to achieve the call purpose. The Nutritionist establishes rapport with the participant, assists her in choosing a theme, explores and summarizes why she chose the theme, and peaks her interest in M2.

A major focus of the call involves exploring the participant's theme of choice. The goal is for the participant to look at how her theme of choice can help her become more successful in WHI. This exploration helps her build on what she identifies as important. This exploration also peaks her interest in M2, since the materials are theme-targeted.

Figure 6.12 - TMC Phone Call Overview provides a general structure to guide the Nutritionist through the TMC Phone Call. *Figure 6.13 - TMC Phone Call Guide* provides sample questions and strategies to assist the Nutritionist in achieving the purpose of the call using a ME approach. Suggestions to assist Nutritionists in getting conversations back on track and more focused following a period of drift from the purpose of the call are provided in *Figure 6.14 - Getting Back on Track.*

The general theoretical background, goals, and key elements of motivational enhancement (ME) are provided in *Vol. 2, Appendix G.5 – Motivational Enhancement Training August 1999. WHI Intensive Intervention Protocol.*

Figure 6.12
TMC Phone Call Overview

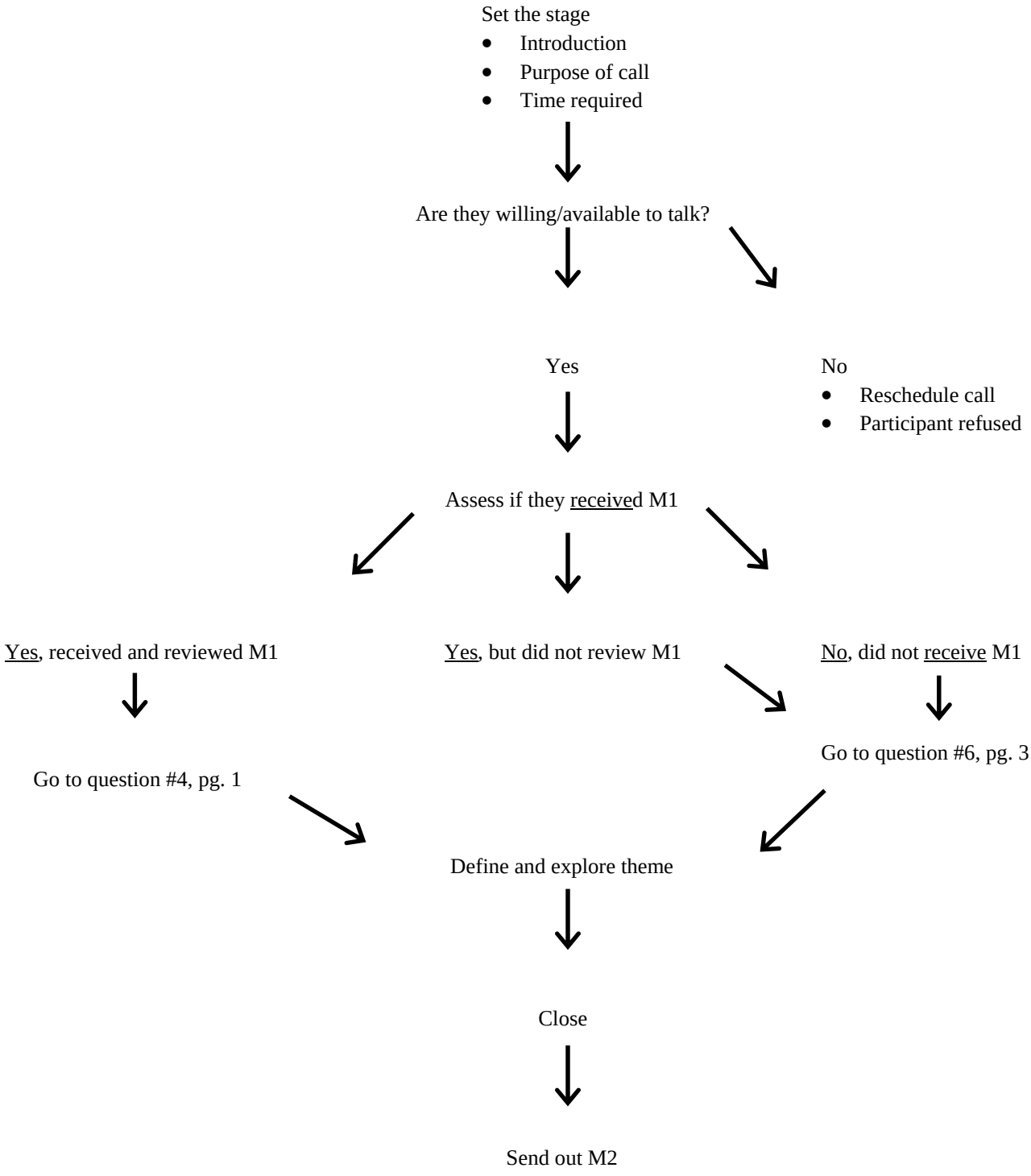


Figure 6.13
TMC Phone Call Guide

Purpose:

1. Help the participant identify which of the five themes, introduced in Mailing 1 (M1), is most important to her participation/success in WHI.
2. Explore reasons why participant chose the theme.
3. Set the stage for Mailing 2.

1. Introduction: Introduce yourself, describe the purpose of the call, share the expected time for the call, establish if this is a good time to talk, and ask permission.	**EXAMPLE:** *"Hello This is _____ from WHI…….., may I please speak to _____? I'd like to take a few minutes of your time to check in with you and follow up on the "It's Gotta be You" packet of cards we recently sent you. This packet contains a variety of colorful cards. The cards reflect a variety of things that a woman may find important when making dietary changes. It came in a medium envelope with a picture of a woman on the outside. What I would like to do is talk with you for about 15 minutes about your reactions to these cards and which ones YOU identify as important when making dietary changes. Is now a good time for you to talk?"*
• If **YES:** go to #2. • If **NO:** Set up an appointment: date/time.	**EXAMPLE:** *"When would be a better time for me to call you back?"*
2. Assess whether the participant <u>received</u> the cards. • If **YES:** go to #3. • If **NO**: **Go to #6**.	**EXAMPLE:** *"Do you recall <u>receiving</u> these cards that I just described?"*
3. Suggest having the cards available to discuss during the call and assess whether the participant <u>reviewed</u> the cards before the call. • If **YES**: go to #4. • If **NO** (Not handy or did not review): **Go to #6**.	**EXAMPLE** *"Do you have the cards handy or near by? The reason I ask is that it will be helpful to have them on hand as we talk about them. I can hold on the phone while you get them."* *"Have you had the opportunity to review the cards?"*
4. Discuss the participant's thoughts about the cards: Use open-ended questions to start the conversation. Remember to reflect and summarize.	***EXAMPLE:*** *"I'd like to spend a few moments hearing from you what you think about the cards. Is that okay with you?"* ***Use An Open-Ended Question:*** • What were your reactions to the cards? • What did you like about the cards? • What, if anything, did you find useful about the cards? • What did you learn from the cards? • What would you like to share about the cards?

REMEMBER TO REFLECT! TELL HER WHAT YOU HEARD HER SAY.

Figure 6.13 (cont.)

5. Help the participant identify which theme is most important to her success in WHI. Have an open discussion, reflecting as you go!

EXAMPLE: *"As you may have noticed, there are several colored cards in the booklet.*

I'm curious…."

Use An Open-Ended Question:

- Which theme did you choose?
- Which one(s) did/do you find yourself most drawn to?
- Which card color did you like the most?
- Look on page 23. Which of the themes stands out for you?

- If the participant easily identifies a theme, go to #7.
- If participant struggles with choosing a theme, **Go to #6.**

6. If participant needs help in choosing a theme (suggested approaches):

Participant did not receive the cards OR did not review the cards.

EXAMPLE:

*"Even if you did not receive the cards… **[OR]***
"Even if you did not get the chance to review the cards…

… it would great if I could talk with you a bit. This should take about 15 minutes. Is now a good time for you to talk?"
[If NO - Reschedule].

"*Great. What I am going to do is read some phrases to you one at a time. After I read each phrase, I want you to tell me if it is important to you when making dietary changes. Would this be okay with you?"*
"Great. I will read a phrase and then you'll tell me either 'yes', that is important for me when making dietary changes, or 'no', that is not important for me when making dietary changes. There are no right or wrong answers. Any questions before we begin?"

USE THE PHRASES LISTED UNDER THE 'WHAT IS IMPORTANT TO MY SUCCESS' SECTION FOR EACH THEME ON PAGE 23 OF THE CARDS.

Participant is having a hard time choosing a theme.
EXAMPLE:

"That's okay if you're not sure which one to choose. Let's try this…I am going to read each phrase one at a time and you tell me how you would rank them on a scale from one to five. One being not very important when making dietary changes, and five being extremely important when making dietary changes. There are no right or wrong answers. Any questions before we begin?"

TIPS:

If participant has M1 in front of her:

"You may find it helpful if we read the phrases on page 23 of the cards together. The phrases are listed under the word, "Key" about ¾ of the way down the page. Let me know when you're ready."

If participant does not have M1 in front of her:

"It may be helpful if you write the phrases down on paper. This way you can see them in front of you. I will read them to you one at a time. Ready…"

USE THE PHRASES LISTED UNDER THE KEY FOR EACH THEME ON PAGE 23 OF THE CARDS.

Participant chooses more than one theme.

EXAMPLE:

"You named three themes that you see as equally important to you when making dietary changes. Now what I would like you to do is put them in order from one to three. One being the most important to you and three, although still important, may not stand out as much as the other two. Although this may be a hard choice, I know you can do it! Remember—there are no right or wrong answers. This is your choice. I will read them again…."

ONCE PARTICIPANT HAS CHOSEN A THEME, GO TO #7

Figure 6.13 (cont.)

7. Summarize.

EXAMPLE: *"Based on what you have just shared with me, it sounds like _____is/are important to you and appeals to you the most when making dietary changes. I want to emphasize that this does not mean that the other themes are not important, just that this one theme stands out more than the others. What else would you like to add?"*

8. Explore reasons for choosing theme, using open-ended questions and reflections.

EXAMPLES FOR EACH THEME BELOW:

Remember to reflect after each question then summarize at the end.

Feel the Difference:

1. *Tell me a bit about why it's important for you to feel healthy and good about what you're doing when making dietary changes. What else…?*
2. *If you could feel healthier and better about what you're doing when making dietary changes, what would need to happen?*
3. *If you decide to, how might you make this happen*?

Taste is Everything:

1. *Tell me a bit about why it's important for your food to taste good when making dietary changes. What else…?*
2. *If your food could taste better when making dietary changes, what would need to happen?*
3. *If you decide to, how might you make this happen?*

It's Got to be Easy:

1. *Tell me a bit about why it needs to be easy to eat low fat when making dietary changes. What else…?*
2. *If low-fat eating could be easier, what would need to happen when making dietary changes?*
3. *If you decide to, how might you make this happen?*

Look at Yourself:

1. *Tell me a bit about why it's important for you to be aware of your choices when making dietary changes. What else…?*
2. *If you could be more aware of your choices when making dietary changes what would need to happen?*
3. *If you decide to, how might you make this happen?*

Family & Friends Count:

1. *Tell me a bit about why it's important for your family and friends to be involved when making dietary changes. What else…?*
2. *If your family and friends could be more involved when making dietary changes, what would need to happen?*
3. *If you decide to, how might you make this happen?*

REMEMBER: WHEN EXPLORING THE THEME—AVOID GIVING ADVICE UNLESS SHE ASKS FOR IT.

9. Close the conversation and introduce Mailing 2.

EXAMPLE: *"We are done! Be sure to watch your mailbox because in the coming weeks you will receive a folder with more ideas and activities around the theme that you said was most important to you. We really hope that you will enjoy them*! *We also included some great recipes."*

10. Express your appreciation and gratitude for her participation.

EXAMPLE: *"Mrs. _____, I really want to thank you for taking the time to talk with me today. Your participation in WHI is a valuable contribution to women's health. We greatly appreciate your time, energy and efforts!"*

Figure 6.14
Getting Back on Track

Getting Back on Track: Keeping the Conversation Focused

One of the greatest challenges in a "brief" telephone call is actually keeping it brief. Yet, we feel uncomfortable interrupting participants, especially when we want them to come back! Yet, it is important to try to keep the phone conversations brief, if possible. Below is a skill that may help you in keeping conversations brief, respectful and useful.

Summarize and Shift!

Summarizing is basically mirroring or reflecting back to the participant what you heard them say. The difference between summarizing and reflecting is that the former pulls together all of the pieces of a conversation. In other words, it is a "big reflection."

Shifting is a way to move the conversation in another direction. This is useful when you encounter resistance, or the participant is wanting to talk about other things and you are feeling crunched for time.

Below is an example of how you can "summarize and shift:"

Mrs. Smith: *"Of course taste is important to me! I won't eat it if it doesn't taste good. Would you? Some of the food I've had lately has been good and some has been so bad. Just the other day, I had lunch with my friend, Joan. She thinks she is a great cook, but she's not as good as she thinks! She lives over in Rochester. I have to take two buses to get there! Anyway…she cooked this chicken that was so dry that it was like chicken jerky! It hurt to chew it. That reminds me, I have to take the chicken out of the freezer or I won't be able to have it for dinner tonight. I found a great new recipe. Her chicken was not only dry; it also didn't have any flavor. Maybe she should add some of that seasoning stuff—Mrs. Dash? That may help…..…"*

Nutritionist:
"Mrs. Smith, let me jump in because I want to make sure that I am hearing you correctly. What you are saying is that your food must taste good, and that sometimes adding some seasonings can really help a dish."

"I need to stop you so I can make sure that I've heard you right. I want to make sure that I get what's important to you! You say that if your food isn't flavorful, you are not going to be happy. It must have some amount of flavor for it to be worth eating."

- After you summarize, shift direction by asking an open-ended question:
- Shifting direction allows you to move the participant from the previous conversation onto a new topic.

Nutritionist:	*"What other themes did you see as important?"*
('No' scenario)	*"Now I am going to read you another statement and you tell me if it is important to you or catches your attention: It's Got to Be Easy—low-fat eating must be as easy as possible."*

- Remember to always end a conversation with a summary of what you discussed.
- Every participant is different. It may be very important to allow time for "chit-chat" prior to attending to the purpose of the call.

Good luck!

6.14.3.4 Mailing 2 (M2) - Sent by the CC

Mailing 2 (M2) is a folder that contains: a) one theme-targeted activity packet, b) four regional menus with recipes and a shopping list, and c) a seeded flower paper. The purpose of M2 is to provide a theme-targeted menu of options that allows the participant to choose an action or activity consistent with her stage of readiness and motivation.

There are six different activity packets, one for each of the five themes and a general packet. The general packet (*It's Gotta Be You*) consists of a combination of activities from the various themes. Nutritionists use the general packet in the following situations:

- When the TMC Phone Call is not done because the participant was: a) not appropriate for the TMC call, b) could not be reached for the TMC call, or c) declined the TMC call.
- When the participant is unable to identify a theme during the TMC Phone Call.

Each M2 activity packet includes six options (two targeted to participants who are "not ready", two targeted to participants who are "unsure", and two targeted to participants who are "ready to change"). Participants receive activities for all three stages of readiness to acknowledge that stage of change is fluid. The "not ready" activities invite women to think more about what is important to them in WHI. The "unsure" activities prompt exploration of ambivalence about dietary change. The "ready" activities invite women to consider action to stimulate or maintain dietary change. *Figure 6.15 – Mailing 2 Activities by Readiness & Theme* provides an overview of each activity, including stage of readiness, general description, and theme-targeted content.

The Nutritionist sends M2 (including the appropriate theme-targeted activity packet) to the participant as soon as possible after the TMC Phone Call contact (ideally within one week). Participants receive only one theme-targeted activity packet.

Assembling Mailing 2:

The CC is responsible for assembling the contents of M2 as follows:

1. Insert the following pieces into each folder:
    - 1 seeded flower paper in the slot provided in the bottom left section of the folder.
    - 4 regional recipe cards in the right section of the folder.
    - 1 theme-targeted activity packet in the center section of the folder.
2. Place/affix a TMC logo sticker (CCC provided) on the front of each envelope (CC provided).

Careful planning was used to design theme-targeted materials that provide equal emphasis on the three different readiness to change levels. For this reason, nutritionists are strongly encouraged not to include additional materials in the M2 folder.

Figure 6.15
Mailing 2 Activities by Readiness & Theme

Readiness	Activity	General Description	Theme – Targeted Content	
Not Ready	What It Means to Me	An activity to help the participant think about what her identified theme means to her.	Feel the Difference	What does feeling healthy and good mean to you?
			Taste is Everything	What does having great tasting food mean to you?
			It's Got to Be Easy	What does having quick and easy low-fat choices mean to you?
			Look at Yourself	What does tracking progress and being aware of choices in WHI mean to you?
			Family & Friends Count	What does involving your family and friends in WHI mean to you?
	One Day at a Time	An activity to help the participant think about how easy or hard it was on a given day to focus on WHI.	Feel the Difference	The positive impact that WHI has on your life may be more obvious on some days than others—your energy level, how you feel physically, your sense of accomplishment and much more. Think about today. How did your WHI activities feel? [Not Great – Great!]
			Taste is Everything	On some days, you may feel more satisfied with your food than on other days. Think about today. How would you say your food tasted overall? [Bland & Boring – Absolutely Delicious]
			It's Got to Be Easy	Some days may go more smoothly than others. Think about today. How easy or difficult has it been to keep WHI on your mind? [Difficult – Easy}
			Look at Yourself	You may be more conscious of your WHI choices on some days than on others. Think about today. How aware were you of your WHI choices? [Not Aware – Very Aware]
			Family & Friends Count	The positive impact that your family, friends, co-workers, and neighbors have in supporting your WHI efforts may be more obvious on some days than on others. Think about today. Did you have the support you needed? [Felt Unsupported – Felt Supported!]

Figure 6.15 (Cont.)

Readiness	Activity	General Description	Theme – Targeted Content	
Unsure	I Can Choose	An activity to help the participant think about her interest/motivation to take action that supports meeting WHI goals.	**Feel the Difference**	Activities about feeling good (physically and emotionally) about WHI participation: • List the ways WHI helps you feel healthy. • Eat a fruit or vegetable that makes your body feel good. • Identify the thing that makes you feel most happy about being a part of WHI. • Pat yourself on the back for all you do for WHI. • My idea:
			Taste is Everything	Activities about taste: • Eat a favorite fruit or vegetable. • Explore new seasonings: spices, herbs or flavored vinegar. • Look for new recipes. • Call a group member who likes to cook and ask her for ideas. • My idea:
			It's Got to Be Easy	Activities that are easy: • Grab a fruit or vegetable for a snack. • Eat 2 vegetables for dinner. • Make a salad into a meal. • Drink your fruit - mix up a smoothie. • My idea:
			Look at Yourself	Activities about being aware of choices: • Fat budget before you eat a high-fat meal away from home. • Think about your food choices on the days you don't record. • Practice positive self-talk. • List the things you do routinely to eat low fat. • My idea:
			Family & Friends Count	Activities about the importance of family and friends: • Ask for help with your biggest WHI challenge. • Share a low-fat meal with a friend or family member. • Talk with your family or friends about what being in WHI means to you. • Attend more WHI group meetings. • My idea:

Figure 6.15 (Cont.)

Readiness	Activity	General Description	Theme – Targeted Content	
Unsure	Now & Then	An activity to help the participant identify and explore the importance (past and present) of a theme-targeted subject.	Feel the Difference	What are a few of your eating habits from the past? What new habits have you discovered since joining WHI? What about your new eating habits makes you feel good?
			Taste is Everything	What are a few of your favorite foods from the past? What delicious new foods have you discovered by participating in WHI? What makes your new favorites important to you?
			It's Got to Be Easy	What are a few of your favorite foods from the past that are easy to prepare and eat? What are the new easy food favorites you've discovered by participating in WHI? What makes your new favorites important to you?
			Look at Yourself	What are a few of your eating habits from the past? What new habits have you discovered since joining WHI? What differences do you see in your eating habits since joining WHI? What makes your new eating habits important to you?
			Family & Friends Count	What are some of the most important ways you helped your family and friends in the past? How has your participation in WHI helped your family and friends? What makes helping your family and friends important to you?

Figure 6.15 (Cont.)

Readiness	Activity	General Description	Theme – Targeted Content	
Ready	Secrets to My Success	An activity to help the participant assess eating behaviors for the purpose of identifying an action step that supports meeting WHI goals.	Feel the Difference	How do your servings compare to others in WHI? What ideas do you have for ways to boost fruits and vegetables or cut fat that would help you feel healthy and good? Choose one you might do and write it here: _____.
			Taste is Everything	How do your servings compare to others in WHI? What ideas do you have for ways to boost fruits and vegetables or cut fat that would be tasty and delicious? Choose one you might do and write it here: _____.
			It's Got to Be Easy	How do your servings compare to others in WHI? What ideas do you have for ways to boost fruits and vegetables or cut fat that would be easy to do? Choose one you might do and write it here: _____.
			Look at Yourself	How do your servings compare to others in WHI? What ideas do you have for ways to boost fruits and vegetables or cut fat? Choose one you might do and write it here: _____.
			Family & Friends Count	How do your servings compare to others in WHI? What ideas do you have for ways to boost fruits and vegetables or cut fat that would be popular with family or friends? Choose one you might do and write it here: _____.

Figure 6.15 (Cont.)

Readiness	Activity	General Description	Theme – Targeted Content	
Ready	Seeds of Change	An activity to help the participant identify an action step that supports meeting WHI goals.	Feel the Difference	Goals about <u>feeling good</u> (physically or emotionally) about WHI participation: • Take time in the next month to think about all the dietary changes you've made since joining WHI. • Eat a low-fat food today that makes you feel healthy. • List the positive feelings you had about the WHIse choices you made this week. • At the end of each day, think about the ways WHI helps you feel healthy - - do this every day for a week.
			Taste is Everything	Goals about <u>taste</u>: • Try one new low-fat meal each week for a month. • Combine different vegetables and fruits for new flavors and colors - - do this for 3 days this week. • Browse through low fat cookbooks and WHI recipes to find 4 new recipes to try in the next month. • Experiment with a new low-fat seasoning during the next week.
			It's Got to Be Easy	Goals about doing something <u>easy</u>: • Have a fruit or vegetable with every evening meal for a week. • Keep a daily tally of your fruit & vegetable servings for a week. • Look through your WHI recipe collection during the next month to find recipes that are easy. • Eat a meatless meal once a week for a month.
			Look at Yourself	Goals about <u>being aware</u> of choices: • Consider tackling a WHI challenge you've been thinking about. • Keep track of your fruits and vegetables every day for a week. • Count fat grams every time you eat away from home in the next month. • The next time you choose a high-fat food, take a few moments to think about the reasons you're eating it.
			Family & Friends Count	Goals about the <u>importance of family and friends</u>: • Talk with the people who support you in WHI - - tell them what they currently do that helps you. • Prepare a meal for a friend - - ask her to pick the low-fat entrée. • Attend an additional WHI group meeting each year. • Exchange low-fat recipe ideas with family members or friends.

6.14.4 TMC Data Collection

The Nutritionist uses *Form 67 – TMC Phone Call (Ver. 1)* and progress notes to document the result of the participant's TMC Phone Call contact.

Form 67

Form 67 – TMC Phone Call (Ver. 1) is a data collection form that documents the following information:

- If the participant received the TMC Phone Call, including reasons for not receiving the call. And, if the participant did not receive the call, whether the Nutritionist opted to send the *It's Gotta Be You* M2 packet.
- If the participant received and reviewed M1 before receiving the TMC Phone Call.
- Theme the participant identified during the TMC Phone Call.
- If the participant was unable to identify a theme during the TMC Phone Call (and, therefore, received the *It's Gotta Be You* M2 packet).
- If the participant refused M2.
- Date M2 packet was sent (optional).

Form 67 – TMC Phone Call is computer-generated from WHILMA. Refer to the WHILMA v. 43 Upgrade Notes (available in the Outlook Public Folders in January 2001) for information about how to generate this form from WHILMA.

For each participant scheduled to receive the TMC Phone Call, the form shows the following pre-printed information:

- Participant name and ID (including barcode).
- Participant phone number (including work number if specified OK to call).
- Participant DM Intervention status (active vs. stopped).
- Nutritionist ID.
- Group number.
- Participant Mailing 1 Month.
- Participant TMC Call Month.
- TMC Notes (key-entered in the TMC Tracking Screen).

The Nutritionist generates *Form 67 – TMC Phone Call* before contacting the participant for the TMC Phone Call, most likely the month prior to the call. Example: in January, the Nutritionist generates the form for all participants scheduled to receive the TMC Phone Call in February. The form (pre-printed with the participant-specific information outlined above) can then be used as a 'tickler' file for managing upcoming calls. Refer to the WHILMA v. 43 Upgrade Notes for information about parameters that allow the Nutritionist to generate the form using various selection criteria (e.g., TMC Phone Call Month, Nutritionist ID, Group #, etc.). The programming for generating this form also includes the capability to print participant mailing labels for M2. This allows the Nutritionist to generate *Form 67 – TMC Phone Call* and the corresponding M2 mailing label at the same time. Refer to the WHILMA v. 43 Upgrade Notes for information about printing the M2 mailing labels.

The Nutritionist completes and key-enters *Form 67 – TMC Phone Call* only when: a) the TMC Phone Call has been done or b) the Nutritionist makes the final determination that the TMC Phone Call will not be done.

Below are examples of how to complete *Form 67, Qx. 3 – Contact Result* in various situations. For complete details and instructions, refer to *Vol. 3 – Forms, Instructions for Form 67 – TMC Phone Call (Ver. 1)*

- *Participant Not Appropriate for TMC Call* (Qx. 3 – Option 1): The Nutritionist marks this option when her/his clinical judgement indicates that the participant should not be approached for the TMC Phone Call. This decision may occur because a participant has a crisis situation (e.g., serious personal or family illness, the death of spouse, etc.). As noted above, the Nutritionist completes and key-enters the form for this situation only when the final determination is that the TMC Phone Call will not be done. At this point, the Nutritionist has the option to send the *It's Gotta Be You* M2 packet to a participant who will not receive the TMC Phone Call.

- *Participant Not Reached for TMC Call* (Qx. 3 – Option 2): The Nutritionist marks this option when her/his judgement indicates that the participant cannot be reached for the TMC Phone Call. As noted above, the Nutritionist completes and key-enters the form for this situation only when the final determination is that the TMC Phone Call will not be done. Clinical Center discretion determines the minimum number of attempts to make before deciding that the participant cannot be reached. Suggestion: attempt to contact the participant 10 times (different days/times) before making the final determination that she cannot be reached for the TMC Phone Call. At this point, the Nutritionist has the option to send the *It's Gotta Be You* M2 packet to a participant who will not receive the TMC Phone Call.
- *Participant Declined TMC Call* (Qx. 3 – Option 3): The Nutritionist marks this option when the participant is reached, but declines the TMC discussion (i.e., participant indicates that this is not a good time and is unwilling to re-schedule the call). As noted above, the Nutritionist completes and key-enters the form only when the final determination is that the TMC Phone Call will not be done. At this point, the Nutritionist has the option to send the *It's Gotta Be You* M2 packet to a participant who will not receive the TMC Phone Call.
- *TMC Call Done* (Qx. 3 – Option 4): The Nutritionist marks this option when the TMC Phone Call (using a ME-style) discussion has occurred and Form 67, Qxs. 3.2 – 3.5 have been answered.

Progress Notes

In addition to *Form 67 – TMC Phone Call* (Ver. 1), the Nutritionist will want to keep notes about each TMC Phone Call. The purpose of the progress notes is to help the Nutritionist manage TMC Phone Call contact information that is not data entered, but is important for continuing to support and build the participant's motivation in future contacts. The notes include, but are not limited to, information gathered during the exploration of the participant's identified theme. Notes about exploration of the identified theme might include the participant's:

- Description of what her chosen theme means to her.
- Description of why that particular theme is important to her.
- Ideas about how things surrounding her identified theme could be different in order to enhance her personal success in WHI.
- Thoughts about how she might make these differences happen.

Refer to *Figure 6.13 – TMC Phone Call Guide* for examples of ways to explore the participant's identified theme. Keeping notes is required; the method used to keep the notes is the Nutritionist's option.

6.14.5 TMC Management

TMC activities begin in the Fall of 2000 with the WHI Making WHIse Choices (Kickoff) newsletter and continue through December 31, 2001.

The Lead Nutritionist appropriately allocates resources to complete TMC activities per the studywide timeline. To manage the TMC workload, the Lead Nutritionist does the following:

- Identifies which participants will participate in the TMC.
- Identifies when participants will begin the TMC process by receiving M1.
- Determines the number of participants each month that will begin the TMC process by receiving M1.
- Determines the number of participants who will receive the TMC Phone Call contacts each month.
- Defines the process for assembling and mailing M2 each week.
- Tracks participant progress through the TMC.

When allocating staff resources for the TMC, the Lead Nutritionist also considers the following:

- The number of nutrition staff available to conduct the TMC Phone Call contacts (e.g. workload distribution, part-time staff, vacations, etc.).
- Availability of participants for the TMC Phone Call contacts (e.g. available only on evenings or weekends, or extended travel (snowbirds).
- CC staff resources available to assemble and mail the M2 packets to participants.

The Lead Nutritionist manages local TMC operations using WHILMA resources as outlined in *Section 6.14.6 – WHILMA Resources for TMC Management.*

6.14.6 WHILMA Resources for TMC Management

The *TMC Tracking* screen, *Mailing 1 Summary* screen (and corresponding *Mailing 1 Summary* report), and the *TMC Member Tracking* report provide tools to help the Lead Nutritionist schedule and monitor progress of TMC activities. Refer to the TMC WHILMA Upgrade Notes (available in the Outlook Public Folders in October 2000) and the WHILMA v. 43 Upgrade Notes (available in the Outlook Public Folders in January 2001) for details about using the WHILMA resources.

TMC Tracking Screen

The TMC Tracking screen provides the mechanism for the Lead Nutritionist to determine:

- Which participants will participate in the TMC.
- When each participant will begin the TMC process by receiving Mailing 1.
- Each participant's TMC language preference.

The *TMC Tracking* screen (published to CCs October 2000) distributes participants evenly by M1 month (January through August 2001), Nutritionist, and DM group. Clinical Centers may modify this distribution as necessary (within the January through August timeframe) to meet local participant and staffing needs. However, changes to the *TMC Tracking* screen must be final before the scheduled database freeze as outlined below.

CCC Database Freeze. The CCC freezes the *TMC Tracking* screen data for M1 approximately 6 weeks before each M1 Month begins. For example, the CCC will freeze the *TMC Tracking* screen for the March mailing on January 15th. Nutritionists finalize the participant list for each M1 Month **the day before** the scheduled database freeze. Refer to the TMC WHILMA Upgrade Notes for the exact date for each mailing month.

Mailing 1 Summary Screen

The *Mailing 1 Summary* screen provides a summary of the distribution of participants by M1 month and by Nutritionist. It provides a summary of each Nutritionist's potential TMC workload for the eight-month period between January and August 2001. Nutritionists can use this summary screen to obtain a quick picture of their workload for TMC Phone Call contacts. For example, M1s mailed in January will result in TMC Phone Calls in February. Any changes made in the *TMC Tracking screen* will be reflected in the *Mailing 1 Summary* screen. A hardcopy of the *Mailing 1 Summary* screen may be obtained by a) printing the screen (click on the Print Screen button) or b) running and printing the *TMC Mailing 1 Summary* (TMC002) report.

TMC Member Tracking Report

The *TMC Member Tracking* (TMC001) report includes all DM Intervention participants eligible for TMC and provides information about several key TMC variables (i.e., Participant Name and ID; DMI Status; Nutritionist ID; DM Group; M1 Month; TMC Call Month; TMC Status; TMC Phone Call Contact Date; TMC Phone Call Contact Result; Theme; Date M2 Mailed).

The Lead Nutritionist (or designee) uses the *TMC Member Tracking* report to manage local implementation of the TMC. The report facilitates the following:

- Identifying the M1 and TMC Phone Call month for each participant.
- Tracking TMC Phone Call date and result for each participant.
- Tracking the theme chosen by each participant.
- Tracking the M2 mailing date (optional) for each participant.

It is recommended that Nutritionists run the *TMC Member Tracking* report monthly. For more details about running the *TMC Member Tracking* report, refer to the WHILMA v. 43 Upgrade Notes (available in the Outlook Public Folders in January 2001).

6.14.7 TMC Integration with Maintenance Sessions

The quarterly DM Maintenance sessions present an opportunity to provide follow-up for M2. After the participants in a given DM group have received M2, the Nutritionist is encouraged to use the *Group Sharing/Next Steps Follow-up* segment at the beginning of the next session to engage participants in a discussion about the theme-targeted activity packets. The purpose of the group discussion may be any, or all, of the following:

- Share experiences using the theme-targeted activity packets.
- Share discoveries related to a specific activity (e.g., *What It Means to Me*, etc.).
- Discuss and explore specific activities that pertain to the whole group (e.g., *Secrets to My Success*, etc.).
- Help participants continue to explore ambivalence, choices, and confidence in considering dietary changes around their specific targeted themes.

The discussion questions could be general (e.g., "What activities have you tried?") or focused on a specific activity (e.g., Would someone like to share your response to the *I Can Choose Activity*?).

6.14.8 TMC Evaluation

The FFQ will be used to evaluate the TMC. The TMC evaluation has the following objectives:

- Monitor completeness of the protocol implementation at the clinic level.
- Estimate effect of the TMC on change in percent energy from fat in Dietary Change participants.

Evaluation of Protocol Completeness

The CCC will use data collected from *Form 67 – TMC Phone Call* to evaluate TMC implementation. These contacts will provide the numerator for determining the completeness of the protocol implementation, where the denominator is the (live) Dietary Change cohort. This procedural monitoring will provide an unbiased assessment of the degree of protocol implementation, both trialwide and at the clinic level.

Estimate Effect of the TMC on Change in Percent Energy from Fat in Dietary Change Participants

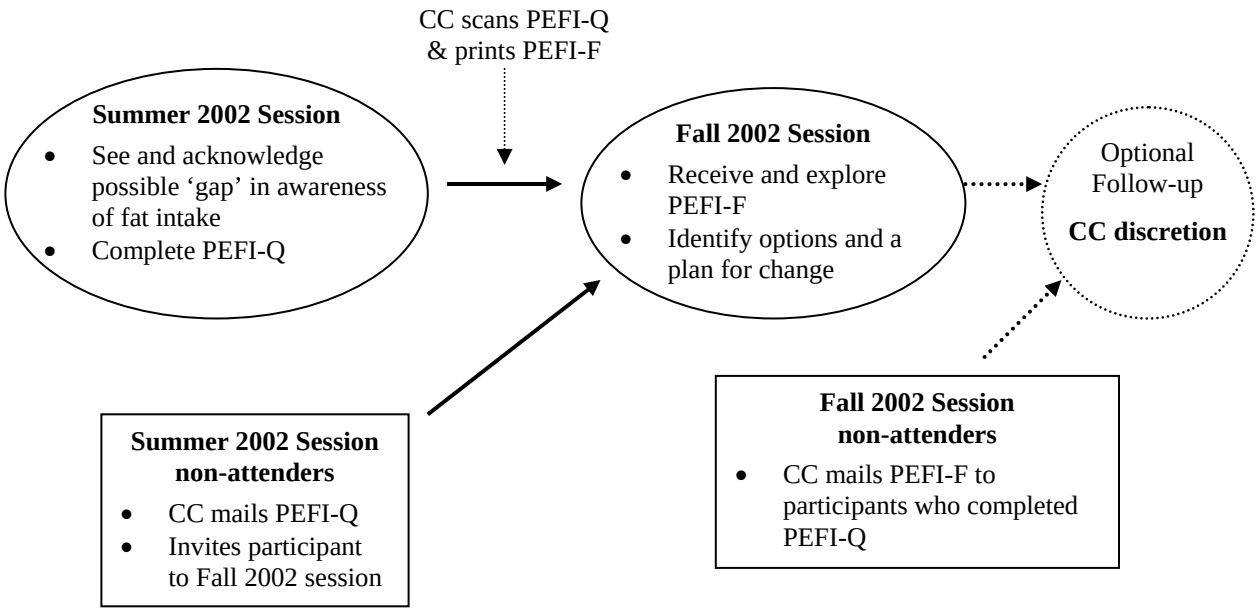
The CCC will conduct a before-and-after analysis based on the fact that 100% of Dietary Change participants complete an AV-1 FFQ and about a third will complete an FFQ during 2001, while the TMC is being implemented. Therefore, we will be able to compare participants who completed an FFQ before receiving the TMC (i.e., a TMC control group) with participants who completed an FFQ after receiving the TMC (i.e., a TMC intervention group). The outcome variable will be change in percent energy from fat from AV-1 to the most recent FFQ and the model will be controlled for potential covariates such as age, race/ethnicity, education, visit year, and clinic effects. These data permit a pairwise analysis of the effect of the TMC on Dietary Change participants' fat intake in the "TMC control" vs. "TMC intervention" groups. The sample sizes should provide a reliable trialwide estimate but are likely too small to provide precise clinic-specific estimates of the TMC effect.

We acknowledge that the TMC protocol, as implemented in WHI, is not designed for a rigorous test of the effectiveness of this intervention campaign component in reducing fat intake for, at minimum, the following reasons: variability in administration; concurrent effects of the main intervention; and, lack of an appropriate comparison group.

6.15 Personalized Evaluation of Fat Intake (PEFI)

The Personalized Evaluation of Fat Intake (PEFI) is an augmented intervention to support and improve DM Intervention adherence. The overall goal of the PEFI intervention is to help participants find their own motivation to make dietary changes to meet or maintain their fat gram goal. For most participants this means lowering their fat intake. For some participants, this means maintaining their low fat intake. All DM Intervention participants will have the opportunity and encouragement to consider making dietary changes. The process for motivating this dietary change is to have participants complete a self-assessment questionnaire of fat intake (PEFI-Q) and receive computerized tailored feedback based on the questionnaire (PEFI-F). PEFI intervention implementation will be supported primarily through group sessions where participants will complete the self-assessment questionnaire (Summer 2002) and discuss their tailored feedback (Fall 2002). Alternative support may occur through mailings with optional in-person or phone contacts based on existing CC resources and nutritionist discretion. The PEFI intervention and materials were developed by the WHI Dietary Modification Working Group (DMWG), which included representation from the Clinical Coordinating Center (CCC), Lead Nutritionists, Dietary Modification Committee (DMC), Behavioral Advisory Committee (BAC), and Special Populations Advisory Committee (SPAC). PEFI intervention implementation begins June 2002 and continues through November 2002, with data consolidation in February 2003. *Figure 6.16 – PEFI Intervention* provides an overview of the PEFI intervention.

Figure 6.16 – PEFI Intervention



6.15.1 Behavioral Foundation

The behavioral foundation of the PEFI intervention is based upon the principles of motivational enhancement (ME), group facilitation, adult learning, self-assessment, and tailored feedback. The nutritionist uses fundamental skills and key strategies to support and implement these principles throughout the intervention.

The following sections describe these principles, skills, and strategies.

6.15.1.1 Principles

This section describes how the principles of motivational enhancement (ME), group facilitation, adult learning, self-assessment, and tailored feedback are incorporated in the PEFI intervention. Although the principles are listed categorically for emphasis, they are interwoven with each other.

Motivational Enhancement (ME)

Motivational enhancement is incorporated in the PEFI intervention by:

- *Creating an atmosphere* that acknowledges and respects participants' choice and readiness to change. This atmosphere reduces resistance and paves the way for increasing participants' interest in exploring potential change.
- *Empowering participants* to make changes based on choice and readiness – changes that fit for them. Empowering participants supports self-efficacy – their belief that they can succeed and maintain change.
- *Building motivation* by helping participants identify a discrepancy between current and desired fat intake through the use of personalized feedback. Developing discrepancy between where a participant is and where she wants to be creates 'tension' for the participant, leading to increased motivation.

Group facilitation

Group facilitation is incorporated in the PEFI intervention by:

- *Engaging participants* in a way that supports adult learning and enhances group cohesion. Facilitated discussion, exploration and goal setting in a group setting increases active involvement of the participant in the learning process, promotes group cohesion, and supports accountability for making changes.

Adult learning

Adult learning is incorporated in the PEFI intervention by:

- *Identifying participants' existing interests, knowledge, strengths and skills* that support behavior change. Participants become involved and empowered when their interests, knowledge, strengths and skills are recognized, reinforced, and supported.

Self-assessment

The Personalized Evaluation of Fat Intake Self-Assessment Questionnaire (PEFI-Q) and the *Summer 2002 session discussion* form the core self-assessment elements of the PEFI intervention.

- The self-assessment process is important because it creates an opportunity for the participant to have an active role by defining beliefs and expectations about her fat intake. Expressing opinions and expectations increases ownership and responsibility regarding any future behavior change. Ownership and responsibility are important because any information or feedback the participant receives is more likely to be valid in her eyes when she is an active part of the process. This may also set the stage for being more open, in general, to feedback relating to her fat intake. Active involvement in the process also serves to support self-efficacy, the personal belief that one is capable of change.

Tailored feedback

The computerized tailored feedback (PEFI-F) and the *Fall 2002 session discussion* form the core tailored feedback elements of the PEFI intervention.

- Tailored feedback involves receiving personalized information regarding a specific behavior. In the PEFI intervention, the feedback is based on the participant's self-assessment of her fat intake. Receiving tailored feedback allows the participant to reflect upon and be aware of the gap between her present situation and where she would like to be. Awareness of this discrepancy can create 'tension' for the participant, leading to increased motivation.

6.15.1.2 Skills and Strategies

This section describes the fundamental skills and key strategies the nutritionist uses to support and implement the principles guiding the PEFI intervention. The skills are 'learnable abilities' and the strategies are 'techniques'. The skills are necessary to implement the strategies.

Fundamental Skills

- The ability to use open-ended questions, affirmations, reflective listening, and summarizing (OARS).
- The ability to remain directive to the goal while supporting participant choice.
- The ability to facilitate a group discussion by finding the "common threads" among group members, managing group differences, and addressing participant questions.
- The ability to assess and be flexible regarding the varying levels of readiness among participants.
- The ability to manage a variety of emotions, tension, and beliefs relating to the PEFI intervention.

Key Strategies

- Use the participant as a source of expertise and knowledge for herself and for others in the group.
- Provide opportunities to develop and explore the tension created by discrepancy.
- Recognize, reflect, and emphasize participant self-motivational statements (change talk).
- Use tailored feedback to help the participant to identify and explore options for change.
- Provide an opportunity for the participant to develop and share her plan for change.

The Group Nutritionist materials for the Summer and Fall 2002 sessions provide extensive guidelines for delivering these sessions using the principles, skills, and strategies outlined above. Refer to *Vol. 2, Section 6.15.3 – PEFI Implementation* and *Vol. 4, Group Nutritionist Manual, Summer 2002 – Take a Closer Look and Fall 2002 – A Closer Look: What Do I See?*. For additional information, refer to the following WHI resources:

- *ME Corner of the WHI Times dated 1/12/01, 4/27/01, 5/25/01, 6/22/01, 7/27/01* (Outlook Public Folders\All Public Folders\The WHI Times).
- *Volume 2, Appendix G.5 – Motivation Enhancement Training August 1999, WHI Intensive Intervention Protocol.*

6.15.2 PEFI Components

This section describes the Personalized Evaluation of Fat Intake Self-Assessment Questionnaire (PEFI-Q) and the computerized tailored feedback (PEFI-F).

6.15.2.1 PEFI Self-Assessment Questionnaire (PEFI-Q)

The PEFI-Q is a computerized self-assessment tool for dietary fat. The questionnaire provides a view of usual fat intake over the past month. In general, the questionnaire does not ask about foods containing little or no fat, such as fruits and vegetables. It does include reduced-fat and fat-free versions of fat-containing foods.

The role of the PEFI-Q in the PEFI intervention is to provide each participant with a self-assessment opportunity – a chance for each participant to learn more than she already knows about her fat intake. The questionnaire is a supplement to self-monitoring (i.e., not a replacement, not better, not perfect). The questionnaire is not a dietary assessment instrument used to monitor the study.

6.15.2.1.1 Design and Content

The PEFI-Q is a 12-page mark-sense form. It includes a front page and two sections asking about foods.

- The front page includes a place for the participant to write her name, date and group #, and a 'OFFICE USE ONLY' box for CC staff to complete.
- Part I (pages 2-5) – *Usual Food Choices:* consists of 24 adjustment questions that ask about the fat in foods. The questions in this section are used to adjust the information provided on pages 6-12.
- Part II (pages 6-12) – *Usual Food Use:* includes individual food items organized by food groups. This section asks about specific foods: how often they were eaten in the past month and the usual serving size.

Part I (Pages 2-5) – Adjustment Questions

Types of Adjustment Questions

Adjustment questions are used to adjust the amount of fat in the food line items of the questionnaire (pages 6-12). There are two types of adjustment questions used in the PEFI-Q:

- **Frequency of Use:** These questions ask about how often the participant chose a fat-free/low-fat food or how often a mixed dish/soup was prepared to be lower in fat. Examples are shown in *Table 6.6 – Types of Adjustment Questions Used in the PEFI-Q.*
- **Type of Food:** These questions ask about the type of food the participant usually ate. An example is shown in the *Table 6.6 – Types of Adjustment Questions Used in the PEFI-Q.*

Table 6.6 - Types of Adjustment Questions Used in the PEFI-Q

Type of Adjustment Question	Examples
Frequency of Use	Page 2: *Qx. 1 – Did you eat pancakes, waffles or French toast?* *1a – When you ate these foods, how often were they fat-free or low-fat?* Page 5: *Qx. 24 – When you ate mixed dishes or soups, how often were they prepared to be lower in fat?*
Type of Food	Page 3: *Qx. 9 – Did you eat ground meat, ground poultry, or meatless burgers?* *9a – When you ate these foods, what type did you usually eat?* *(Mark all that apply.)*

OPTIONAL READING: *Vol. 2, Appendix G.7.1 – PEFI-Q Adjustment Questions* provides additional information about how the two types of adjustment questions work and the specific line items on the PEFI-Q that are 'adjusted' by the adjustment questions.

Part II (Pages 6-12) – Food Items

Frequency and Serving Size

Frequency choices range from 'Never or less than once a month' to '2+ per day' for food items and '6+ per day' for beverages. The serving size allows the participant to choose between small, medium and large. A medium serving is given as an example on the questionnaire. The PEFI-Q also includes six portion-size graphics (pages 8 and 10) depicting small, medium and large servings for meats and mixed dishes. These graphics are provided to help participants estimate their own usual portion sizes.

Food Line Items

The food items on the PEFI-Q were chosen using the following criteria: a) data-based identification of major contributors of fat in the US diet; b) incorporation of clinical center (CC) suggestions for regional and ethnic foods; and c) incorporation of CC suggestions for low-fat and fat-free modified foods to provide participants the chance to capture dietary changes they have made during the DM Intervention.

It is not possible for the questionnaire to incorporate all the foods that people eat. To include the greatest number of foods for participants, food line items are described in general terms (e.g., *Stews, casseroles or pot pies*), rather than very specific terms. This helps participants identify where their food or mixed dish might fit – instead of looking for a specific food or dish that might not be listed. For example, the foods shown below are not listed on the questionnaire, but they could fit under the following 'general' line items:

- *Beef stroganoff* – fit under the mixed dish line item – *Stews, casseroles or pot pies.*
- *Fudgesicles* – fit under the line item – *Frozen desserts (all types).*

Equivalency Help Sheet:

A number of ethnic-specific dishes were included based on input from clinical centers with diverse populations. Examples: foods added within the existing line items (e.g., *potted or canned meat* added to existing line item 44) or foods added as specific line items (e.g., new line item 56 includes *Egg rolls, lumpia, dim sum (fried varieties), or cone sushi with fried tofu wrap).* In addition, clinical centers have the option to develop Equivalency Help Sheets for their ethnically-diverse populations, if they feel that there are some frequently-consumed high-fat food items that are not included on the questionnaire.

Before developing an Equivalency Help Sheet, the Lead Nutritionist considers the following:

- Is the food or mixed dish already on the PEFI-Q?
- Is the food or mixed dish a major contributor of fat for participants?

The Lead Nutritionist creates an Equivalency Help Sheet that includes only foods that are major contributors of fat for participants, and only foods that are not already on the PEFI-Q. An Equivalency Help Sheet that provides too much (or necessary information could confuse or frustrate some participants.

Figure 6.17 – Template: Equivalency Help Sheet for Local Foods provides a sample template that CCs could use when developing an Equivalency Help Sheet.

Figure 6.17 – Template: Equivalency Help Sheet for Local Foods

The PEFI self-assessment questionnaire was developed for Dietary Change participants across the United States. So, you may not be able to find some of the foods that are special to our area of the country. Below, we have listed some local favorites and indicated where you might mark them on the questionnaire. If you cannot find a food that you frequently eat, please ask your nutritionist for help.

Local Food	Where to Mark Questionnaire	Page
Grain Products and Salty Snacks		
Meat, Poultry, Fish and Eggs		
Fats Used at the Table or Added in Cooking		
Mixed Dishes and Soups		
Milk, Cheese and Yogurt		
Sweets		
Milk as Beverages		

6.15.2.1.2 Quality Control

The goal for the quality control measures for the PEFI-Q is to balance the quality of tailored participant feedback with the amount of staff time needed to follow-up on incomplete questionnaires. Two types of measures comprise the quality control: defaults for missing information and errors that prevent analysis.

6.15.2.1.2.1 Defaults for Missing Information

Defaults are used when responses to adjustment questions are missing or inconsistent with the associated line item. Defaults are also used when serving sizes are missing.

Adjustment Question Defaults: The defaults used for PEFI-Q adjustment questions are based on food choices analyzed from AV1 FFQs of Dietary Change participants. There are two types of defaults used: 'frequency of use' and' type of food'. Examples of adjustment question defaults are outlined on the following page.

Adjustment Question (Examples)	Default Used if Adjustment Question

	Not Answered (Examples)
Frequency of use: - *Qx. 2a – When you ate these breads, how often were they fat-free or low-fat?* - *Qx. 10a – When you ate beef, pork, ham, or lamb, how often did you eat the fat?*	Frequency of use: - *Sometimes* - *Rarely*
Type of food: - *Qx. 9a – When you ate these foods, what type did you usually eat? (Mark all that apply.)* - *Qx. 13a – When you used fat <u>at the table</u>, what kind of fat did you usually use? (Mark all that apply.)*	Type of food: - *Extra lean* - *Butter, margarine, olive or other oil*

If a default is used, the computer programming will use the fat grams assigned to the default to calculate total fat, but the food will not be included in the participant's top 10 foods listed on Page 3 of the PEFI-F. For example:

- PEFI-Q marked this way: If for Qx. 45 (pg. 8) a participant marks that she ate a medium serving of *All types of ground meat or ground poultry* – once a week, but she does <u>not</u> complete the associated adjustment question (Qx. 9a, pg. 3) – *When you ate these foods, what type did you usually eat?*),
- Result: The computer will use the fat grams assigned to the default (extra lean) to calculate total fat, but the food – 'Ground meat or ground poultry' will not appear in the participant's list of top 10 foods on the PEFI-F.

When an adjustment question default is used, a warning message appears on the *PEFI Scanning Results* report. For information about warning messages, refer to the PEFI Upgrade Notes (Outlook Public Folders\All Public Folders\WHILMA Resources\PEFI Upgrade Notes).

<u>Serving Size Default</u>: If a participant does not mark a serving size, a "medium" serving will be used as the default.

<u>OPTIONAL READING</u>: *Vol. 2, Appendix G.7.1 – PEFI-Q Adjustment Questions* provides more information about the how defaults work and specific defaults that are used for each adjustment question when information is missing.

6.15.2.1.2.2 Errors that Prevent Analysis

If any of the following errors occur, the PEFI-Q will not be analyzed:

- Missing 'OFFICE USE ONLY' information (Qxs. 1-6)
- An entire page of questionnaire not completed.
- More than 5 questions missing on pages 2-4.
- More than 3 items missing for Qx. 24 (pg. 5).
- More than 31 food line items missing on pages 6-12.

When an error prevents analysis, an error message appears on the *PEFI-Q Scanning Results* report. For information about error messages refer to the PEFI Upgrade Notes (Outlook Public Folders\All Public Folders\WHILMA Resources\PEFI Upgrade Notes).

6.15.2.2 Tailored Feedback (PEFI-F)

Participants completing the PEFI-Q receive a packet of computerized tailored feedback (PEFI-F). The information in the PEFI-F is tailored for the participant based on her responses on the PEFI-Q. The role of the PEFI-F in the PEFI intervention is to provide the participant with tailored feedback about her dietary fat intake. The tailored feedback sets the stage for building motivation to consider dietary change to meet (or maintain) fat gram goal. Refer to *Vol. 2, Section 6.15.1 (including subsections) – Behavioral Foundation.*

Note: The Summer and Fall 2002 session materials refer to the PEFI-F as 'personalized information' and 'PEFI packet' rather than 'tailored feedback' and 'PEFI-F'. This was done to use more participant-friendly wording.

Design and Content

The PEFI-F sets the stage for building motivation to consider dietary change by prompting the participant to explore the following: her fat intake compared to her fat gram goal, her sources of dietary fat (food groups and foods), and options for dietary change that she would consider making. The participant's fat grams reported on the PEFI-Q determine the PEFI-F's dietary change focus according to the following three fat gram categories:

- **Participants over fat gram goal:** receive a PEFI-F that focuses on reducing fat intake.
- **Participants ≤ fat gram goal, but ≥ 15 grams of fat:** receive a PEFI-F that focuses on maintaining fat intake, or making changes (to reduce fat) if they seem right.
- **Participants < 15 grams of fat:** receive a PEFI-F that focuses on exploring how closely the information matches what the participant eats and making changes if they seem right. The changes considered likely depend on how closely the information matches what the participant eats. Examples of changes to consider: to change amount of fat – increase or decrease; to change type of fat; etc. Refer to *Vol. 2, Section 6.15.4.2.3 – Managing Participants Who Report <15 Grams of Fat.*

The PEFI-F includes four pages plus a cover page. A brief description of each page follows immediately below. *Table 6.7 – Summary of PEFI-F Pages* provides a detailed description of each page of the PEFI-F as determined by the participant's fat grams reported on the PEFI-Q. Refer to *Vol. 2, Appendix G.7.3 – PEFI-F Samples* to see a sample PEFI-F for each of the three fat gram categories listed above. *Vol. 4, Group Nutritionist Manual, Fall 2002 – A Closer Look: What Do I See?* provides additional information about what each page prompts the participant to think about as she explores her tailored feedback.

Cover Page – *Your Personalized Evaluation of Fat Intake*
The cover page provides privacy and allows the participant to control whether others see her tailored feedback. The cover page includes the participant's name and the date the PEFI-Q was completed.

Page 1 – *Where Are You in Relation to Your WHI Fat Gram Goal?*
Page 1 provides a comparison of the participant's fat grams reported on the PEFI-Q and her fat gram goal. This is illustrated two ways: a bar graph and arithmetically. For participants above fat gram goal per the PEFI-Q, this page also includes a comparison of fat grams over goal per day and per week (using a second bar graph). The participant's fat grams reported on the PEFI-Q (see the three fat gram categories above) determine the text at the bottom of this page.

If a negotiated fat gram goal is used for the PEFI intervention, it is reflected on this page. Refer to *Vol. 2, Section 6.15.4.2.2 – Managing Participants with a Negotiated Fat Gram Goal* for information about using a negotiated fat gram goal in the PEFI intervention.

Page 2 – *Where Does Your Dietary Fat Come From?*
Page 2 shows the participant's distribution of fat grams reported on the PEFI-Q by food group. This is illustrated using a pie chart that shows the percent (%) of fat contributed by each food group. This page also points out the two food groups providing the most fat.

Page 3 – *Top Ten Foods That Provide Fat in Your Diet*
Page 3 shows the participant's top 10 sources of fat reported on the PEFI-Q, including the number of fat grams each provides per week. The top 10 fat sources are listed in order from highest to lowest fat grams. This page also offers tailored ideas for lower-fat choices for each of the top 10 foods and shows fat gram savings per week if the lower-fat choices were used. The participant's fat grams reported on the PEFI-Q (see the three fat gram categories above) determine the text at the top and bottom of this page.

OPTIONAL READING: For information about how the tailored low-fat message ideas for each of the top 10 foods are determined, refer to *Vol. 2, Appendix G.7.2 – Tailored Messages for Top Ten Foods on PEFI-F.*

Page 4 – *Next Steps: Where Do You Go From Here?*
Page 4 provides space for the participant to develop a list of change options she might consider. The participant's fat grams reported on the PEFI-Q (see the three fat gram categories above) determine the content

of this page. Participants over fat gram goal or ≤ fat gram goal, but ≥ 15 grams of fat receive a page that provides structure to identify options for change to reduce fat intake. Participants <15 grams of fat receive a page that encourages a meeting with the nutritionist to explore the feedback further and provides space for the participant to think about the following: how closely the very low fat intake matches what she eats, whether any high-fat foods may have been missed on the PEFI-Q, and whether she is interested in making changes in what she eats. Refer to *Vol. 2, Section 6.15.4.2.3 – Managing Participants Who Report <15 Grams of Fat.*

Implementation

Refer to the following WHI Manual references for additional information about the PEFI-F: *Vol. 2, Section 6.15.3.2 – Fall 2002 (9F) Maintenance Session* and *Vol. 4, Group Nutritionist Manual, Fall 2002 – A Closer Look: What Do I See?*.

Table 6.7 – Summary of PEFI-F Pages

Page	Page Heading	Fat Grams Reported on PEFI		
		over fat gram goal	**≤ fat gram goal, but ≥ 15 grams fat**	**< 15 grams fat**
Cover Page	Your Personalized Evaluation of Fat Intake (PEFI)	• Cover sheet with participant name and date questionnaire completed. • Provides general information about what is in packet. • Informs participant that the Fall session will provide an opportunity to discuss the PEFI feedback. • Thanks participant.	Same	Same
Page 1	Where Are You in Relation to Your WHI Fat Gram Goal?	Two graphs: • Fat grams reported on PEFI compared to fat gram goal • Fat grams OVER goal (per day and per week) Text next to graph: Points out difference in fat grams between fat gram goal and fat grams reported on PEFI. Text at bottom: Prompts participant to: • Think about ways she could begin to reduce weekly fat intake. • Look at how even small changes can make a big difference.	One graph: Fat grams reported on PEFI compared to fat gram goal Text next to graph: Points out that fat intake is AT or BELOW her fat gram goal. Text at bottom of page: Prompts participant to: • Think about how closely the information matches what she eats. • Consider how she might use the information to maintain current fat intake, or make some changes if they seem right.	One graph: Fat grams reported on PEFI compared to fat gram goal Text next to graph: • Points out that estimated fat intake is very low. • Encourages participant to talk with her nutritionist to explore the information further. Text at bottom of page: Prompts participant to: • Think about how closely the information matches what she eats. • Consider how she could use the information to make some changes, if they seem right.
Page 2	Where Does Your Dietary Fat Come From?	Pie chart: % of fat contributed by each food group Text: • Points out the two food groups providing the most fat in the participant's diet. • Prompts participant to go to next page.	Same	Same

Table 6.7 – Summary of PEFI-F Pages (Cont.)

Page	Page Heading	Fat Grams Reported on PEFI		
		over fat gram goal	**≤ fat gram goal, but ≥ 15 grams fat**	**< 15 grams fat**
Page 3	Top Ten Foods that Provide Fat in Your Diet	Text at top: There are many different ways that you can reduce your fat intake. Below are some ideas for lower-fat choices. Top 10 fat sources: • Food (serving size & frequency) • Fat grams per week • Lower fat choices • Fat gram savings per week Text at bottom: Circle the foods she might change.	Same	Text at top: Based on your responses on the PEFI self-assessment questionnaire, your fat intake appears to be very low. Think about whether any of these ideas for lower-fat choices seem right for you. Top 10 fat sources: • Same Text at bottom: • None
Page 4	Next Steps: Where Do You Go From Here?	Text at top: Look at the foods you circled on page 3. Use the statements below to help you think about as many ideas for change as you wish. Then, consider which changes you might make. Remember…the choice is yours! Changes to consider: • Reduce portion. • Change frequency. • Cut back on fat used to prepare or cook food. • Choose a low-fat or fat-free food instead of regular full-fat choice. • Other Idea: _____	Same	Text at top: Based on your responses on the PEFI self-assessment questionnaire, your estimated fat intake is very low. Consider asking yourself the questions below to help you think about your eating pattern. Questions: • How closely does this very low fat intake match what I eat? • Are there any high-fat foods that I missed recording on my PEFI self-assessment questionnaire? If yes, high-fat foods I missed? How often do I eat these foods? • Am I interested in making some changes in what I eat? If yes, what changes might I consider? Examples provided. Text at bottom: We encourage you to talk with your nutritionist to explore your personalized information further.

6.15.3 PEFI Implementation

The PEFI intervention uses the existing Dietary Change group session structure. The Summer and Fall 2002 sessions work together to accomplish the goal of the PEFI intervention. Participants complete the PEFI-Q at the Summer 2002 (8SU) session and receive computerized tailored feedback (PEFI-F) at the Fall 2002 (9F) session. Alternative support may occur through mailings with optional in-person or phone contacts based on existing CC resources and nutritionist discretion. Refer to *Vol.2, Section 6.15.4.2.1 – Managing Participants Who Complete 8SU and/or 9F by Mail or Phone.*

6.15.3.1 Summer 2002 (8SU) Session

The overall goal of the Summer 2002 (8SU) session is to build participant interest in a) completing the PEFI-Q and b) receiving computerized tailored feedback about dietary fat intake based on the information provided in the questionnaire. This will be accomplished by providing an opportunity for the participant to:

- discuss the benefits of self-assessing and receiving tailored feedback about fat intake,
- complete the PEFI-Q, and
- explore expectations about the information she might receive about her dietary fat intake.

The discrepancy segment in this session is designed to help the participant see a possible 'gap' in awareness of her fat intake. Acknowledging a gap in awareness of fat intake can build interest in completing the PEFI-Q and receiving tailored feedback. The session materials strive to keep balance between building interest in the PEFI-Q and maintaining interest and perceived value in on-going self-monitoring. The materials accomplish this by a) presenting PEFI-Q as something to supplement self-monitoring (i.e., not a replacement, not better, not perfect) and b) acknowledging the critical role that participant self-monitoring plays in being aware of fat intake and meeting (or maintaining) fat gram goal. *Table 6.8 – Summer 2002 (8SU) Session* summarizes the key points for each session component. The Group Nutritionist session materials provide extensive guidelines for delivering the session using motivational enhancement, group facilitation skills, and adult learning principles. Refer to *Volume 4, Group Nutritionist Manual, Summer 2002 – Take a Closer Look.*

6.15.3.2 Fall 2002 (9F) Session

The overall goal of the Fall 2002 (9F) session is to guide and support the participant's efforts to develop a plan for meeting (or maintaining) her fat gram goal. This will be accomplished by providing an opportunity for the participant to:

- become more aware of fat intake by receiving tailored feedback based on the PEFI-Q,
- build motivation to meet (or maintain) her fat gram goal by exploring tailored feedback to identify possible discrepancy between current and desired fat intake, and
- develop a plan for meeting (or maintaining) her fat gram goal after identifying and exploring options for dietary change.

The session materials strive to empower the participant by creating an atmosphere that acknowledges and respects participant choice and readiness. The materials accomplish this by providing the opportunity for the participant to a) generate thoughts and statements about the value of awareness, b) explore her tailored feedback and compare her 'expectations' about what PEFI-F may tell her to what PEFI-F 'actually' tells her, and c) possibly find motivation to make (and share her plan for) dietary change. The discrepancy segment in this session is designed to build motivation by helping the participant see a possible 'gap' in current vs. desired fat intake. This segment builds on the discrepancy segment in the 8SU session. Helping the participant see a gap in awareness of fat intake and then a gap in her fat intake can help move her along the continuum of change. *Table 6.9 – Fall 2002 (9F) Session* summarizes the key points for each session component. Note: An activity is included for participants who do not have a PEFI-F available, thus supporting their full participation in the session. Refer to *Volume 2, Section 6.15.4.2.4 – Managing Participants Who Attend 9F, but Do Not Have PEFI-F.* The Group Nutritionist session materials provide extensive guidelines for delivering the session using motivational enhancement, group facilitation skills, and adult learning principles. Refer to *Volume 4, Group Nutritionist Manual, Fall 2002 – A Closer Look: What Do I See?.*

Table 6.8 – Summer 2002 (8SU) Session

Session Component	Key Points
Group Sharing/Next Steps Follow-Up Purpose: To build group cohesion and participant self efficacy.	The focus of the **Group Sharing/Next Steps Follow-Up** component for this session is limited to brief group sharing (for group cohesion and bonding). Limiting the focus of this segment helps maximize the amount of time available (later in the session) for completing the PEFI-Q.
Setting the Stage for Skill Building Purpose: To identify participant's interest and needs for skill building.	The focus of the **Setting the Stage for Skill Building** component is to: a) briefly outline the skill building segments and b) assess participant relative interest in the segments. Assessing relative interest in the segments enables the nutritionist to acknowledge and support participant interest while including all segments.
Skill Building Purpose: To provide opportunities for life-relevant discussion and/or practice.	Each of the segments in the **Skill Building** component builds on the previous. All parts together form the foundation for completing the PEFI-Q. Therefore it is important to include each segment. The amount of time devoted to each segment will be determined by a) the amount of time needed to complete the PEFI-Q and b) participant interest in each segment relative to the others. Building Interest: The intent of the first segment is to help the participant identify possible discrepancy between where she perceives her current fat intake and where she would like her fat intake to be, as well as how closely self-monitoring fat scores represent her fat intake. A participant worksheet (*Worksheet 1 – A Closer Look)* supports this segment. The second segment provides an opportunity for participants to discuss the benefits of knowing what you eat when working toward or maintaining fat gram goal. The sequential discussion of discrepancy and then benefits builds interest by providing an opportunity for the participant to come to (some or all of) the following conclusions: • *I see a difference between where I am (or where the study is) and where I would like to be in terms of fat intake.* • *I see that there may be a difference between my self-monitoring fat scores and my fat intake.* • *For me to meet or maintain my fat gram goal, I need to know as much as I can about my fat intake.* • *I would like to complete the PEFI Self-Assessment Questionnaire so that I'll receive personalized information that might help me learn even more than I already know about my fat intake.* PEFI-Q: The second half of the session focuses on completing the PEFI-Q. This should take approximately 30-40 minutes.
Next Steps Purpose: To increase the likelihood that participants will apply session information and skills.	The **Next Steps** component focuses on briefly exploring expectations about the information that may come from completing the questionnaire. The exploration of expectations is supported by a participant worksheet (*Worksheet 2 – My Expectations*). This segment is intended to a) increase participant anticipation and excitement about receiving personalized information from the PEFI self-assessment questionnaire and b) increase participant ownership of the information.
Food Tasting Purpose: To increase the likelihood that participants will use recipes and food that support WHI goals.	The **Food Tasting** component provides participants with the opportunity to taste low-fat foods that support WHI goals.

Table 6.9 – Fall 2002 (9F) Session

Session Component	Key Points
Group Sharing/Next Steps Follow-Up Purpose: To build group cohesion and participant self efficacy.	The focus of the **Group Sharing/Next Steps Follow-up** component for this session is to: a) have the nutritionist very briefly recap key points from the previous session and then b) have participants revisit the concept of awareness (of fat intake) also discussed in the previous session. Having participants share and discuss 'how being more aware of fat intake can help meet (or maintain) fat gram goal' sets the stage (and continues to build interest) for the rest of the session where participants receive and explore their personalized information about fat intake.
Setting the Stage for Skill Building Purpose: To identify participant's interest and needs for skill building.	The focus of the **Setting the Stage for Skill Building** component is to: a) briefly outline the skill building segments and b) assess participant relative interest in the segments. Assessing relative interest in the segments enables the nutritionist to acknowledge and support participant interest while including all segments.
Skill Building Purpose: To provide opportunities for life-relevant discussion and/or practice.	Each of the segments in the **Skill Building** component builds on the previous. All segments together form the foundation for the participant to identify options and a plan for dietary change to meet (or maintain) fat gram goal. Therefore it is important to include each segment. The amount of time devoted to each segment will be determined by participant interest in each segment relative to the others. Receive Personalized PEFI Packet: The overall intent of this segment is to build participant awareness of her dietary fat intake. The segment has two parts: a) brief orientation to the packet and b) review of the personalized content. This segment provides an opportunity for the participant to become familiar with and understand the content of the packet through brief orientation and discussion. Build Discrepancy: This segment provides an opportunity for the participant to explore thoughts and feelings about her fat intake. The intent of this segment is to help the participant identify possible discrepancy between where she sees her fat intake and where she would like her fat intake to be. *Worksheet 2 – My Expectations* (completed during the 8SU session) supports this segment. Identify Options & Plan**:** This segment provides an opportunity for the participant to identify options for change in a step-wise fashion. First, she'll have the opportunity to develop a list of possible options. Then she'll have the chance to narrow the options to the few that she might consider over the next ~3 months. Finally, she'll have the chance to select the one option she sees herself most likely doing in the near future and create a plan for making it happen. The intent of this segment is to help the participant prepare for dietary change.
Next Steps Purpose: To increase the likelihood that participants will apply session information and skills.	The **Next Steps** component provides an opportunity for the participant to share her personalized plan for dietary change in an atmosphere that acknowledges and respects personal choice and readiness. *Worksheet 1 – My Plan* provides the framework for the discussion. This segment emphasizes public disclosure of intended behavior change – as a way to help the participant strengthen her awareness of and commitment to the intended change she's identified.
Food Tasting Purpose: To increase the likelihood that participants will use recipes and food that support WHI goals.	The **Food Tasting** component provides participants with the opportunity to taste low-fat foods that support WHI goals.

6.15.4 PEFI Management

This section describes policies and procedures for managing PEFI intervention operations.

6.15.4.1 Lead Nutritionist Responsibilities

The Lead Nutritionist oversees management of the following PEFI intervention operations:

- Sample
- Staffing
- Participant Materials Management
- Implementation
- Intervention Issues

Sample. All DM Intervention participants are eligible to participate in the PEFI intervention.

The PEFI intervention is designed for implementation within Dietary Change group sessions and, therefore, is anticipated to be offered primarily to participants having active DM Intervention participation status. Refer to *Vol. 2, Section 6.10.6.2.2 – Active Participation* for the definition of active DM Intervention participation status.

Offering the PEFI intervention to participants having inactive DM Intervention participation status (i.e., marked 'stop' DM Intervention on *Form 7 – Participation Status*) is optional per CC discretion and staffing resources. The Lead Nutritionist uses procedures outlined in *Vol. 2, Section 6.15.4.2.1 – Managing Participants with Stop DM Intervention Status* when opting to include inactive participants in the PEFI intervention.

Staffing. As noted in previous sections, the PEFI intervention is designed for implementation within Dietary Change group sessions. Therefore, the Lead Nutritionist applies usual staffing configurations for delivery of this intervention and works with the Clinic Manager to determine which staff (within the CC) are best suited to scan the PEFI-Q and generate the computerized tailored feedback (PEFI-F). Refer to *Section 6.15.5* (including all subsections) – *PEFI Data Processing* for information about scanning the PEFI-Q and generating PEFI-F.

If staffing resources permit, the Lead Nutritionist may want to consider having the Group Nutritionist plus a second staff person (who is familiar with the PEFI-Q) at the Summer 2002 group session. The second staff person's main role would be to review the completed PEFI-Qs for missing items while the Group Nutritionist facilitates the remaining portion of the session (i.e., *Next Steps* component). The in-session review of the questionnaires could maximize efficiency by eliminating the need to follow-up on missing items after the session. Refer to *Vol. 2, Section 6.15.2.1.3 – Quality Control* for information about Quality Control measures for the PEFI-Q.

Participant Materials Management. The PEFI-Q and Summer 2002 (8SU) participant materials are designed to be given to the participant at the same time and, ideally, in a group setting. The same is true for the PEFI-F and the Fall 2002 (9F) participant materials. To support delivery of the PEFI intervention as designed, the Lead Nutritionist is strongly encouraged to use the procedures outlined below when offering these materials to participants:

1. Do not mail these materials to participants at the beginning of the quarter (i.e., before they have had the opportunity to attend a group session).
2. Offer these materials when participants attend the group session.
3. Mail these materials to individual participants when the nutritionist knows the participant will not be attending the session. Use the makeup procedures outlined in *Vol. 2, Section 6.15.4.2.5 – Managing Participants Who Complete 8SU and/or 9F by Mail or Phone.*

Implementation. The Lead Nutritionist manages local PEFI intervention implementation. To guide Lead Nutritionist efforts, the DMWG (with support and approval of the DMC) developed definitions and goals for completion. The completion definitions apply to the PEFI sessions (8SU and 9F) and the overall PEFI intervention. The completion goals apply to the PEFI sessions.

Completion Definitions:

Completion of the 8SU and 9F sessions is not dependent on completing the PEFI-Q. Similarly, the PEFI intervention can be completed by a route other than the 8SU and 9F sessions (e.g., individual contact). Refer to *Vol. 2, Section 6.15.4.2.5 – Managing Participants Who Complete 8SU and/or 9F by Mail or Phone.* The definitions outlined below support routes for session and PEFI intervention implementation that are flexible and inviting for the participant.

- 8SU completion: Participants attending or making up 8SU will be considered to have completed the session; completion of the PEFI-Q is not required for 8SU completion. Example: A participant who completes the session (in-person or by mail) but declines to complete the questionnaire will be considered to have completed 8SU.
- 9F completion: Participants attending or making up 9F will be considered to have completed the session; completion of the PEFI-Q and/or receiving the PEFI-F is not required for 9F completion. Example: A participant who completes the session (in-person or by mail) will be considered to have completed 9F even if she did not complete the PEFI-Q and/or receive a PEFI-F.
- PEFI intervention completion: Participants having a scannable PEFI-Q that produces a PEFI-F will be considered to have completed the PEFI intervention. Receipt and discussion of the PEFI-F is assumed and documentation is not tracked or required centrally. PEFI intervention completion does not require 8SU or 9F session completion.

Completion Goals:

There are no protocol-mandated completion goals for the PEFI intervention or sessions. However, the DMWG (with support and approval of the DMC) recognizes the value of having goals to work toward for implementation. Therefore, the Lead Nutritionist at each center is encouraged to establish CC-specific implementation goals that encourage local nutritionists to stretch slightly beyond session completion rates for the Summer and Fall 2001 sessions (i.e., 7SU and 8F). The Lead Nutritionist is encouraged to establish realistic goals (e.g., ~5% above the Summer and Fall 2001 completion rates). These goals will be for local use only, and will not be used for CC or studywide monitoring.

The Lead Nutritionist tracks PEFI intervention implementation progress using WHILMA resources outlined in *Section 6.15.6 – WHILMA Resources for PEFI Tracking.*

Intervention Issues. The Lead Nutritionist oversees management of interventions issues as described in *Section 6.15.4.2* (including all subsections*) – Intervention Issues.*

6.15.4.2 Intervention Issues

The Lead Nutritionist manages intervention issues as outlined below.

6.15.4.2.1 Managing Participants with 'Stop' DM Intervention Status

If staffing resources permit and the Lead Nutritionist determines that the PEFI-Q could be a useful tool for discussing re-engagement, the PEFI intervention may be offered to participants having inactive DM Intervention participation status (i.e., marked 'stop' DM Intervention on *Form 7 – Participation Status*). Refer *to Vol. 2, Section 6.15.4.1 – Responsibilities (Sample).* **Important note:** A participant having inactive DM Intervention participation status should not be approached for the PEFI intervention if she has 'Absolutely No Contact' follow-up status on *Form 7 – Participation Status*.

Inactive participants who complete the PEFI-Q should be reinstated to active DM Intervention status (i.e., marked 'active' DM Intervention on *Form 7 – Participation Status*). These participants are no longer refusing all contact with the Group Nutritionist and other CC nutrition staff. Refer to *Vol. 2, Section 6.10.6.2 – Definition of Non-Participation and Active Participation.*

6.15.4.2.2 Managing Participants with a Negotiated Fat Gram Goal

Many participants who received the higher fat gram goals early in the trial (29 - 37 grams) have volunteered to strive for a "negotiated" fat gram goal that is lower than their assigned fat gram goal. Additionally, some participants having extreme difficulty meeting their assigned fat gram goal have negotiated with their nutritionist to strive for a slightly higher goal. The PEFI intervention has been designed to recognize and support the efforts of participants who have negotiated with their nutritionist to strive for a fat gram goal that is different than their assigned fat gram goal.

If a participant has been working toward a negotiated fat gram goal prior to the start of the PEFI intervention, this goal may be used to tailor the computerized feedback generated from the PEFI-Q. This should not be a goal established specifically for the PEFI intervention, nor should it be a goal established without participant involvement.

To use a negotiated fat gram goal for the PEFI intervention, the nutritionist records the negotiated fat gram goal in the 'OFFICE USE ONLY' box on the PEFI-Q as outlined in *Vol. 3, Forms, Instructions for Form 73 – PEFI Self-Assessment Questionnaire*. When the questionnaire is analyzed, the negotiated fat gram goal will be used instead of the assigned fat gram goal to determine the tailored feedback for the PEFI intervention. Only the negotiated fat gram goal will appear in the PEFI-F for the participant; there is no mention of her assigned fat gram goal. **Important note:** Using the negotiated fat gram goal for the PEFI intervention does NOT change the assigned fat gram goal in the WHILMA database.

6.15.4.2.3 Managing Participants Who Report <15 Grams of Fat

Participants reporting fat intake <15 grams/day on the PEFI-Q receive tailored feedback encouraging them to meet with their nutritionist to explore the feedback further. The tailored feedback also prompts the participant to begin exploring the feedback on her own. Refer to *Vol. 2, Section 6.15.2.2 – Tailored Feedback* for a complete description of the information given to participants reporting <15 grams/day.

An individual meeting (in-person or phone) occurs after the participant's initial exploration of her personalized feedback, if she and the nutritionist determine that an individual meeting would be helpful. The purpose of the individual meeting would be to help the participant continue exploring how closely the estimated very low fat intake matches what she eats, whether any high-fat foods may have been missed, and possible next steps for dietary change. A discussion of next steps for dietary change will likely be influenced by the participant's perception of how closely the <15 gram/day intake represents what she eats. The following paragraphs provide some guidelines for what might occur in an individual meeting, based on the participant's perception of how closely the <15 gram/day intake represents what she eats (i.e., not close or close).

Not Close to What She Eats

If a participant determines that her estimated very low fat intake of <15 grams/day on the PEFI-Q is not close to what she typically eats, she and the nutritionist could explore whether any high-fat foods may have been missed and which foods these may have been. The participant's list of missing high-fat foods could be used to generate discussion about next steps for dietary change as outlined on the *Next Steps: Where Do You Go From Here?* page of the participant's PEFI-F. **Important note:** If the participant is considering changes to reduce her fat intake, she may find it helpful to use a *Next Steps* page that provides more structure for changes to reduce fat intake. The *Next Steps* page in the *A Closer Look* packet can be used for this purpose. Refer to *Vol. 4, Group Nutritionist Manual, Fall 2002 Session, Group Nutritionist Resource 1 – Managing Participants Without a Personalized PEFI Packet.*

If a participant determines that her estimated fat intake is very low because she was eating atypically during the month captured in the questionnaire (e.g., illness), she and the nutritionist could explore whether any high-fat foods may have been missed and which foods these may have been. A discussion of next steps for dietary change, as described for the scenario above, could follow this exchange. Alternatively, the participant could (if she's interested) add the missing foods to her PEFI-Q and have it re-scanned. If the participant chooses this option, use procedures for re-scanning the "PEFI 1 Contact" outlined in the PEFI Upgrade Notes (Outlook Public Folders\All Public Folders\WHILMA Resources\PEFI Upgrade Notes).

Close to What She Eats

If a participant determines that her estimated very low fat intake of <15 grams/day on the PEFI-Q is close to what she typically eats, then she and the nutritionist could explore the participant's interest in making dietary changes as outlined on the *Next Steps: Where Do You Go From Here?* page of the participant's PEFI-F. This exploration of interest could include an assessment of her very low fat eating pattern as described in *Vol. 2, Section 6.13 – Guidelines for Participants Self-Reporting Scores Consistently <15 grams/day.* Pending the participant's interest in making some changes in what she eats, a discussion of next steps for dietary change could follow this exchange. A discussion of possible dietary changes would likely focus on changes to increase variety and balance in food choices and fat sources, and could also include discussion of possible changes to increase fat intake. There is no expectation that a participant whose estimated fat intake is very low (<15grams/day) would further reduce her fat intake.

6.15.4.2.4 Managing Participants Who Attend 9F, but Do Not Have PEFI-F

It is possible that a participant attending the Fall 2002 (9F) session will not have a PEFI-F to receive at the session. The most likely scenario for this happening will be the hard-to-reach participant who arrives unexpectedly at the 9F session without having completed the 8SU session and/or the PEFI-Q. If a participant arrives at the 9F session and the nutritionist does not have a PEFI-F for her, the primary goal is to facilitate this participant's involvement in the session discussion and activities. The nutritionist facilitates this involvement by offering a brief self-assessment instrument that is completed during the session. Refer to *Vol. 4, Group Nutritionist Manual, Fall 2002 Session, Nutritionist Resource 1 – Managing Participants Without a Personalized PEFI Packet.* **Important note**: If the participant would like to complete the PEFI-Q, the nutritionist works with the participant after the session to arrange this. The participant should not complete the questionnaire during the session. Completing the questionnaire during the session would prohibit the participant from joining the discussion and activities.

6.15.4.2.5 Managing Participants Who Complete 8SU and/or 9F by Mail or Phone

Nutritionists use the procedures outlined below to manage participants who complete 8SU and/or 9F by mail or phone. For related information, refer to *Vol. 2, Section 6.15.4.1 – Responsibilities (Participant Materials Management* and *Implementation).*

The nutritionist initiates the mail or phone makeup process when she knows the participant will not be attending the session. For some participants, this will be at the beginning of the quarter (e.g., participants who are traveling or otherwise away from the CC). For some participants, this will be during the quarter (e.g., participants who miss their group session and know at that time that they won't be able to attend another group). For many participants, this will be at the end of the quarter (e.g., participants who have not attended or completed the session by the time all group sessions have been offered).

The nutritionist initiates the mail or phone makeup process by sending the participant the materials outlined below.

8SU

Materials to send for 8SU makeup:

- The *Summer 2002 – Take A Closer Look* participant materials.
- The *Makeup for Summer 2002 Group Session* sheet (see *Vol. 4, Group Nutritionist Manual, Summer 2002 Session*).
- A copy of the PEFI-Q (unless Not Applicable or Refused completing the questionnaire).
- Self-monitoring tools, as appropriate.
- A self-addressed stamped envelope.

Documenting 8SU session completion:

The nutritionist documents (in WHILMA using *Form 64 – Individual Data Sheet*) completion of the session when any of the following occur:

- The participant returns the completed *Makeup for Summer 2002 Group Session* sheet and completed PEFI-Q.
- The participant returns only the completed *Makeup for Summer 2002 Group Session* sheet.
- The participant returns only the completed PEFI-Q.
- The participant and nutritionist discuss the session via telephone and the discussion includes dialogue related to the questions on the *Makeup for Summer 2002 Group Session* sheet. Important note: Do not have the participant complete the PEFI-Q over the phone.

Suggestion for 8SU makeup by phone:

Begin by asking the participant to share her thoughts (and questions) about the session materials. As part of the discussion, guide the participant to respond to the three questions outlined on the *Makeup for Summer 2002 Group Session* sheet.

9F

Materials to send for 9F makeup:

- The *Fall 2002 – A Closer Look: What Do I See?* participant materials.
- The *Makeup for Fall 2002 Group Session* sheet (see *Vol. 4, Group Nutritionist Manual, Fall 2002 Session*).
- The participant's PEFI-F packet (or *A Closer Look* packet if she doesn't have a PEFI-F).
- Self-monitoring tools, as appropriate.
- A self-addressed stamped envelope.

Documenting 9F session completion:

The nutritionist documents (in WHILMA using *Form 64 – Individual Data Sheet*) completion of the session when any of the following occur:

- The participant returns the completed *Makeup for Fall 2002 Group Session* sheet.
- The participant and nutritionist discuss the session via telephone and the discussion includes dialogue related to the questions on the *Makeup for Fall 2002 Group Session* sheet.

Suggestion for 9F makeup by phone:

Begin by asking the participant to share her thoughts (and questions) about the session materials. If the participant has a PEFI-F to explore, use the text in the participant session materials as a guide for discussion. As part of the discussion, guide the participant to respond to the three questions outlined on the *Makeup for Fall 2002 Group Session* sheet.

6.15.4.2.6 Managing Participants Who Are Guests from a Different Clinical Center

Participants sometimes attend Dietary Change group sessions as a guest at a different clinical center. When this occurs, the participant's data cannot be entered at the 'guest CC' and must be sent back to the 'home CC' for processing. Nutritionists use the procedures outlined below to manage participants who complete the 8SU and/or 9F sessions at a guest CC.

Guest at 8SU

1. The nutritionist from the home CC contacts the nutritionist at the guest CC to arrange the specific Dietary Change group that the participant will attend.
2. The participant attends at the guest CC and completes the session activities, including completing the PEFI-Q.
3. The nutritionist at the guest CC does the following: a) documents the participant's interactions during the session on a Progress Note, b) collects any self-monitoring tools she brought to the session, c)

collects her completed PEFI-Q and *Worksheet 1 – My Expectations*, d) reviews the PEFI-Q for completeness (making changes as needed before the participant leaves the session), and e) sends the collected materials to the home CC nutritionist for data entry and processing. The nutritionist at the guest CC does not record the participant's attendance on any DM Intervention data collection forms.

4. The nutritionist at the home CC receives the materials above and does the following: a) documents session completion on *Form 64* (including a note on the form indicating that the participant attended the session at the guest CC), b) scans the PEFI-Q and c) prints the PEFI-F. If the participant will be attending 9F at her home CC, then the nutritionist follows procedures as usual. If the participant will be attending 9F at the guest CC, then both nutritionists use the procedures outlined below.

Guest at 9F

1. The nutritionist from the home CC contacts the nutritionist at the guest CC to arrange the specific Dietary Change group that the participant will attend.
2. The nutritionist from the home CC sends the nutritionist at the guest CC a copy of each of the following: a) the participant's completed PEFI-Q (i.e., in case the participant has questions about what she marked on the questionnaire), b) the participant's PEFI-F; c) the participant's completed *Worksheet 1 – My Expectations* and d) any Progress Notes related to the 8SU session.
3. The participant attends at the guest CC and completes the session activities, including receiving her PEFI-F. If the participant did not complete the PEFI-Q, then the nutritionist at the guest CC uses procedures outline in *Vol. 2, Section 6.15.4.2.4 – Managing Participants Who Attend 9F, but Do Not Have PEFI-F*.
4. The nutritionist at the guest CC does the following: a) documents participant's interactions during the session on a Progress Note (including what she shares as her plan for dietary change), b) collects any self-monitoring tools she brought to the session, and c) sends the collected materials (including the PEFI-Q, if at the guest CC) to the home CC nutritionist for data entry and processing. The nutritionist at the guest CC does not record the participant's attendance on any DM Intervention data collection forms.
5. The nutritionist at the home CC receives the materials above and documents session completion on *Form 64* (including a note on the form indicating that the participant attended the session at the guest CC).

6.15.4.2.7 Managing Participants with Adherence and Retention Challenges

The WHI Adherence and Retention Working Group (A&R WG) conducted a survey of all WHI staff during Fall 2001 to identify common adherence and retention challenges. This survey resulted in an extensive list of challenges categorized by study arm. The survey and results can be found in the Outlook Public Folders (OutlookPublicFolders\A&R Resources\Survey Results.Summary and Survey Results.DM). The A&R WG and DMWG developed suggestions for managing the common challenges identified for DM Intervention participants during PEFI implementation. These suggestions emphasize utilizing existing resources to manage challenges in a manner that is flexible, supportive, and inviting for participants. Refer to *Table 6.10 – Suggestions for PEFI Implementation in Response to A&R Survey.*

Table 6.10 – Suggestions for PEFI Implementation in Response to A&R Survey

Approved by DMWG Dec 18, 2001

A&R Survey-Identified Challenge	Suggestion for PEFI Implementation
AGE POOR VISION LOW LITERACY	• Try to have an additional WHI staff member attend the 8SU session to help women complete the PEFI-Q. • For 8SU mail make-up (which may include completing the questionnaire), suggest that a family member or friend read the questions out loud and mark the participant's responses.
TRANSPORTATION	• Arrange transportation for women who need rides – either taxies, vans or buddy rides. • Complete the PEFI-Q by mail (as part of 8SU make-up). Follow-up by phone per available resources.
DECLINING SESSION ATTENDANCE	• Sponsor "bring a group member" to PEFI session – play up as special session – DON'T MISS IT. • Encourage women to attend a session even if not with their own group. • Arrange session make-up in conjunction with a clinic visit. • If missed 8SU, mail PEFI-Q (as part of make-up) and follow-up with phone call encouraging 9F attendance.
SELF-MONITORING (FATIGUE, BURN-OUT, or NOT DOING)	• Be sensitive to and acknowledge those women who do not self-monitor so they will not feel pressured or guilty. • Engage these women in all aspects of 8SU and 9F discussions. See the numerous *Nutritionist Notes* and *Group Facilitation Suggestions* in the GN Facilitation Outlines for these sessions.
NOT MEETING GOALS	• Be sensitive to and acknowledge those women who have not been meeting their fat goal so they will not feel pressured or guilty. • Engage these women in all aspects of 8SU and 9F discussions. See the numerous *Nutritionist Notes* and *Group Facilitation Suggestions* in the GN Facilitation Outlines for these sessions.
FAMILY DEMANDS LIFESTYLE	• During 9F, help participants consider and explore challenges (e.g., family demands or illness, lifestyle conflicts, or eating out/social events) as they identify their options and plan for meeting (or maintaining) their fat gram goal.
NEED MORE INDIVIDUAL CONTACT TO ADDRESS INDIVIDUAL DIFFERENCES	• Allow women the chance to stay after sessions to discuss specific problems they are having. • Call participants as needed and per available resources.

6.15.5 PEFI Data Processing

The following section describes the procedures for processing the PEFI self-assessment questionnaire (PEFI-Q) and generating the tailored feedback (PEFI-F).

6.15.5.1 Collection, Review, and Processing of the PEFI-Q

The PEFI-Q is a scannable mark-sense form. The Lead Nutritionist works with the Clinic Manager to determine which staff (within the CC) are best suited to scan the PEFI-Q and generate the PEFI-F.

PEFI-Q Collection and Review

Ideally, the PEFI-Q is briefly reviewed before the participant leaves the Summer 2002 (8SU) session. This review may be done by a nutritionist or other designated staff. *Section 6.15.4.1 – PEFI Management (Staffing*) provides suggestions for how this review could be accomplished during the 8SU session.

The purpose of the brief review is to catch obvious errors, such as blank pages or multiple marks, and then to have the participant make the necessary changes before leaving the session. Guidelines for this cursory review and pre-scan edit are provided in *Vol. 3 – Forms, Instructions for Form 73 – PEFI Self-Assessment Questionnaire* and the PEFI Upgrade Notes (Outlook Public Folders/All Public Folders/WHILMA Resources/PEFI Upgrade Notes).

Before scanning the PEFI-Q, the nutritionist (or designated staff) completes the questions in the 'OFFICE USE ONLY' box. A description and item instructions for each of these questions (1-7) are provided in *Vol. 3 – Forms, Instructions for Form 73 – PEFI Self-Assessment Questionnaire*. There are two questions in the 'OFFICE USE ONLY' box that are unique to the PEFI intervention:

- Question 6 (PEFI Contact) is used to distinguish the PEFI-Q completed as part of the PEFI intervention from any subsequent PEFI-Qs. The PEFI-Q completed for the PEFI intervention is marked 'PEFI 1'.
- Question 7 (FGG) is used to capture a participants 'negotiated fat gram goal'. This is an optional field and should be marked ONLY if the participant has a negotiated fat gram goal. Refer to *Section 6.15.4.2.2. – Managing Participants with a Negotiated Fat Gram Goal* for information about using a negotiated fat gram goal in the PEFI intervention.

After the PEFI-Q has been reviewed and the questions in the 'OFFICE USE ONLY' box have been completed, the questionnaire is ready for scanning.

PEFI-Q Scanning

Ideally, the PEFI-Q is scanned as soon as possible after the Summer 2002 (8SU) session to provide the Lead Nutritionist with the most up-to-date information for PEFI implementation tracking. Refer to *Vol. 2, Section 6.16.6 – WHILMA Resources for PEFI Tracking.* As noted in previous sections, participants receive their PEFI-F at the Fall 2002 (9F) session. The ~3-month timeframe between the Summer and Fall sessions provides ample time for the nutritionist (or designated staff) to review and scan the questionnaire, correct errors (if necessary), and generate the PEFI-F.

The PEFI-Q is scanned in the same way as other WHI mark-sense forms. Procedures describing how to scan the PEFI-Q are provided in the PEFI Upgrade Notes. If needed, additional information about scanning mark-sense forms can be found in *Vol. 5 – Data System, Section 7.2.1.1. – Some Tips for Successful Scanning* and *Section 7.2.2. – Scanning a Mark-Sense Form.*

Clinical centers (CCs) may find it helpful to scan the PEFI-Q in batches according to DM group, one group at a time. This will make it easy to:

- Review the scanning results by DM group. The *PEFI-Q Scanning Results* report for the batch will apply to participants in a single DM group. This will be particularly important if the CC has determined that each nutritionist reviews the *PEFI-Q Scanning Results* report for participants in her own DM groups.
  - If participants from multiple groups are scanned together, multiple copies of the *PEFI-Q Scanning Results* report may be needed to complete the review (i.e., a copy for each nutritionist reviewing the results of the batch).
- Print copies of the PEFI-F for participants in a batch. If all participants in a given scanning batch are in the same DM group, printing the PEFI-F for all participants in the batch can be accomplished simply by printing the PEFI-F for the entire DM group.
  - If participants from multiple DM groups are scanned together, printing the PEFI-F for all participants in the batch requires that the PEFI-F be printed for each group in the batch, or for each participant individually.

Reviewing the PEFI-Q Scanning Results Report

The *PEFI-Q Scanning Results* report automatically appears on the WHILMA screen after a batch of PEFI-Qs has been scanned. This report shows the scanning result for each PEFI-Q in the batch. The possible scanning results include: 'Accepted', 'Accepted with warnings', and 'Failed'. The staff person responsible for scanning the PEFI-Qs gives a copy of the *PEFI-Q Scanning Results* report, along with the batch of scanned PEFI-Qs, to the nutritionist (or designated staff) to review. Refer to the PEFI Upgrade Notes for information about error and warning messages that appear on the *PEFI-Q Scanning Results* report. For information about errors that prevent PEFI-Q analysis and defaults that are used when responses to PEFI-Q adjustment questions are missing, refer to *Vol. 2, Section 6.15.2.1.2 – Quality Control.*

By reviewing the *PEFI-Q Scanning Results* report, the nutritionist (or designated staff) is able to:

- Identify PEFI-Qs that have a 'Failed' result and contact participants, as necessary, to capture missing information.
- Review the warning messages for PEFI-Qs that have an 'Accepted with warnings' result. This review provides the nutritionist with information about the amount of tailoring in the participant's PEFI-F. If time and staff resources permit, the nutritionist has discretion to follow-up with the participant to clarify warning messages (e.g., inconsistent or missing responses) and, thereby, maximize tailoring of the PEFI-F.

Re-Scanning the PEFI-Q

The PEFI-Q is re-scanned if changes are made after the initial scanning (e.g., after correcting errors or after discretionary follow-up on warnings). When a PEFI-Q is re-scanned (i.e., the same booklet number passes through the scanner), the existing PEFI data, including PEFI-F, is overwritten. For more information about how WHILMA handles the data when a PEFI-Q is re-scanned, refer to the PEFI Upgrade Notes.

Note:

- Each participant can have only one PEFI-Q that is completed as part of the PEFI intervention (i.e., Qx. 6 – PEFI Contact marked 'PEFI 1').
- If a participant's 'PEFI 1' questionnaire needs to be replaced instead of re-scanned (i.e., a different booklet number), use the procedures in the PEFI Upgrade Notes. This situation will be very rare. Example: The participant's 'PEFI 1' questionnaire has a scanning result of 'Accepted with warnings'. When the nutritionist reviews the PEFI-Q, it is somehow damaged to the point that it cannot be re-scanned. The nutritionist completes a different booklet (marked 'PEFI 1') to replace the damaged 'PEFI 1' questionnaire.

Storing the PEFI-Q

The nutritionist stores the scanned PEFI-Q with the participant's DM Intervention file or in an easily retrievable manner.

6.15.5.2 Generating Tailored Feedback (PEFI-F)

When the PEFI-Q is successfully scanned, it is automatically analyzed and the data necessary to generate the PEFI-F are stored in WHILMA. Refer to *Vol. 2, Section 6.15.2.2 – Tailored Feedback (PEFI-F)* for a complete description of the PEFI-F.

Printing PEFI-F

The PEFI-F can be generated and printed any time after the PEFI-Q has been successfully scanned. There are many printing options for the PEFI-F. These include:

- Printing multiple copies. This option gives the nutritionist the ability to print a copy of the PEFI-F that will be given to the participant as well as a copy to keep in the participant's DM Intervention file.
  - It may be most efficient to print two copies of the PEFI-F as soon as the analysis is complete. Consider storing the copies of the PEFI-F with the PEFI-Q in the participant's DM Intervention file or in an easily retrievable manner.

- If a center has many participants completing sessions by guest attendance, it may be helpful to develop a plan in advance of the Fall 2002 (9F) session to ensure that the nutritionist has ready access to the PEFI-F of participants who attend as a guest.

- Printing select copies. The PEFI-F may be printed using a number of different selection parameters (e.g., for an individual, for a specific DM group, by language [English or Spanish]).
  - The option to print the PEFI-F by "individual or group" gives the nutritionist flexibility to print the PEFI-F for all participants in a specified group or a single individual. The nutritionist will most often print the PEFI-F by group. The option to print for an individual could be useful when a participant completes the Fall 2002 (9F) session by guest attendance (at a group other than her own) or when she completes makeup by mail.
  - The option to print the PEFI-F in English or Spanish gives the nutritionist flexibility to provide a participant with a Spanish language PEFI-F if that is the participant's preference. The copy for the participant's file can be printed in English or Spanish per the nutritionist's preference.

  Note:

  - The PEFI-F cannot be printed by scanning batch. See the information above regarding scanning the PEFI-Q in batches by DM group.
  - The PEFI-F cannot be printed in color (as a result of Oracle software programming limitations).

For more information about printing the PEFI-F and using the different print parameters, refer to the PEFI Upgrade Notes.

6.15.6 WHILMA Resources for PEFI Tracking

This section describes the WHILMA resources for PEFI tracking. This includes the *PEFI Tracking Screen* and the *PEFI Contact 1 Tracking* report. Supporting information can be found in the PEFI Upgrade Notes (Outlook Public Folders/All Public Folders/WHILMA Resources/PEFI Upgrade Notes).

6.15.6.1 PEFI Tracking Screen

The *PEFI Tracking Screen* enables the nutritionist to key-enter optional data for tracking PEFI intervention implementation. The optional data includes:

- Date PEFI-Q Provided
- Date PEFI-F Provided
- Reason PEFI Not Completed

Date PEFI-Q Provided (Optional)

The 'Date PEFI-Q Provided' field represents the date the PEFI-Q was provided to the participant. There are at least two ways that this optional field could be used:

- Use for all participants who are provided the PEFI-Q.
  - For participants who are provided the PEFI-Q at the 8SU session, the date of the 8SU session would be the 'Date PEFI-Q Provided'.
  - For participants who are provided the PEFI-Q by mail, the date the PEFI-Q was mailed to the participant would be the 'Date PEFI-Q Provided'.
- Use for only those participants who are provided a PEFI-Q by mail. This could help the nutritionist quickly distinguish participants who may need follow-up to collect the PEFI-Q from those who attended the 8SU session (and, therefore, likely completed and turned-in their questionnaire during the session).
  - For participants who attend the 8SU session, the nutritionist would leave the 'Date PEFI-Q Provided' field blank.
  - For participants who are provided the PEFI-Q by mail, the date the PEFI-Q was mailed to the participant would be the 'Date PEFI-Q Provided'.

Date PEFI-F Provided (Optional)

The 'Date PEFI-F Provided' field represents the date the PEFI-F was provided to the participant. This field could be used in a manner similar to that described above for 'Date PEFI-Q Provided'.

- Use for all participants who are provided a PEFI-F.
  - For participants who are provided the PEFI-F at the 9F session, the date of the 9F session would be the 'Date PEFI-F Provided'.
  - For participants who are provided the PEFI-F by mail, the date the PEFI-F was mailed to the participant would be the 'Date PEFI-F Provided'.
- Use for only those participants who are provided the PEFI-F by mail. This could help the nutritionist quickly distinguish participants who may need follow-up to discuss the PEFI-F from those who attended the 9F session (and, therefore, likely received their PEFI-F during the session).
  - For participants who attend the 9F session, the nutritionist would leave the 'Date PEFI-F Provided' field blank.
  - For participants who are provided the PEFI-F by mail, the date the PEFI-F was mailed to the participant would be the 'Date PEFI-F Provided'.

If a clinical center chooses to not track the optional data outlined above, the Summer 2002 (8SU) and Fall 2002 (9F) session information can be used as a marker that participants have received the PEFI-Q and PEFI-F. Refer to *Vol. 2, Section 6.15.6.2 – PEFI Contact 1 Tracking Report (Implementation Tracking).*

Reason PEFI Not Completed (Optional)

The 'Reason PEFI Not Completed' field represents the reason that the participant did not complete the PEFI-Q. Options include: Not appropriate, Declined, Not reached. Examples of how to select 'Reason PEFI Not Completed':

- *Not appropriate:* The nutritionist selects and enters this option when her/his clinical judgement indicates that the participant should not be approached to complete the PEFI-Q. This decision may occur because a participant has a crisis situation (e.g., serious personal or family illness, the death of spouse, etc.).
- *Declined:* The nutritionist selects and enters this option when the participant is offered, but declines to complete the PEFI-Q.
- *Not reached:* The nutritionist marks this option when her/his clinical judgement indicates that the participant cannot be reached to complete the PEFI-Q (e.g., the participant does not return a PEFI-Q that was provided by mail).

Data Entry in the PEFI Tracking Screen

If a clinical center chooses to enter optional data (described above) in the *PEFI Tracking Screen*, staff have two options for completing the data entry:

- Use direct data entry (i.e., enter the information without hard copy documentation).
- Document the optional data on a hard copy tracking sheet before the information is key-entered. This option may be particularly useful at clinical centers where nutritionists do not perform their own data entry. *Figure 6.18 – Sample PEFI Tracking Sheet* provides an example tracking sheet that nutritionists may use.

How the PEFI Tracking Screen Links to the PEFI Contact 1 Tracking Report

The *PEFI Tracking Screen* lists all Dietary Change participants, except those who are deceased. Active participants assigned to a DM group are listed by their group number. Active participants who are not assigned to a DM group and inactive participants (i.e., marked 'stop' DM Intervention on *Form 7 – Participation Status*) are listed in the 'unassigned' category.

- For active participants, optional data that are entered in the *PEFI Tracking Screen* appear on the *PEFI 1 Contact Tracking* report.
- For inactive participants, optional data that are entered in the *PEFI Tracking Screen* do not appear on the *PEFI 1 Contact Tracking* report. Inactive participants who complete the PEFI-Q should be reinstated to

active DM Intervention status (i.e., marked 'active' DM Intervention on *Form 7 – Participation Status*). Refer to *Vol. 2, Section 6.15.4.2.1 – Managing Participants with Inactive DM Intervention Status.*

Figure 6.18 – Sample PEFI Tracking Sheet

Nutritionist ID: _____ Group #: _____	ID: __ __ __ __ - ___ ___ ___ - __ First Name _____M.I._____ Last Name _____

1. Date PEFI-Q provided: ⌊__⌋⌊__⌋-⌊__⌋⌊__⌋-⌊__⌋⌊__⌋
   Month Day Year

2. Date PEFI-F provided: ⌊__⌋⌊__⌋-⌊__⌋⌊__⌋-⌊__⌋⌊__⌋
   Month Day Year

3. Reason PEFI not completed:
   - ☐1 Not appropriate
   - ☐2 Declined
   - ☐3 Not reached

6.15.6.2 PEFI Contact 1 Tracking Report

The Lead Nutritionist (or designee) uses the *PEFI Contact 1 Tracking* report *(PEFI 0001)* to track local implementation of the PEFI intervention in active DM Intervention participants. The report shows data for only the following:

- The 'PEFI 1' contact. This is the PEFI-Q completed as part of the PEFI intervention. For a complete description of the 'PEFI 1' contact, refer to *Vol. 3 – Forms, Instructions for Form 73 – PEFI Self-Assessment Questionnaire.*
- Active DM Intervention participants. For information about tracking inactive DM Intervention participants in the PEFI intervention, refer to *Volume 2, Section 6.15.6.1 – PEFI Tracking Screen (How the PEFI Tracking Screen Links to the PEFI Contact 1 Tracking Report).*

Implementation Data

The *PEFI Contact 1 Tracking* report captures all aspects of PEFI intervention implementation. For each participant listed, the report provides the following information:

- *Summer Scheduled:* the scheduled date for the participant's 8 Summer (8SU) session.
- *Summer Completed:* the date the participant completed the 8SU session.
- *PEFI-Q Provided*: the date the PEFI-Q was provided to the participant (optional data; shown if entered in the *PEFI Tracking Screen).*

- *Latest PEFI 1 Event*: information about the latest PEFI 1 event. This includes questionnaire scanning status, analysis completion, and printing PEFI-F.
- *Latest PEFI 1 Event Date*: the date of the latest PEFI 1 event.
- *Reason PEFI Not Completed*: the reason the participant did not complete the PEFI-Q (optional data; shown if entered in the *PEFI Tracking Screen*). Options include: Not appropriate, Declined, and Not reached.
- *9 Fall Scheduled:* the scheduled date for the participant's 9 Fall (9F) session.
- *9 Fall Completed:* the date the participant completed the 9F session.
- *PEFI-F Provided:* the date the PEFI-F was provided to the participant (optional data; shown if entered in the *PEFI Tracking Screen).*

Implementation Tracking

The Lead Nutritionist (or designee) uses the *PEFI Contact 1 Tracking* report to track the following:

- Participants who have had the opportunity to begin the PEFI intervention. This can be tracked using the *8 Summer Scheduled* and *8 Summer Completed* columns.
- Participants who have received a PEFI-Q. This can be tracked two ways:
  - Use the *Date PEFI-Q Provided* column if this optional data item has been entered in the *PEFI Tracking Screen*.
  - Use the *8 Summer Completed* column as a marker for receiving PEFI-Q; i.e., assume that the participant received PEFI-Q if she completed the session.
- Participants who have completed a PEFI-Q. This can be tracked using the *Latest PEFI 1 Event* and *Latest PEFI 1 Event Date* columns.
  - Use the *Reason PEFI Not Completed* column for additional information, if this optional data item has been entered in the *PEFI Tracking Screen.*
- Participants who have received their PEFI-F. This can be tracked two ways:
  - Use the *Date PEFI-F Provided* column if this optional data has been entered in the *PEFI Tracking Screen.*
  - Use the *9 Fall Completed* column as a marker that the participant received her PEFI-F; i.e., assume that the participant received her PEFI-F if she completed the session.

It is recommended that the Lead Nutritionist run the *PEFI Contact 1 Tracking* report monthly.

Using the PEFI Contact 1 Tracking Report

The *PEFI Contact 1 Tracking* report has many parameters that allow data to be sorted and filtered. The default sort order for the report lists groups by nutritionist in order of their 8SU scheduled date. This sort order can be changed to list groups by nutritionist in order of group number or by the 9F scheduled date. Refer to the PEFI Upgrade Notes for a complete description of parameters for this report.

Below are two simple examples of how parameters can be used to sort and filter the *PEFI Contact 1 Tracking* report.

- Tracking overall implementation progress

  1. Run the *PEFI Contact 1 Tracking* report from the WHILMA report menu.
  2. Leave all parameters as they appear on the screen.

  This version of the report lists all groups by nutritionist in order of the 8SU scheduled date. Within each group, participants are listed alphabetically by name. This provides an overall picture of PEFI implementation by nutritionist (i.e., all groups and all participants within each group) sorted in the order you would expect participants to begin PEFI activities. Sorting the report this way helps distinguish groups (and participants) that have started the PEFI intervention from those that have not yet started.

- Tracking participants who have received the PEFI-Q

  Note: This example applies only if the optional data for 'Date PEFI-Q Provided' have been entered in the *PEFI Tracking Screen*.

  1. Run the *PEFI Contact 1 Tracking* report from the WHILMA report menu.
  2. PEFI-Q Provided: Choose "Yes".

  This report lists only those participants who have a 'Date PEFI-Q Provided' in WHILMA. Participants are listed in order by nutritionist and group. For each participant listed, you can track the status of the PEFI-Q by looking at the Latest PEFI 1 Event column. This will allow you to identify participants who have a successfully scanned and analyzed PEFI-Q, those with a PEFI-Q that needs follow-up, those who have had their PEFI-F run (printed), and those who do not yet have a PEFI 1 event (i.e., PEFI 1 Event column blank). Filtering the report this way helps narrow the tracking focus.

6.15.7 Scientific Issues

This section addresses two scientific issues related to the PEFI intervention: bias and evaluation.

1. Bias refers to the possibility that women exposed to the PEFI-Q and PEFI-F will provide more socially desirable responses to subsequent WHI FFQs.
2. Evaluation refers both to monitoring protocol completion and to evaluating the effect of the PEFI intervention on the C-I.

The paragraphs below describe each of these issues in detail.

Bias in Dietary Self-report

A legitimate concern regarding the PEFI intervention is the possibility that completion of the PEFI-Q, and receiving the PEFI-F, will bias subsequent dietary self-report in DM Intervention women. Specifically, the hypothesis is that women exposed to the PEFI intervention will provide more socially desirable responses to WHI FFQs used for trial monitoring. If such social desirability bias did occur, it would result in a widening of the C-I that would not be distinguishable from real changes in dietary behavior. The WHI Steering Committee considered the issue of bias when it approved the PEFI intervention and felt that the benefit to the trial justified the potential risk to trial monitoring activities (i.e., the C-I as estimated by the WHI FFQ).

There are two major reasons why the potential for dietary self-report bias associated with the PEFI intervention was deemed an acceptable "risk":

- The potential for introducing social desirability bias already exists in the self-monitoring tools and the dietary change program materials. Therefore it is not clear that the PEFI intervention will significantly increase intervention-associated bias above what already exists.
- The WHI DM is a randomized controlled trial with disease outcomes and therefore bias in dietary self-report cannot threaten the integrity of the main trial results.

There will likely be secondary analyses of diet-disease relationships in the WHI DM trial. However, most of these analyses will rely on "baseline" (i.e., AV1) dietary data that are already collected. Therefore any intervention-associated bias introduced by the PEFI intervention does not threaten these types of diet-disease analyses.

Evaluation of the PEFI Intervention

The evaluation of the PEFI Intervention has two components:

1. Monitor completeness of the protocol implementation.
2. Estimate effect of the PEFI intervention on change in percent energy from fat in Dietary Change participants using the WHI FFQ.

Completeness of the protocol implementation

The PEFI intervention is of relatively short duration. Therefore it will not be feasible to monitor ongoing protocol implementation, although a final report on the completion rates for the PEFI intervention will be prepared after conclusion of the intervention. This report will show protocol completeness studywide and by CC. In addition, the *PEFI Contact 1 Tracking Report (PEFI0001)* will be available to allow CCs to track PEFI intervention implementation. However this CC report is for operational support rather than performance evaluation.

Effect of the PEFI intervention on change in percent energy from fat in Dietary Change participants

The CCC will conduct a before-and-after analysis using data from the AV-1 FFQ and FFQs completed during the PEFI intervention. Specifically, we can compare participants who completed an FFQ before receiving the PEFI intervention (i.e., a PEFI control group) with participants who completed an FFQ after receiving the PEFI intervention (i.e., a PEFI intervention group). The outcome variable will be change in percent energy from fat from AV-1 to the most recent FFQ and the model will be controlled for potential covariates such as age, race/ethnicity, education, visit year, and clinic effects. These data permit a pairwise analysis of the effect of the PEFI intervention on Dietary Change participants' fat intake in the "PEFI control" vs. "PEFI intervention" groups. The sample sizes should provide a reliable studywide estimate, but are too small to provide precise clinic-specific estimates of the PEFI intervention effect.

The PEFI intervention protocol, as implemented in WHI, is not designed for a rigorous test of the effectiveness of this augmented intervention in reducing fat intake for the following reasons: variability in administration, concurrent effects of the main intervention, and lack of an appropriate comparison group.

6.16 Personalized Evaluation of Fat Intake 2003 (PEFI 2003)

The PEFI 2003 intervention is a self-help version of the original PEFI intervention with the overall goal of supporting and improving DM Intervention adherence. This intervention offers self-guided materials to help participants find their own motivation to make dietary changes to meet or maintain their fat gram goal. All interested DM Intervention participants will have the opportunity to complete PEFI 2003. For many participants this will be their second PEFI intervention. PEFI 2003 implementation begins September 2003 and continues through January 2004 with data consolidation in February and May 2004. The PEFI 2003 materials are modeled after the original PEFI intervention materials. Refer to *Vol. 2, Section 6.15 – Personalized Evaluation of Fat Intake (PEFI).*

6.16.1 PEFI 2003 Components

This section describes PEFI 2003 components: PEFI-Q Cover Letter/Instructions, PEFI-Q (ver. 2), PEFI-F, and Guide for Your PEFI Packet.

6.16.1.1 PEFI-Q Cover Letter/Instructions

The PEFI-Q Cover Letter/Instructions will be mailed with the PEFI self-assessment questionnaire (PEFI-Q ver. 2). The PEFI-Q Cover Letter/Instructions is a brief (2-page) document. It has three main goals: a) to offer participants the opportunity to complete the questionnaire, while emphasizing the voluntary nature of this activity, b) to provide key tips to help participants complete the questionnaire, and c) to highlight potential problem areas for participants to check before returning their completed questionnaire. The information provided in the PEFI-Q Cover Letter/Instructions is intentionally brief to encourage reading. Refer to *Vol. 2, Appendix G.8.2., Figure G.4* to see a sample of the PEFI-Q Cover Letter/Instructions.

6.16.1.2 PEFI-Q (ver. 2)

The PEFI-Q (ver.2) is almost identical to the PEFI-Q used in the original PEFI intervention. Modifications were made in the text of a few adjustment questions and line items to improve clarity and participant understanding (e.g., adding the words “diet lean” to the ground meat adjustment; adding “tuna fish” to the fish line items). Changes to the PEFI-Q database were considered (e.g., changes in fat grams and serving sizes), however, no objective data were available to evaluate the impact of the suggested edits on data accuracy and comparability between the original PEFI-Q and PEFI-Q (ver. 2). Therefore, no changes were made in the database. For detailed information about the design and content of the PEFI-Q, refer to *Vol. 2, Section 6.15.2.1 – PEFI Self-Assessment Questionnaire (PEFI-Q).*

Quality Control Measures

The goal for the quality control measures for the PEFI-Q (ver. 2) is to balance the quality of the tailored feedback with the amount of staff time needed to follow-up on incomplete questionnaires. This goal is unchanged from the original PEFI-Q. Two types of measures comprise the quality control: defaults for missing information and errors that prevent analysis.

Defaults for Missing Information

The defaults used for *PEFI-Q (ver. 2)* are unchanged from the original PEFI-Q. For information, refer to *Vol. 2, Section 6.15.2.1.2.1 – Defaults for Missing Information.*

- Central (CCC) Administration: The CCC will use defaults when responses to adjustment questions are missing or inconsistent with the associated line item.
- Local (CC) Administration: CCs will have the option to use defaults or to contact participants to clarify items generating a warning message.

Errors that Prevent Analysis

The errors that prevent analysis of the PEFI-Q (ver. 2) are unchanged from those used for the original PEFI-Q. For additional information, refer to *Vol. 2, Section 6.15.2.1.2.2 – Errors that Prevent Analysis*. The following procedures are used to reduce the number of PEFI-Q (ver.2) errors.

Central (CCC) Administration:

- Provide the PEFI-Q Cover Letter/Instructions that prompts the participant to review her questionnaire for blank pages and unanswered questions on pages 2-5.
- Use programming defaults to complete the information required in the "Office Use Only" box on the PEFI-Q (ver. 2).

Local (CC) Administration:

- Provide the PEFI-Q Cover Letter/Instructions that prompts the participant to review her questionnaire for blank pages and unanswered questions on pages 2-5.
- Review the completed PEFI-Q (ver. 2) before scanning to ensure the items in the "Office Use Only Box" are appropriately completed.

6.16.1.3 PEFI-F

Participants completing the PEFI-Q (ver. 2) will receive a packet of computerized tailored feedback (PEFI-F). The PEFI-F for PEFI 2003 is a modified version of the original PEFI-F. Some text was modified to support the self-help nature of the PEFI 2003 and to enhance participant acceptance of the materials. The most significant change was made to the < 15 grams of fat packet. This packet no longer includes ideas for lower fat choices.

The participant's fat grams reported on the PEFI-Q determine the PEFI-F's dietary change focus according to the following three fat gram categories: 1) participants over fat gram goal receive a PEFI-F that focuses on **meeting** fat gram goal; 2) participants $\leq$ fat gram goal, but $\geq$ 15 grams of fat receive a PEFI-F that focuses on **maintaining** fat gram goal; and 3) participants < 15 grams of fat receive a PEFI-F that focuses on **exploring** how closely the information matches what the participant eats and making changes if they seem right for her. Refer to *Vol. 2, Appendix G.8.2., Figures G.6, G.7, and G.8* to see a sample PEFI-F for each of the three fat gram categories.

6.16.1.4 Guide for Your PEFI Packet

The Guide for Your PEFI Packet will be mailed with the participant's PEFI-F. The brief (2-page) guide orients the participant to each page of her PEFI-F and provides a few questions for thought as she explores her tailored feedback. Refer to *Vol. 2, Appendix G.8., Figure G.9* to see a sample of the Guide for Your PEFI Packet.

6.16.2 PEFI 2003 Implementation

Participation is optional for Clinical Centers and participants. CCs may choose to implement PEFI centrally (CCC) or locally (CC) or not at all. The Lead Nutritionist uses the *PEFI 2003 Mailing Selection Screen* to designate which participants will receive PEFI 2003 and how the intervention will be delivered (i.e., centrally or locally). Refer to *Section 6.16.3.1 – PEFI Mailing Selection Screen.* To support participant self-empowerment, nutritionists are not expected to discuss the PEFI-F with participants, although they are encouraged to be available to discuss questions received from individual participants.

6.16.2.1 Central (CCC) Administration of PEFI 2003

During September to November 2003, the CCC will mail the following materials to DM Dietary Change participants designated to receive PEFI 2003 centrally: PEFI-Q Cover Letter/Instructions; PEFI-Q (ver.2); self-addressed return envelope; and a pencil. Approximately one-third of participants will receive the questionnaire and accompanying materials each month. During October 2003 to January 2004, the CCC will scan the questionnaire and mail the PEFI-F with the Guide for Your PEFI Packet to participants. Participants

will receive their tailored feedback within approximately four weeks of CCC receipt of the completed questionnaire. The CCC will accept and process completed questionnaires through March 31, 2004.

PEFI Failures:

- Follow Up for First PEFI Failure:
  If a PEFI-Q (ver. 2) fails (i.e., cannot be analyzed), the CCC will return the questionnaire to the participant with a return envelope. A letter (PEFI-Q Request for Additional Information) will accompany the questionnaire, explaining why the form is being returned and listing the pages that the participant needs to check and complete before returning the questionnaire (i.e., missing or lightly marked circles). A sample of the letter is included in *Vol. 2, Appendix G.8, Figure G.5.*

- Follow Up for Second PEFI Failure:
  If a PEFI 2003 questionnaire fails a second time, a printed message (i.e. Second Failure) will appear on the *PEFI Tracking Report* so that the local nutritionist can follow up with the participant. Nutritionists can contact their CCC Nutrition Liaison to request the participant's failed PEFI-Q. Refer to the PEFI 2003 Upgrade Notes. (Outlook Public Folders/All Public Folders/WHILMA Resources/PEFI 2003 Upgrade Notes.)

Printing the PEFI-F

CCs will be able to print the PEFI-F for centrally scanned PEFI-Qs (ver. 2). Refer to the PEFI 2003 Upgrade Notes.

6.16.2.2 Local (CC) Administration of PEFI 2003

Clinical Center nutrition staff determine how participants will receive the PEFI materials (e.g., by mail or in-person) and monitor the intervention using the *PEFI 2003 Tracking Report*. Refer to *Section 6.16.3.4 - PEFI 2003 Tracking Report.*

The CCC will use the information from the *PEFI 2003 Mailing Selection Screen* to determine the quantity of materials required to support CCs who choose local implementation. These materials include: PEFI-Q (ver. 2); PEFI-Q Cover Letter/Instructions; Guide for Your PEFI Packet, and pencils. CCs implementing PEFI 2003 locally will be able to scan the PEFI-Q (ver. 2) at their CC and print the PEFI-F and PEFI Request for Additional Information letter. (Refer to the PEFI 2003 Upgrade Notes). CCs are responsible for all administrative costs associated with local implementation (e.g. distribute and scan PEFI-Q (ver. 2); print PEFI-F; postage, envelopes, participant mailing and identification labels etc.). All CCs will receive a small supply of PEFI 2003 materials described above.

PEFI 2003 Reminder Postcard

A PEFI 2003 Reminder Postcard is available for use with all PEFI 2003 participants at CC discretion.

- The postcard provides a reminder to return the completed questionnaire. CCs opting to use the postcard will send it to the participant approximately two weeks after her PEFI-Q (ver.2) has been mailed. Refer to *Section 6.16.3.4 - PEFI 2003 Tracking Report* for information about tracking when the questionnaire is mailed.

- The postcard is located in the Outlook Public Folders/All Public Folders/Manual Information/CC Print Materials. CCs opting to use the postcard will print it from the Outlook Public Folders. Printing and postage for the postcard are at CC expense.

- The postcard was developed by the Lead Nutritionist Regional Chairs (LNRCs) and approved by Participant Material Review at the CCC. CCs opting to modify the postcard (or use a different postcard) should submit the revised (or new) postcard to Participant Material Review at the CCC per usual procedure.

Review and Processing of PEFI-Q (ver. 2)

The procedures for scanning PEFI-Q and generating PEFI-F are similar to those used for the original PEFI intervention. For guidelines about reviewing the completed PEFI-Q, refer to *Vol. 3, Form 73 – Personalized Evaluation of Fat Intake Self-Assessment Questionnaire (PEFI-Q) Instructions, Ver. 2.*

Printing the PEFI-F

When the PEFI-Q (ver. 2) is successfully scanned, it is automatically analyzed and the data necessary to generate the PEFI-F are stored in WHILMA. CCs will be able to print the PEFI-F to both locally (CC) and centrally (CCC scanned PEFI-Qs. Refer to information in *Vol. 2, Section 16.15.5.2 – Generating Tailored Feedback (PEFI-F)* and the PEFI 2003 Upgrade Notes.

6.16.3 WHILMA Resources for PEFI 2003

The section below describes the WHILMA resources available for PEFI 2003. This includes the *PEFI 2003 Mailing Selection Screen, PEFI 2003 Mailing Selection Report, PEFI 2003 Tracking Screen,* and the *PEFI 2003 Tracking Report.* Supporting information can be found in the PEFI 2003 Upgrade Notes.

6.16.3.1 PEFI 2003 Mailing Selection Screen

The *PEFI 2003 Mailing Selection Screen* includes all DM-I participants except participants who are: a) stopped DM intervention plus no mail follow-up status, b) absolutely no contact follow-up status, or c) deceased. During April through June 2003, nutritionists used the *PEFI 2003 Mailing Selection Screen* to designate: a) who will receive PEFI 2003, b) when (month) the PEFI-Q (ver. 2) will be mailed, and c) how the intervention will be delivered at each CC (i.e., centrally, locally, or not at all). Each CC was able to choose to do all participants centrally, all participants locally or a combination of central and local administration. All selections were made by July 1, 2003 when the *PEFI 2003 Mailing Selection Screen* was frozen in the WHILMA database. For information about the *PEFI 2003 Mailing Selection Screen*, refer to the PEFI 2003 Upgrade Notes.

6.16.3.2 PEFI 2003 Mailing Selection Report

The nutritionist uses the PEFI 2003 Mailing Selection Report to review the distribution of participants by mailing month and PEFI Administration (CCC, Local or None). The report can be sorted by nutritionist, group, or other parameters (e.g. undeliverable addresses). For further details about the report, refer to the PEFI 2003 Upgrade Notes.

6.16.3.3 PEFI 2003 Tracking Screen

The *PEFI 2003 Tracking Screen* allows the nutritionist to a) follow CCC and local implementation of PEFI 2003 and b) to enter optional data for local implementation. There are two tabs for the *PEFI Tracking Screen*: One for CCC administration and one for Local administration.

Central (CCC) Administration

The CCC tab of the *PEFI 2003 Tracking Screen* enables nutritionists to view participant progress in completing central administration of PEFI 2003. For each participant's PEFI-Q (ver. 2), the screen shows: dates PEFI-Q and PEFI-F labels were printed; date PEFI-Q was scanned, latest PEFI-Q event, reason PEFI-Q not mailed; and reason PEFI-F not mailed. This is read-only information, (i.e., staff cannot change data for central administration). The CCC will update the PEFI 2003 data weekly.

Local (CC) Administration

The Local tab of the *PEFI 2003 Tracking Screen* enables nutritionists to key-enter optional data for tracking local implementation. The optional data for PEFI-Q (ver. 2) include: date PEFI-Q provided, reason PEFI not

completed, and date PEFI-F provided. This is the same procedure used for the original PEFI intervention. Refer to *Vol. 2, Section 6.15.6.1 – PEFI Tracking Screen* for more information on how to enter optional data.

The Local tab also provides the PEFI-Q Form date and the Latest PEFI-Q event. The scanning process generates this information automatically. Nutrition staff do not need to data enter this information.

For more details about how to use the *PEFI 2003 Tracking Screen*, refer to the PEFI 2003 Upgrade Notes.

6.16.3.4 PEFI 2003 Tracking Report

The Lead Nutritionist (or designee) uses the *PEFI 2003 Tracking Report* to track implementation of PEFI 2003 for Central and Local administration. The report can be sorted by PEFI administration, nutritionist, group, and other parameters (e.g. latest PEFI-Q event, reason PEFI not completed).

Central (CCC) Administration

The *PEFI 2003 Tracking Report* provides the following information for each participant's PEFI-Q (ver. 2): PEFI-Q label date, reason PEFI-Q not mailed, PEFI-Q form date, latest PEFI-Q event, PEFI-F label date, reason PEFI-F not mailed.

Local (CC) Administration

The *PEFI 2003 Tracking Report* provides the following information for each participant's PEFI-Q (ver. 2): PEFI-Q form date, latest PEFI-Q event. Optional data (e.g. date PEFI-Q provided, reason PEFI not completed, and date PEFI-F provided) will only be displayed on the report if the CC enters the optional data on the *PEFI 2003 Tracking Screen.*

For further details about the *PEFI 2003 Tracking Report*, refer to the PEFI 2003 Upgrade Notes.

6.16.4 PEFI 2003 Intervention Summary

A summary of the completion rates for PEFI 2003 will be prepared after conclusion of the intervention. The summary will be modeled after the *PEFI Summary Report (PEFI 0003)* used for the original PEFI intervention. This report will show completion studywide and by CC. A preliminary report will be published from the February 2004 database and a final report will be published from the May 2004 database.

6.17 Closure of the DM Intervention Sessions

This section documents procedures for closure of the DM Intervention sessions.

6.17.1 Year 10 Sessions Overview

DM Intervention Year 10 began September 1, 2003 and ends August 31, 2004. Year 10 includes four sessions: Fall 2003 (10F), Winter 2003 (10W), Spring 2004 (10SP), and Summer 2004 (10SU). The overall theme for the final year of the DM Intervention sessions is *Protecting Your Investment.*

The overall goals for Year 10 are to: a) provide opportunities for participants to feel positive about the WHI and their contributions, b) promote participant dietary adherence through the WHI close-out visit, and c) prepare participants for closure of the DM Intervention sessions. Each Year 10 goal is addressed in every session – with more or less emphasis, depending on the particular session. The four sessions work together to accomplish the overall goals for Year 10. An overview of Year 10 is shown in *Figure 6.19 – Year 10 Sessions Overview*. Refer to *Volume 4 – Dietary Modification Intervention, Group Nutritionist Manual – Maintenance Sessions (Years 1998+)* and *Participant Manual – Maintenance Sessions (Years 5-9)* for the Nutritionist Guidelines and Participant Materials.

6.17.2 Final DM Intervention Session

Summer 2004 (10SU): Celebrating Your Investment in Women's Health is the final DM Intervention session. The overall goal of the session is to celebrate the WHI and acknowledge each woman's contribution. The 10SU session activities and materials are designed to provide a memorable and meaningful experience for participants. These materials and activities include:

- *"Celebrating Your Investment in Women's Health"* newsletter (also referred to as 'Dietary Change Fun Facts').
- Certificate of Completion (centrally developed, printed locally from WHILMA).
- WHI Dietary Change Session Summary (centrally developed, generated locally from WHILMA). [Optional]

The CCC will also provide special folders for these and other locally developed materials.

<u>"Celebrating Your Investment in Women's Health" Newsletter</u>

The *"Celebrating Your Investment in Women's Health"* newsletter and supporting session activity provide a way to thank participants for their extraordinary contributions to WHI and help them celebrate their participation in the DM Intervention sessions. Refer to *Volume 4 – Dietary Modification Intervention, Participant Manual – Maintenance Sessions (Years 5-9)* to see a sample of the "*Celebrating Your Investment in Women's Health"* newsletter.

<u>Certificate of Completion</u>

The Certificate of Completion acknowledges (and helps celebrate) that each participant has reached the end of the DM Intervention sessions. Refer to *Volume 4 – Dietary Modification Intervention, Participant Manual – Maintenance Sessions (Years 5-9)* to see a sample of the Certificate of Completion.

<u>WHI Dietary Change Session Summary (Optional)</u>

The WHI Dietary Change Session Summary recognizes each participant's contributions with a personalized summary of her DM Intervention session participation. Refer to *Volume 4 – Dietary Modification Intervention, Participant Manual – Maintenance Sessions (Years 5-9)* to see a sample of the WHI Dietary Change Session Summary.

6.17.3 Activities for Women Who Miss the Summer 2004 (10SU) Session

The 10SU session includes a make-up component divided into two parts (Part I and Part II). All participants who do not attend the 10SU session will receive the make-up Part I. As many of these participants as possible will also receive the make-up Part II.

Part I:

When a participant does not attend the 10SU session, send her the 10SU missed session packet. This packet includes:

- Cover Letter (Summer 2004 Group Session): centrally developed, CC-modifiable, printed locally from Public Folders.
- *"Celebrating Your Investment in Women's Health"* newsletter.
- Certificate of Completion.
- WHI Dietary Change Session Summary. [Optional]

The mailing and receipt of this packet is assumed; therefore, documentation is not tracked in WHILMA (i.e., no forms need to be completed and "make-up" is not documented).

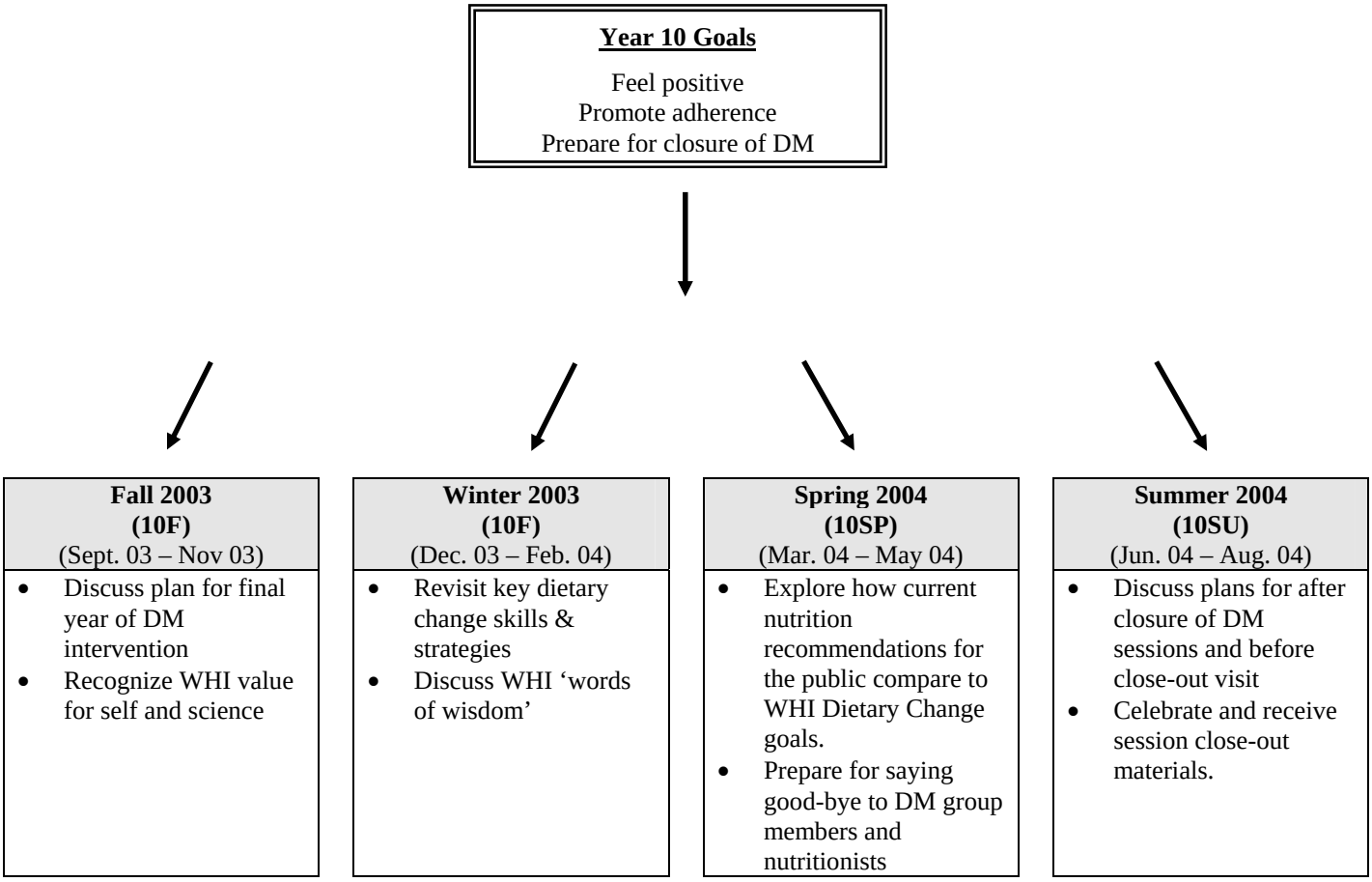
Part II:

After sending the 10SU missed session packet, contact the participant for an interactive discussion that includes a thank you for participating in the WHI Dietary Study and an opportunity to comment on her WHI experience (e.g., *What new things did you learn about your contributions to the WHI Dietary Study*? *What are your fondest memories about your participation in the WHI Dietary Study?*). Additional examples of questions to ask participants regarding their WHI experience are presented in the Nutritionist Guidelines for this session. The interactive discussion may take place in-person, by phone, or by mail (including e-mail) per the participant's needs and the staffing configuration at your CC. After completing the interactive discussion, document completion of the session in WHILMA using *Form 64 – Individual Data Sheet* (record '10SU' for *Qx. 5 – Purpose of Contact*).

Note: CCs who choose to do make-up by mail have the option to add the Make-up for Summer 2004 Group Session sheet to the 10SU missed session packet (printed locally from Public Folders). If the participant completes this sheet, document completion of the session in WHILMA using *Form 64 – Individual Data Sheet* (record '10SU' for *Qx. 5 – Purpose of Contact*).

All 10SU make-up activities, including data entry, are strongly encouraged to be completed by September 30, 2004.

Figure 6.19 – Year 10 Sessions Overview



Section 6
Dietary Modification (DM)

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