G.1 Questions and Answers:

This section contains questions asked commonly by WHI participants and appropriate answers that CC staff can provide. This Q & A is **not** a participant handout and should not be formatted or printed as such. It is intended as a resource for CC staff so they can provide clear, accurate responses to participant questions during clinic or phone contacts.

G.1.1 Calcium & Vitamin D Trial (For CC Staff)

Calcium

"Why is it all right with WHI if I keep on taking my own calcium?"

Many people are already taking calcium or making sure that they get it in their diets. You may keep doing this—it is safe and will not hurt the study. We will be studying the effects of taking higher doses of calcium compared to lower doses of calcium. No matter which group you are randomized to, you can take your own calcium supplements. If you are randomized into the active group, you will not be taking too much calcium, and if you are randomized to the inactive group, you are still assured of getting the amount you want.

"How much calcium is too much? Is it possible to take too much?"

WHI scientists who are experts in this field have reviewed the studies on this question, and could find little basis for establishing an upper limit of calcium intake in WHI. A higher calcium intake has not been proven scientifically to cause kidney stones or high blood calcium. Also, the body adapts itself by not absorbing as much calcium when you take too much at a time.

A calcium intake of 2000 to 4000 mg a day has been safe, which is far more than what you would probably get from the active study pill and your own supplements. However, you may want to limit your own intake to no more than two supplements a day.

"How will the study be able to evaluate the effects of calcium if I am taking my own as well?"

We ask you every six months how much calcium you are taking on your own. This amount is entered into the computer, which also knows if you are taking the active or inactive study pill. The computer can figure out the TOTAL amount of calcium you are taking, and this will help us learn about the effects of calcium on fractures and colon and rectal cancer.

"Should I try to take the amounts of calcium recently recommended by the National Academy of Sciences?"

The National Academy of Sciences (NAS) stresses that meeting the daily recommendations (1,200 mg for adults 51 years old and older) is necessary for good health. There is no known benefit for healthy people to go beyond these amounts, although the goal of CaD Intervention is to test for benefits, such as lowering risk for fractures and colorectal cancer.

"If I am in the Calcium/Vitamin D trial, should I follow these recommendations too"

Yes, even if you're in the Calcium/Vitamin D trial, you should be sure to get 1,200 mg of calcium each day in your diet. This amount is safe and will still allow the WHI to get the scientific answers about the effects of calcium/Vitamin D on fractures and colon and rectal cancer.

"Can I get enough calcium if I don't eat dairy foods?"

While dairy foods supply 75 percent of all the calcium in the U.S. food supply, there are many other foods that provide large amounts of calcium. For ideas about non-dairy food sources of calcium, look at the WHI handout, *About Calcium in Your Diet*.

"Should I take a calcium supplement?"

Health and nutrition experts recommend that you try to get your calcium by eating enough calcium-containing foods and by selecting a diet that contains a variety of foods. Foods contain many nutrients that work with calcium to keep your bones healthy. If you use a supplement instead of eating foods with calcium, you may not get enough of the other important nutrients. If you have food allergies or other reasons that limit your food choices, ask your doctor about a calcium supplement.

Vitamin D

"Why do you add vitamin D to the calcium?"

Vitamin D increases the amount of calcium that is absorbed in your body. The calcium is thought to prevent bone loss.

"Why do I have to limit the amount of vitamin D I take?"

Unlike calcium, you can take too much vitamin D. Very high doses of vitamin D can result in high blood calcium levels. WHI scientists have chosen 1000 International Units (IU) as a cutoff to ensure that if you are taking your own vitamin D, and the active study pill, you would not be getting too much vitamin D. Probably up to about 2000 IU of vitamin D a day is safe, which is probably far more than you would get if you were taking the active study pill and your own supplements.

"Do I need to limit the food I eat or the milk I drink if it has a lot of vitamin D in it?"

No. Most foods you eat, even if high in vitamin D, will result in only small amounts of the vitamin in your body; this is why supplements are sometimes suggested by health care professionals. Some food products, especially milk, are now being fortified with vitamin D. However, as long as you keep your own vitamin D supplement use to less than 1000 IU you will be safe.

CaD Study Pills

"What are the pills made of? I have to watch my sugar and salt intake."

We have a list of the ingredients in the study pills. In general, each pill averages 10 calories. At the most you would get about 2 gm of sugar and a very small amount of sodium (less than 136 mg) in each pill. Let us know if you are allergic to anything that is commonly used in pills.

The active ingredient in the active pills are calcium carbonate. This form was chosen because it is widely available and has good absorption.

"I hate chewing the tablets—they're chalky and I don't like the taste."

Yes, sometimes the tablets can be an acquired taste! However, you don't have to chew them—you can also break them into smaller pieces and swallow them, or mash them into a soft food such as applesauce or hot cereal, or even mash them up and add them to water or juice and drink it. There is also a study pill form that can be swallowed. You can choose this swallowable pill if you would like. You would swallow one of these pills twice a day, like you would any other pills. There is also a new form of the study pills that can be swallowed. You can switch over to this swallowable pill at any time. This study is so important— we really appreciate you working with us to figure out how to make the pills easier for you to take.

"Can I take both pills at once? I always forget to take the second one."

We'd prefer that you take one pill at two different times each day, because the body can best absorb smaller amounts of calcium at a time. If you find you forget your pills regularly, however, we can work with you on how to remember.

If it is impossible to take one pill two times a day, the best choice may be to take the two pills together once a day. Please talk to one of our clinic staff before you decide to do this; perhaps we can together work out a solution.

"I've read about the vinegar test for pills. Can I do this on these tablets?"

This test appears in magazines every so often because people are concerned about the freshness and solubility of the medications and supplements they buy in the drugstore. Our study pills, though, are designed to be chewable, so the test is not valid. Also, although vinegar tries to match the acidity of the stomach contents, a person's actual acidity depends on their stomach contents, and other factors, such as age, etc., thus making the test inaccurate.

*"**Does it matter if I take my Calcium/Vitamin D study pill with or without food?"***

Experts agree that calcium is best absorbed when taken with food. Food helps to provide enough acid to help your body take in the calcium.

Study Pill Side Effects

When participants ask about any side effects, emphasize that some women may get symptoms and some may not. The symptoms may not be caused by the study pills and may be different for each person. Many studies show that women will have the same range of side effects taking either placebo or active calcium. If the participant does start to develop some side effects that do not resolve with the self-care efforts described below, ask her to step-down her own supplements and/or the study pills and add them back as she feels comfortable.

"My constipation has gotten worse since I've been taking those pills"

This may or may not be related to the study pills. Constipation is a very common problem as we get older. It can be caused by many things, and it is usually difficult to find the exact cause. It could be the foods you eat, the amount of fluids you drink, or how active or inactive you've been. The form of calcium you're taking was chosen because it is usually tolerated well. Constipation usually doesn't last forever—your body will probably get used to the changes in food, drink, activity, or supplements. Whatever the cause, we can offer some suggestions so that you feel better:

- Increase the amount of fluids you drink—the more water you drink, the more passes on to your intestines to soften the stool.
- Increase the amount of roughage you eat, like fresh (not cooked) fruit and vegetables, prunes and prune juice.
- Take a mild stool softener (available in the drug store) for a few days.
- Decrease the amount of your own calcium supplements.

"I've noticed that my stomach is very gassy and bloated since taking the study pills."

This may or may not be related to your pills. Some people feel very gassy after eating certain foods, drinking carbonated water, chewing gum, or when they're under stress. The form of calcium you're taking was chosen because it is usually tolerated well. There are many things you can do to feel better when you have a gassy or bloated feeling:

- Take your study pill with meals.
- Drink lots of water and/or fluids to help break up the gas, and move it more quickly through your system.
- Use simethicone (you can get this in the drugstore, often sold as Mylicon® or Gas-X®), which also helps to break up the gas.
- Lie down for 1/2 hour after meals

- Wear clothing with a loose waistline.
- Decrease the amount of your own calcium supplement.

"I've noticed more heartburn since I've started taking the study pills"

This may or may not be due to the study pills—some foods also cause this same feeling. The form of calcium you're taking was chosen because it is usually tolerated well. You can try:

- Taking the pill with a full glass of water to wash it down well.
- Taking the pill with meals, so that it mixes in with everything else in your stomach.
- Sitting up for an hour after meals, and not eating an hour or more before bed.
- Decreasing the amount of your own calcium supplements.

Chewable Pill vs. Swallowable Tablet

"What can I do? The CaD study tablet is just too hard and I have been having problems chewing it."
OR
"I don't like the peppermint taste of the calcium tablet."
OR
"The study tablet leaves a chalky feeling in my mouth and coats my tongue."

The WHI now has a new form of CaD study pill that you can swallow. This means that twice a day, you can swallow the study pill just like you would any other pill and skip the chewing (*or* the peppermint flavor, *or* the chalky feeling). You can switch over to this swallowable pill at any time.

"Other than being swallowable, are the new study pills the same as the chewable tablets?"

If you are assigned to the placebo group, the new study pills are exactly the same as your chewable tablets. If you are assigned to the active group, the new study pills contain exactly the same amount of calcium as the chewable tablets – 500 mg each. There is, however, slightly less Vitamin D in each of the swallowable pills than in the chewables. The WHI scientists feel that this lower amount is still enough to do the job and is a safe amount.

Will changing to the swallowable study pills make my symptoms (constipation, bloating, etc.) go away?

Because the swallowable study pills you receive will have exactly the same amount of calcium the chewable tablets you were assigned, it is unlikely that your symptoms will change. There are steps that you and your clinic practitioner can try to see if symptoms can be lessened or made to go away. (See answers to questions on bloating and constipation.) And, the clinic practitioner will always evaluate your symptoms to make sure it is still safe for you to continue on the CaD study.

CaD Intervention

"How do you track the effects of calcium without bone density measurements?" (non-BD sites)

WHI is not using bone density at all clinics. Instead, we are looking at fractures, which can be related to poor bone density and are a major cause of disability in older women.

"What other medications that I'm taking would prevent me from taking the study pills?"

If you are taking corticosteroids by mouth (orally), you should not join the calcium trial. Oral corticosteroids like Prednisone can cause low calcium levels and decreased bone density—so you would not want to take the chance of

being in the inactive pill group. If you take calcitriol, you should also not join this program. Calcitriol (Rocaltrol®, Calcijex®) is a very strong form of vitamin D, and you shouldn't take additional vitamin D. This medication is given for health conditions that cause low blood calcium, such as chronic renal failure or hyperparathyroidism. If you start taking calcitriol after you join the CaD trial, your study pills will be stopped until you are no longer taking this medication.

You should also not take 600 IU or more of vitamin D. This will ensure that, if you are randomized into the active pill group, you will not get too much vitamin D each day.

G.1.2 HRT (For CC Staff)

General Questions

"Why should I start hormones now? What benefit would I get from them?"

The WHI is a randomized study. This means that you have a 50/50 chance of being assigned to a group that takes hormones or a group that takes inactive (no-hormones) pills. Medical science doesn't know for sure how you or any individual woman benefits from taking hormones after menopause. Because the computer assigns you to a hormone or no-hormone group, we can only tell you the possible benefits and risks of being assigned to either group. All women, however, benefit from the health tests associated with WHI and the monitoring of your health over the course of the HRT study. In addition, all future women will benefit from the important health care answers that result from your participation in the WHI.

"For women thinking about hormone washout for screening: Why should I stop my hormones now? Shouldn't I be on hormones? My doctor wants me to take them because he believes HRT saves lives and prevents heart disease and osteoporosis."

Most doctors prescribe hormones to women for menopause symptoms. Hormones do stop some of the symptoms of menopause like hot flashes and fatigue. Some women also take hormones to prevent heart disease and maintain bone mass. However, there have been no clinical studies proving that hormones prevent heart disease or prevent fractures. WHI will get at the truth. By stopping your hormones (washing out) and participating in the WHI, you will help find answers to these questions.

"My doctor doesn't think I need hormones and shouldn't risk the problems they might cause."

It is always best that you check with your doctor about your decision of whether to join the study or not. There are no clear scientific trials that tell us that hormones definitely cause breast cancer or even if they prevent heart disease or osteoporosis. Part of the purpose of WHI is to answer those questions. To help decrease any risks, there are many built in "safety checks" in WHI that allow us to monitor you carefully for any possible side effects. This keeps your personal risk for developing problems very low.

"Why aren't you using "natural" hormones for the study? Aren't they safer?"

The WHI is using Premarin® as its source of estrogen. This is the most common form of estrogen used in the United States, and the most is known about it. Not much is known about "natural" hormones (for example, herbal preparations). It is not known whether they really work, and their safety has not been proven. In addition, all estrogens, even natural ones or those made by a woman's own body, may increase the risk of diseases such as breast cancer.

"I have high blood pressure and my doctor says that hormones will make it worse."

The idea that estrogen replacement therapy for menopause can cause high blood pressure was based on results from studies using oral contraceptives (birth control pills). However, oral contraceptives are much stronger than the estrogen we use for menopause and in WHI. There is no evidence that estrogen, at the dosages used in WHI,

causes high blood pressure. Each person, however, is different and you should discuss this further with your own physician.

"Why do I need all these tests before I can join the study?"

Before you join the HRT study, we want to make sure that it is safe for you to participate. This means that we will check your breasts, female organs (such as your cervix and the lining of your uterus), blood, and other health factors that might be affected by estrogens. We want to make sure there are no problems that might be made worse by our study pills.

"Why can't I choose to be on active/placebo or know what I am taking?"

Because this is a research study, we must follow certain scientific methods. In order to get the answers we're all seeking, it is important that women are randomly assigned by chance to the hormone or no-hormone group. Scientifically, we must avoid any possible bias and if we allowed women to choose, this bias could not be avoided.

"Why can't I take my own hormones?"

If HRT participants were allowed to take their own hormones there would be several problems. First, the WHI needs to use sound scientific methods in order to produce valid answers. Second, the woman and staff would know that she was taking "real" hormones and this might influence the data obtained. Third, there are many, many different forms of hormones available. We could never know for sure what effect was due to which hormone.

"Why do you need to contact me every 6 months?"

The WHI wants to check in with you for a health status update and to make sure that there are no safety concerns.

"If hormones have been around so long, why is this study necessary?"

Hormones have been around for many years, but they have never been studied for these questions in a scientific method such as the WHI HRT trial. Most previous studies tried to come to conclusions by looking at smaller numbers of women who were already taking hormones. These were women who chose to take hormones and they may have been very different from those who chose not to. By having the computer assign you, and thousands of other women, to the hormone or no-hormone group by chance, we will know for sure.

"If science is unsure about hormones, aren't you putting thousands of women at risk?"

No, the doctors and scientists who designed the WHI carefully studied all the scientific data about hormones and took this into account when they planned the HRT portion of the study. As a result, the participants are as well-protected as possible from any potential risks and may gain some real benefits. (See answers to other questions regarding screening and follow-up to ensure safety.)

"Some groups have made claims that the maker of Premarin® is cruel and inhuman in their treatment of pregnant mares, is this true?"

Recent inspection by independent veterinarians, as well as the USDA, the American Association of Equine Practitioners and the Canadian Farm Animal Care Trust indicate that the horses used in the production of Premarin® are well taken care of. In addition, all Premarin® ranches are required to follow the Recommended Code of Practice for the Care and Handling of Horses in Pregnant Mare Urine operations.

"My doctor says that I have low bone density or osteopenia and that I should stop the study pills and take real hormones."

There are many ways other than hormones, to treat low bone density that allow you to stay in the HRT trial on your study pills. The WHI clinic practitioners and gynecologists would like to work with your doctor to make sure that you get appropriate care for this condition and, if possible, stay in the trial.

Symptom/Adverse effects questions

"What kind of side effects will I have if I take these pills? Are there things I can do to make them go away?"

Not every woman who takes the study pills will experience side effects. If you do have any, they usually last only a short amount of time while your body gets used to you taking the pills. The *HRT Handbook* has helpful suggestions for dealing with these problems. In addition, our clinic practitioners will help with side effects, and may be able to change the way you take your study pills to decrease the discomfort.

"Will I get cancer from taking these hormones?"

There have been many studies done on hormones and breast cancer, and none of these studies have proven that long-term hormones cause breast cancer. Health research to date has provided very mixed results. The WHI will monitor your health very closely and keep in touch at least every 6 months. It will be through WHI that we get the answers about hormones and cancer.

"Will I gain weight if I take these hormones?"

The Postmenopausal Estrogen/Progestin Intervention (PEPI) study has recently released results that suggest many postmenopausal women gain weight whether they are on hormones or not. Hormones are probably not a major cause of weight gain.

"Won't I get Alzheimer's if I don't take hormones?"

The study which showed that women who take hormones are less likely to suffer the effects of Alzheimer's disease was done by looking at women who were already taking hormones. These were women who chose to take hormones and they may have been very different from those who chose not to. The HRT trial will give us the answers to questions about hormones and Alzheimer's.

"Will I bleed again?"

Women who still have their uterus may bleed again. It is difficult to predict who will bleed and who will not. The bleeding, however, will eventually stop. In addition, the clinic practitioners and gynecologists are able to offer temporary medications that may help decrease or stop the bleeding. By the way, the study pills will have no effect on your fertility status - you will not be able to get pregnant if you take the study pills.

"Will the study pills make my fibroids grow?"

Estrogen can make some fibroids grow. This is why we like to monitor your symptoms every six months and examine you yearly to catch any changes early. In addition, if you should have any concerns or questions at other times, our clinic practitioners are always available.

"What if I have problems and need to stop the study pills?"

The HRT trial has been designed to be flexible and accommodate any problems that you may have. If you experience discomforts, we may be able to change how you take your pills to help the problem go away. If serious problems arise, we may ask you to stop your study pills for a while or maybe even permanently. Even if we ask you to stop your study pills, you are still a very important part of the study and we would like you to continue your contacts and visits.

"What if the study pills cause me harm?"

Before you join the HRT study, you will undergo many medical tests to make sure that you will not be harmed by taking hormones. In addition, you will have many contacts with the clinic staff to make sure that it is safe for you to continue taking your study pills. If, however, a harmful situation should arise, and it is felt that this might be due to the pills or could be made worse by the study pills, we will ask you to stop your study pills immediately and contact your doctor. Even if you stop your study pills, you are still an important part of the study and we would like you to continue your contacts and visits.

G.1.3 Venous Thromboembolism (Deep Vein Thrombosis [DVT] and Pulmonary Embolism [PE])

(Note that much of the Q&A below repeats information the participant in the fact sheet "What you should know about Deep Vein Thrombosis." See *Appendix F.3.5* and *F.3.6*)

"Why are you giving out this fact sheet?"

We have developed this fact sheet to give you some information about deep vein thrombosis or blood clots. A small number of women (and men, for that matter) can develop these types of blood clots in the veins of their legs or lungs. Studies published recently report that women taking hormone replacement therapy (HRT) can have an increased risk of blood clots in the legs or lungs. In some of these studies, the women were not as healthy as participants in the WHI or the HRT dosage was higher than the dosage used in our study. The actual risk of DVT was still much lower in these studies than that of other health problems like heart attacks or strokes. We hope this information helps you to reduce your risk of developing deep vein thrombosis.

"What is DVT?"

Deep vein thrombosis or DVT is not common. It occurs when a blood clot forms in the large blood vessels of the legs (this is not the same as varicose veins). A small DVT usually does not cause problems. A large clot in the deep veins of the legs can cause problems because it can block blood flow. The most serious problem with DVT is that the clot can break loose, travel up to the lungs, and affect the lungs and heart. Usually, even a large clot will dissolve if treated early, and there will be little or no long-term health problems. Problems with DVT are far less common than heart attacks or strokes.

"What causes blood clots?"

Blood clotting is a normal reaction of the body. Blood clots often form because of an injury to your blood vessels (for example, a cut). Blood clots may also be caused by changes in your blood circulation. Blood circulation in your legs slows when you spend a long time in bed or are seated for many hours without moving, such as during a long plane flight or car trip.

Changes in blood clotting can also happen after a hip fracture or a major operation or when you have a severe illness, such as a heart attack, stroke, or some cancers. If you have had a blood clot in the past, you may have a higher risk of having one again. In a small number of people there is a family tendency to have more blood clots.

Questions the participant may ask about herself

"Should I be concerned about being in the HRT Program?"

At this time, most women in the HRT program do not need to stop their WHI hormone study pills. You are at a very **low** risk for deep vein thrombosis. None of the tests done during your WHI visits increase your risk for developing these types of clots. We will stop your study pills if you develop certain health changes that might increase your risk of DVT. *(See "Are there times when I should stop my hormone study pills?" below.)*

"How will I know if I develop these blood clots?"

Most of the time blood clots cause no problems. If the clot is small, you may not ever know you had it. Larger clots that form in the leg can cause swelling or pain of the affected leg. Deep vein thrombosis, or a blood clot in your legs, can feel like a tender calf muscle in your leg, with warmth and can show swelling and/or redness. If both legs are swollen, it is probably not because of DVT, but you should see your doctor. The symptoms of a pulmonary embolism, or a blood clot in your lungs, include sudden shortness of breath or painful breathing. Usually swelling and pain in the leg happens before shortness of breath and pain in the chest. You should call your own physician if you think you have any of these types of problems. The WHI clinic staff would be happy to talk with your or your physician about these concerns.

"What can I do to prevent these kinds of blood clots?"

These types of clots can have many causes, and some--like accidents or injuries--cannot be avoided. One thing you **can** do to avoid these clots is not sitting for long periods of time. If you are take a car ride that will be more than an hour, stop every so often to walk about. If you are in a car or plane and cannot walk around, do leg movements like flexing your ankles up and down while you sit (*point out exercise graphics on "What You Should Know About Deep Vein Thrombosis"*).

If you go into the hospital, ask your doctor about your risk of getting blood clots. Usually, leg exercises, special stockings, or equipment can help keep the blood flowing. In some cases you may be given a pill or shot to thin your blood. Be sure to tell your doctor that you are taking WHI hormone study pills, so that the doctor can decide whether to continue or stop your study pills while you are in the hospital. Your doctor can call the WHI clinic for more information.

"Are there times when I should stop my hormone study pills?"

At this time, most women in the HRT program do not need to stop their WHI hormone study pills. If a doctor ever tells you that you have a blood clot in your legs or lungs (deep vein thrombosis or DVT; pulmonary embolus or PE), please **notify us immediately** about **permanently** stopping your hormone study pills.

You may need to **temporarily** stop your hormone study pills for certain health changes, such as:

- A broken leg, hip, or back, or any other reason for having a cast on your leg.
- An operation during which you are put to sleep (general anesthesia) or have an anesthetic given in your back (regional or spinal anesthesia).
- A serious injury, such as a car accident, or a burn that requires hospitalization.
- A stroke or heart attack.
- Any severe illness that causes you to be in bed and unable to get up for more than 5 days.
- Any other health change that your doctor or the WHI clinic staff believes may increase your risk of blood clots.

Once you are better, you should be able to start taking your pills again. The WHI clinic staff can work with you and your doctor to decide on the right time.

G.1.4 Bone Density (For CC Staff)

General

"What causes low bone density?"

Losing bone density is a natural process that occurs with aging. The single biggest factor in determining your personal bone density is heredity. Low bone density has also been associated with factors like thinness, being tall, being Caucasian or Asian-American, a low activity level, and diet and personal habits like smoking and low calcium intake.

"What is the relationship between low bone density and osteoporosis?"

Low bone density is associated with increased risk of bone fractures in both men and women. Having a fracture is the hallmark sign of osteoporosis. Still, we can't determine from your bone density level who will actually have a fracture and who won't, only who has higher and lower chances of a future fracture. By the age of 70 or so, 9 out of 10 women have bone density low enough to be classified as osteoporosis or osteopenia (low bone density).

"How can I tell if I have osteoporosis?"

If you have had a fracture after the age of 50 caused by a fall or other minor accident, that is the major sign of osteoporosis. Loss of height (especially greater than 2.5 inches) and forward curvature of the spine (known as kyphosis or Dowager's hump) are other signs of osteoporosis. Having a bone density scan can provide information on bone strength that helps determine when osteoporosis is present.

"At what age should I get my first bone density scan?

For most women, decisions about the prevention of osteoporosis can be made without having a bone density scan. Whether or not you should have one is a decision to make with your primary care provider.

"How frequently should I have a bone density scan after the first one is performed?"

Non bone density sites: You should discuss with your primary care provider whether and how often you should have scans performed.

Bone density sites: While you are a part of the Clinical Trial in the WHI at this bone density site, you will have a bone density scan during your screening visits, at your annual and third annual visit and then every three years after that. It takes time for changes in bone density to occur, so there is usually no need to have them very often.

"Why are there only 3 Bone Density sites for WHI?"

Three sites will give us the needed information about the effect of the treatments we are using in WHI on bone density in a cost efficient manner.

HRT Participants: *"My doctor says that I have low bone density and that I should be taking hormones. Can you tell me whether or not I am taking active hormones?"*

This is a blinded scientific study, so neither you nor the clinic staff know that information. We encourage you to discuss your bone density with your primary care provider before. Please feel free to give him/her our number if there are any questions.

HRT Participants or Other WHI Participants taking Hormones: *"My doctor says that I have low bone density and that I should be taking Fosamax (or alendronate). Is there any problem taking this medicine along with hormones?*

Fosamax (or alendronate) is a new option for treatment of osteoporosis. Because this medicine is fairly new, we are still gathering clinical experience in women taking this medicine along with hormones (which may be given for the prevention or treatment of bone loss). However, based on information available at this time, there is no reason to think that such a combination is harmful.

CaD Participants: *"My doctor says that I have low bone density? Should I increase my calcium intake? Should I be taking a bone-strengthening drug like Fosamax or estrogen?"*

Many health care providers recommend that women at high risk for bone fractures take calcium, estrogen, or Fosamax to stop bone loss from occurring. As always, discuss with your primary care provider what course of treatment is right for you.

Specific Questions for WHI Bone Density Sites

"What does a bone density scan measure?"

The bone density scan performed in WHI measures the amount of mineral in or the strength of your bones.

"How does the bone density scan machine work? How long will the scan last?"

An invisible x-ray beam is passed through the bone being tested and a computer automatically calculates the bone's density. A bone density scan takes only minutes!

"Is there a risk from radiation?"

There is very little risk of radiation exposure from a bone density scan. The radiation exposure is about one-fourth of the radiation that you would get on a round-trip cross-country plane ride.

"Can I (or my primary care provider) get copies of my bone density scans?"

Yes, as a WHI participant, you can receive a copy of the initial (baseline) bone density scan done at your screening visit. The WHI clinic can send a copy of this test to your primary care provider with your permission. After the baseline scan, however, no further copies can be provided to either you or your primary care provider until the study is completely over. Not even the WHI clinic staff (except the bone densitometer technician) sees your follow-up scans! However, you will receive a letter informing you of the results and it will indicate if your bone density test reveals you have osteoporosis or excessive bone loss.

"Why can't I get copies of my follow-up scans?"

Because WHI is a scientific research study, the follow-up bone density scans are not given to participants or clinic staff during the course of the study. We are concerned about your safety and therefore have policies in place for letting you and your primary care provider know if you experience a significant loss of bone density or osteoporotic values (brittle, weak bones) as compared to young women on a follow-up scan. Instead, we send you a letter informing you of your results. We do this so that the WHI staff treats all participants the same. Results of the bone density scan may provide clues as to which treatment arm you are in, if you are taking a placebo or active study pills. At the conclusion of the study, all of your scans will be available to you, if you would like them.

"What happens if follow-up bone density scans show that I am losing bone density?"

The follow-up scans are monitored closely by our WHI bone densitometer technician and the Bone Density Coordinating Center at the University of California in San Francisco. If you experience a 10% or greater loss of bone density between scans, you will be notified by a WHI staff person. Small changes in bone density, less than 10% do not necessarily mean that a woman has lost bone. There is some small error inherent in the bone density scans, based on (for example, participant positioning) so larger changes are needed to indicate a real difference in bone density, whether it be an improvement or actual bone loss that has occurred. If a 10% or greater loss is evident copies of your initial and follow-up bone density scans would be sent with your permission to your primary care provider for evaluation of treatment options.

"Can arthritis be detected from a bone density scan?"

No, the bone density scan machine cannot detect arthritis. If you are concerned about arthritis, you should discuss it with your primary care provider.

"Can the bone density scan explain my back pain?"

Back pain may be caused by many things. However, the bone density scan machine only measures bone density. It is not able to diagnose specific causes of back pain. You should discuss these concerns with your primary care provider.

"Why is only the left hip scanned? Why aren't both hips scanned?"

Only one hip is scanned so that scans are done consistently. The left hip is chosen because it is the easiest for the densitometer operator to scan. The right hip is scanned only if there is discomfort or a hip replacement in the left hip area. The density of both hips is very similar because bone loss normally occurs at similar rates in both bones.

"Why are different bones scanned?"

Different bones are scanned to get a good idea of how much overall bone loss you may have experienced. Different types of bones in the body tend to lose density at different rates.

"Why can't I have a pillow during my bone scans?"

While a bone density scan is being performed, it is important that you are lie flat on the bone density scan so that the scan obtained is as accurate as possible. Using a pillow may change the way your scan should really appear (for

example, your spine may appear curved on the scan even though you are only lying crooked.) The pillow may also show up on the scan and blur the picture of your bones.

G.1.5 Clinical Trials (For CC Staff)

What is a double-bind study?

A double-blind study means neither the study staff nor the study participant knows which intervention a participant is assigned to. Research studies are often double-blinded to decrease any possible bias among study staff or participants, and to make sure that all participants are treated equally throughout the study no matter to which group they are randomized.

What is a placebo and why is one needed?

A placebo is an inactive study pill. You may have heard a placebo called a "sugar pill." Using a placebo makes it possible for researchers to analyze the effects of the study intervention by comparing what happens to participants taking a placebo to those who are taking the active study pills.

What is a control/comparison group and why is one needed?

A control or comparison group includes study participants who are not randomized to the active intervention. In the WHI, the control groups are the HRT and CaD participants who are taking placebo or inactive pills and the DM Comparison participants. There is no comparison group in the Observational Study because no intervention or treatment is being tested. The control group is a very important part of the study because we test the intervention by comparing data between the treatment and control groups.

Why am I called a participant and not a patient?

The women who join WHI are called participants because they are generally healthy and voluntarily contribute their valuable time and efforts to the goals of the study. "Patients" are people being treated by a healthcare provider. While the WHI (and WHI CC staff) care about our participants and their health, they do not take the place of a participant's primary care giver.

What does randomization mean?

Women are "randomized" to WHI when they are assigned by chance to an intervention or a control group. WHI randomized its participants using a computer; the computer, not the study staff, chooses which group the participant will be in. An HRT participant can be randomized to either an active hormone or inactive placebo; a CaD participant to either active Calcium and Vitamin D or a placebo; and a DM participant to a Dietary Change or Comparison group. In WHI, a participant is randomized after she has completed the screening process.

Will I ever find out what treatment arm I was randomized to?

All WHI HRT and CaD participants will be told their actual "treatment" assignment (active intervention or placebo) after the study comes to an end. If you are in the Dietary Program, you already know which group you are in. In very special cases, (e.g., for your health and safety) your study group can be determined earlier.

Why are there so many forms to be completed?

The WHI provides an important opportunity to collect information on many topics concerning women's health issues. The information we collect will be used to answer the many research questions that scientists and healthcare providers have about postmenopausal women's health.

Some of the questions that you ask on the forms are embarrassing and personal. Why is it important that you collect this information and what will you do with it?

We realize that some of the questions contained in the forms may be a little embarrassing or personal. We do not intend to make you uncomfortable. It is important to gather as much information as possible related to you and your lifestyle so that scientists and healthcare providers can get answers to the many important questions about women's

health. You do not have to answer any question that you are not comfortable with. And please remember that all of your answers are confidential, only WHI staff (and Food and Drug Administration staff in HRT and DM participants) will have access to your individual data, and only group information will be published.

Who thinks of the studies that are conducted? Where does the money to finance them come from?

Research studies are funded and conducted by many different sources. Much of research is the result of scientists trying to answer specific questions or address issues that already have a good scientific foundation and that are of interest and importance to society. Research may be funded or carried out by public or private institutions, government agencies and institutes and private companies (like drug companies). WHI is the largest women's study to date funded by the National Institutes of Health, a federal government agency located in Washington, DC.

Why can't you "replace" me in the study if I decide that I no longer want to participate?

The success of WHI depends on the recruitment of a specific number of participants at each of the 40 WHI clinical centers across the country. Because we are seeking scientific answers to important questions about women's health, we need to follow only the women who were initially recruited. You are irreplaceable! Therefore, if you join (and fill a recruitment slot) but later decide to drop from the study, that slot cannot be filled by another participant, and the important data you could provide in the future will be lost forever! That's why there are screening visits, to give you time to see if WHI is right for you before you actually join.

Why do I have to sign a medical release each time that I come to the clinic for a visit?

Obtaining medical records allows us to draw scientific conclusions about the effects of interventions and other aspects of women's lives. In fact, obtaining medical records and looking at the health changes you have had are the most important aspects of the WHI study. Without this information, we would not be able to answer important questions about heart disease, cancer and osteoporosis in postmenopausal women.

Who reviews the WHI procedures to make sure I'm safe?

Your clinical center and the WHI Coordinating Center have Institutional Review Boards (IRBs) that review and approve all procedures, consents, forms and participants materials and any changes to these procedures and materials. An IRB is usually composed of diverse persons with varying experiences such as physicians, nurses, clergy and lay people. In addition, scientists from around the country and the Office for the protection of Research Risks reviewed these procedures and forms.

Why do I have to sign more than one consent form?

A consent form basically describes the risks, benefits and procedures for a research study. The consent discussion and the review and signing of the consent form ensures that you have good understanding of the study before you actually join. Each of the study arms of WHI (HRT, DM, CaD, OS) has its own consent form that you are asked to sign to document that you've been told about and understand your rights and responsibilities if you join. All study consents are approved by your clinical center's and the Coordinating Center's Institutional Review Boards (IRBs).

Will I ever be told the results of the study findings?

The result of the study will be reported and published after the study ends. This information will be available to participants as well as the healthcare providers who are waiting for the answers.

G.1.6 The Heart and Estrogen/Progestin Replacement Study (HERS)

(Questions and Answers for CC staff use. This is not a participant material.)

What was HERS?

HERS tested whether the combination of estrogen and a progestin would prevent heart attacks in post-menopausal women with an intact uterus who already had established heart disease. The HERS participants all had a previous

history of heart disease. HERS was a randomized, controlled trial in which about half of the 2,763 women who volunteered received active hormones and half received a placebo. Until the end of the study, neither the women nor the clinic staff knew what treatment a participant was receiving. During the average of 4.1 years that the participants were in the study, they reported new heart attacks, hospitalizations, or any other major illness to the clinics, and the data were collected and carefully analyzed. The data were reviewed regularly by an independent Data and Safety Monitoring Board to evaluate participant safety to be sure the trial was conducted appropriately.

Does WHI differ from HERS?

WHI differs from HERS in many important ways. At the outset of the WHI Hormone Program, the women who volunteered were not required to have a history of heart disease and were on average much healthier than HERS women. However, HERS does provide relevant information to many women in WHI, because as women get older they have more of the underlying conditions that result in a future diagnosis of heart disease. The WHI Hormone Program is testing an estrogen-progestin combination in women with a uterus and estrogen alone in women who have had a hysterectomy. The HERS study included only women with a uterus. Thus, we estimate that less than 2% of participants in the WHI Hormone Program would have qualified for HERS. Importantly, the WHI trial is much larger (27,500 participants compared to 2,763 in HERS), and much longer (average 9 years compared to 4 years in HERS). The size and duration of WHI means that we will be able to see what the overall effects of hormone replacement therapy are on many aspects of women's health, including conditions that may only be affected by many years of treatment. WHI may be the only opportunity to determine these overall effects. The WHI Hormone Program will answer the important question of whether most women should take long term hormone replacement therapy.

What did HERS find in regard to heart disease?

The main finding was that the combination of estrogen and progestin in women with heart disease did not prevent further heart problems over a 4.1-year period. For the entire trial period the total number of heart attacks in the active hormone group was similar to the number of heart attacks in the placebo (no hormones) group.

In the first year of the trial, the active hormone group had somewhat more heart attacks than the placebo group, but after two or more years the active hormone group had somewhat fewer heart attacks.

Why did hormone replacement therapy not reduce heart attacks?

As you were informed when joining WHI, we do not know for sure that hormone replacement therapy will prevent heart attacks, and that is why we are doing the trial of hormones in WHI. The HERS findings point out the uncertainty about whether heart attacks will be prevented, and underscore that it is ethical and necessary to do further trials like WHI. The HERS investigators offer a number of possible explanations for the lack of benefit in their study:

- Firstly, previous studies suggesting benefit may have been misleading. These previous studies were observational studies not clinical trials and, for the most part, included healthy women rather than women with heart disease.
- Secondly, any benefit of estrogen may have been minimized by the progestin.
- Thirdly, the trend towards an increase in heart attacks early on, and a decrease later on, may suggest that there are some early unfavorable effects of hormones (such as increased clot formation) that are counteracted later by favorable changes in blood lipids. Thus, it is important that the WHI is following its participants over a much longer period so that we can learn more about these important results.

What about adverse events in HERS?

HERS did not uncover previously unknown adverse effects of HRT. The active hormone group showed a threefold increase in the risk for blood clots in the deep veins of the legs and in the lungs in the active hormone group, and a smaller one-third increase in the risk for gallbladder disease. However, the number of women who developed clots was far fewer (one-fifth to one-tenth) than the number who developed heart attacks. In WHI, we expect fewer blood

clots than in HERS, because women in WHI are generally healthier than women in HERS. The increased risks for blood clots and gallbladder disease were explained to you when you joined the WHI trial. Appropriate clinic staff will be happy to discuss what you can do to prevent blood clots and can give you a copy of the WHI Update on blood clots.

HERS did not find significant increases in breast cancer or any other cancer, and no increases in any other condition. However, because HERS was a relatively small study, it did not have a big chance of showing any effects on conditions other than heart attacks.

Will the WHI Hormone Program continue?

Absolutely. HERS did not provide answers to the questions asked in the WHI Hormone Program. No one study can provide all the answers, and we certainly need more good information on the benefits and risks of HRT. In fact, the HERS investigators themselves say that the WHI and other randomized trials of HRT in postmenopausal women will help answer some of the questions raised by HERS. The editorial accompanying the HERS results emphasizes the need for WHI and other randomized trials, because HERS identified no new risks. The data collected on all WHI participants is monitored closely by a board of independent scientific experts, the Data and Safety Monitoring Board, who have examined the HERS and WHI data and confirmed that the WHI-Hormone Program will continue.

What actions will the WHI take as a consequence of the HERS results?

The Data and Safety Monitoring Board (DSMB), a group of independent scientific experts, review the WHI. Every 6 months, the DSMB will carefully analyze the data collected from WHI Hormone Program participants who would have qualified for HERS. We will let you know if the results of this analysis show important changes that might affect your participation.

Should I stop my study pills?

WHI recommends that you continue your study pills for the Hormone Program. Remember, the HERS results apply only to women who already have heart disease, and only to women who have a uterus receiving the combination of estrogen and progestin. Because of the finding of no overall benefit, the HERS investigators do not recommend starting HRT for the purpose of secondary prevention in women with coronary heart disease (CHD). Given the favorable pattern of CHD events after several years of therapy, the HERS investigators recommend that women already receiving this treatment should continue. The WHI investigators concur with this opinion, and recommend that you continue with your participation in the study so that we can see whether long term treatment will indeed result in benefit.

In WHI, the independent Data and Safety Monitoring Board, a board of independent scientific experts, continues to examine the WHI trial data every 6 months to see whether there is overall benefit or risk to participants. The DSMB will be examining the HERS results in great detail, together with the data from the WHI trial, and will advise us whether any changes in our study are needed to protect the safety of participants. We will notify you if your participation needs to be reconsidered, but there is no <u>immediate</u> concern. So for now, please do continue to help us find the answers!

Should I go on active hormones for the purpose of preventing a heart attack?

We recommend that you stay on your study pills because the HERS results were essentially neutral (no proven risk or benefit in preventing heart disease). This is the main reason that we are testing hormones in WHI. We don't know enough about the long-term effects of hormones for women <u>without</u> heart disease. These women were not included in HERS.

The HERS results suggest the possibility of benefit from long-term HRT use. However, the WHI will resolve whether HRT is likely to prevent heart problems over a longer period. The results of studies like the WHI are needed to give these answers. That is why your continued participation in the WHI Hormone Program is so important.

What if I already have had a heart attack?

The WHI investigators do not recommend that you stop study pills because of the HERS results, even if you have a history of heart disease. The neutral results in HERS mean that women who had previous heart disease did not increase their overall risk for heart problems by taking hormones. We do not know what the effects of long-term HRT use will show. The WHI Hormone Program can give us these answers.

As you know, you can elect to stop study pills at any time. We also know that some women will, unfortunately, have a heart attack during the course of the study. We recommend stopping study pills only temporarily if you have a heart attack during this time. We do advise women who develop a blood clot in the deep veins of the legs or in the lungs to stop study medications permanently.

Will WHI tell me if I am at risk for heart disease?

Risk for heart disease can be determined in many different ways. For example, the American Heart Association has information that you can use to find out more about risk factors for heart problems. Your personal risk for heart disease, however, is something you should discuss with your doctor; it is not something that WHI can tell you. For now, we ask that you continue contributing towards finding the answers about hormones and the prevention of heart disease! WHI can tell you that we do not know whether hormone replacement therapy will decrease a woman's risk of heart disease. With your help, we will know this by the end of the trial. Our Data and Safety Monitoring Board will be looking very carefully at whether there are groups of women (such as those with heart disease) who might be put at increased risk for heart disease if they take study medications. If your participation needs to be reconsidered, we will notify you immediately.

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G.2 Hot Tips

The following tips are recommendations from the CCs, CCC, and PMC. Keep in mind that these tips need to be evaluated independently by each CC based on your staffing, space, and availability of other resources.

G.2.1 Clinic Management

1. Provide clear leadership by naming PI, Co-PI, or Project Director as head of the CC for operations.
2. Establish clear lines of authority, decision making, communication, and responsibility for lead staff (e.g., have CM report to PI, Co-PI, or Project Director and have other lead staff report to the Clinic Manager). Have a written operational plan defining responsibilities and operations available to all of your WHI Investigators and staff.
3. Delegate day-to-day authority to the Clinic Manager, with the PI maintaining close communications with her or him.
4. Pay close attention to morale of staff, particularly lead staff, and take steps to avoid burnout and staff turnover. Share time with staff, focus on successes, provide staff incentives - fun days, in-services, etc. Promote teamwork.
5. Hold routine (weekly or bi-weekly) meetings with all lead staff. If staff are not all located in the same area, take additional steps to include everyone in meetings and to keep everyone informed.
6. Identify a consulting gynecologist who can be readily available for problem-solving and decision-making.
7. Use all institutional support available, including the GCRC if appropriate.
8. Secure sufficient space for all clinic operations. If recruitment is not at goal, evaluate whether or not your space can handle goal and catch-up, particularly for DM Intervention. If it will not, initiate steps to procure additional space. Look to existing off-site space if necessary.
9. Review the overall clinic workload, including screening and follow-up activities:
   - Determine how many of each type of visit needs to be done (the Randomization Catch-up Plan is one tool for doing this).
   - Provide the corresponding number of appointment slots to each type of visit in the clinic appointment book, taking into account the no-shows, reschedules, etc.
   - Take into account lags due to holidays or vacation times. Anticipate times of poor weather, etc. that may affect clinic attendance.
   - Monitor clinic flow at least monthly and make adjustments as needed.
10. Identify rate limitations for available appointment slots:
    - If not enough women are waiting for SV0/SV1, take steps to increase initial recruitment responses. (See suggestions below under recruitment.)
    - If there is a back log of women waiting to attend screening visits, identify and address the reasons (e.g., limited space, inefficient use of space due to configuration, specifically skilled staff such as CP or gynecologist not available, lack of support staff, etc.). (See suggestions below under general and specific CC issues.) Identify appropriate person/mechanism to address issues and develop an action plan with timeline.
11. Review all correspondence (i.e., bulletins, e-mail, Fed Ex, WHI Times, conference call minutes, and IRS responses) on a regular basis. Review of monthly activity reports and QA visit reports is also crucial.

G.2.2 CC Staffing

1. Use lead staff for appropriate higher level tasks and delegate other tasks to support staff as appropriate. For example, try to avoid lead staff doing routine clerical tasks.
2. Make arrangements to cover for lead staff during times of anticipated or unanticipated leave.
3. Hire part-time staff and cross-train them to carry-out multiple CC activities.

4. Cross-train staff for flexibility of function to accommodate upcoming activities that occur at specific times and for back-up during vacations or other times.
5. Use volunteers, students, residents, fellows, etc., whenever possible. Remember to assure confidentiality in this situation.
6. For satellite sites, use different staff than at main site whenever possible.
7. Train student interviewers to work in the clinic and to be clinic assistants.
8. Train telephone interviewers to have a "smile in their voice" when talking on the phone. One clinic found it effective to buy mirrors for the interviewers to look in while on the phone.
9. Staff should always have a professional, well-dressed appearance. Wearing lab coats to increase professional appearance may work at some sites.
10. All staff should know full protocol, all changes, and why the study is important. Staff dealing with participants should also be comfortable with dispelling participant concerns and answering questions correctly.
11. Keep everyone informed and up-to-date; keep lines of communication open.
12. Offer an incentive for CC staff to work on the weekends. Solicit volunteers before requiring CC staff to work on Saturday. Provide retreats/incentives to staff who work on Saturdays. Stagger work schedules.
13. Respect stresses of other staff.
14. Consider forward-funding temporarily to handle the increased number of women resulting from your increased recruitment efforts to "catch-up" with goal.

Recruitment staff:

15. Recruitment staff should stay "in the loop" with the other clinic staff. Recruitment is integral with all SVs.
16. Use a direct mailing service or other resources for preparing mass mailings, rather than using CC lead or support staff.

CP Staff:

17. Provide RN/LPN support for tasks such as eligibility determination, symptoms screening, 6-week call, and retention activities.
18. Hire part-time CPs so that they can also maintain clinical skills at another job. Lead practitioner job requirements may require more than 50% time.
19. Use on-site CPs rather than off-site CPs whenever possible, as they are more available, particularly with regard to appointment scheduling, lab result consultation, and "hallway consultations".
20. Have some agreement regarding backup for the CP position in case of illness or vacation.
21. Cross-train other staff to cover screening and HRT activities such as functional measurements and physical measurements.
22. Have job descriptions be as accurate as possible. If a position will have a large responsibility for screening and tracking, or other non-clinical functions, say so.
23. Have CP's clerical and non-clinical work delegated as much as possible.

DM Staff:

24. Hire separate Dietary Modification and Dietary Assessment staff, if at all possible.

G.2.3 Facilities

1. Have plenty of phone lines.
2. Do not use touch-tone routing - this can be confusing to older women.
3. Staff phone calls as much as possible so that women don't always get an automated message. An answering machine should not be attached to the main recruitment line to your clinic. You may lose many potential participants who might be more likely to respond to a personal response.
4. Improve answering machine messages - call and listen to your outgoing messages occasionally (including the national 1-800#) to make sure that the messages are friendly and clear. Ensure call-backs within one week.
5. Try not to charge women for parking. If you need to charge, reimburse them fully.
6. Make sure there are clear, welcoming signs from the parking area to the clinic and that the clinic doors are well marked with WHI name and logo. Ask women if they had any problems finding the clinic and, if yes, how you could improve it.
7. Consider recruiting volunteers or students to meet participants at the parking lot or bus to escort them to the clinic.
8. Provide a success chart (e.g., poster, thermometer, etc.) in your waiting room to show where recruitment numbers are in terms of goal. Some clinics use a see-through jar or doll and add a marble or jelly bean every time a woman joins the study. When a woman joins, she moves the thermometer or adds the marble herself.
9. Put up a bulletin board with an area/state map in the waiting room with pins showing locations from where participants come. (Participants can add their own location pins.)
10. Keep reading glasses or a magnifying glass in the room at your clinic where women fill out forms.
11. Consider providing baby-sitting/elder care if feasible (permissible).
12. Use posters, pictures, plants, personal items, etc. to make the clinic a warm and inviting place to visit.
13. Ask some older women (family or friends of staff) to "walk through" the contacts with your clinic. For example, have them call your clinic phone to check out answering machine message clarity, follow your map, and locate your clinic referral agencies (i.e., your mammographer).

G.2.4 Recruitment

For examples of strategies used by successful clinics, refer to the Appendix.

G.2.4.1 General Information

1. Recruitment is a two part process: bringing potential recruits into the clinic and making sure that clinic flow can accommodate the women as they go through the screening process. Successful recruitment therefore requires teamwork between the recruitment coordinator, clinic manager, and other clinic staff. Recruitment catch-up is a clinic team effort.
2. Know your recruitment cell requirements and focus recruitment accordingly. However, don't communicate desperation to meet goals and fill the cells.
3. Always have a recruitment plan and track its success on an ongoing and frequent basis. Make changes when necessary to accommodate unsuccessful strategies. Be flexible!
4. A good system to track recruitment efforts and to follow-up with women is crucial! Keep track of how many mailing are sent out and the number of responses per week. Use this information to modify or increase mailings as needed to fill SV0/SV1 slots. Use whatever system works for you, whether it's a simple paper system or a more complex computer system specifically designed to manage and track mailings.

5. Start looking now for additional populations to recruit from - look to outlying communities for additional women, particularly for HRT.
6. Once a woman has responded by phone or mail, don't make her wait 3-4 months before getting in touch with her. Try to shorten the wait as much as possible. If there is a long wait, send her a card periodically to keep in touch and let her know you're still interested.
7. Get a special recruitment telephone line/number and have it staffed with a live person after local mailings and press releases. Get the name, address, and phone number of each caller.
8. Obtain community support as early as possible (e.g., give talks to the local medical society).
9. Hit potential recruits in 5 different ways: PSAs, mailings, community presentations, print media, telephone, etc. While mailings are the most effective recruitment method for most populations, you should attempt multiple strategies for recruitment.
10. Know your population! Check libraries, census bureau, senior organizations, etc. for relevant information and zip codes for your population.
11. Conduct periodic careful and critical review of barriers to recruitment.
12. Always remember that the women are volunteers. Be sure to treat them with complete respect.
13. It can be effective to recruit women from other studies that have ended or from other health sources, e.g., mammography lists from hospitals.
14. Don't be afraid to take risks and try new things!
15. Refer to focus group and profile of older women information provided by Porter/Novelli for ideas on, for example, how to focus recruitment messages and media habits of these women.

G.2.4.2 Mailings

1. Mailing is the most successful recruitment strategy in WHI. You need to make recruitment multi-faceted, with mailings as its base. Use mass mailing for "hard" numbers. Determine the mailing strategy that fits your budget and will give you the greatest yield for your population. That is, try different types of mailings (see below) and calculate differential response rates to determine where the balance is between minimizing cost while maximizing yield. Don't assume that less "up front" is less expensive in the end. Examples of different types of mailings include:
   - Personalized versus non-personalized mailings.
   - Mailing first class versus bulk.
   - Emphasize that "reply is important."
   - Choose which items to include in the mailing: brochure, survey, return-requested stamped envelope, pre-screen.
2. To catch-up, increase mass mailings: Mass mailing has given the highest recruitment yield for WHI to date. The CCC estimates that studywide, an increase in mailings of 50% over current mailings conducted in the VCCs would allow the VCCs to reach goals. Do second mailings with different materials. Restrict mailings to women most needed, e.g., women aged 60-79. Younger women will self-refer from other recruitment strategies. While mass mailing may not be appropriate for some lower SES racial/ethnic groups, it may still be cost effective for some middle or upper class minority women.
3. If you are not getting a good response with your mailing, look into why not. Evaluate your methods: Are the materials easy to read, attractive, clear? Do they appeal to the women in the target age? Are you mailing to appropriate areas? Mailing strategies that may enhance response:
   - Add a cover letter to the brochure
   - Change your approach letter or other materials as needed
   - Include a pre-screen or some type of interest survey (many CCs have found that this increases response rates dramatically)
   - Shorten the letter and/or increase font size (one CC found that doing this doubled their response rate!)

- Use the invitation format
- Send a letter and short information sheet (instead of brochure), if women are being "overwhelmed" with information
- Include an attractive envelope
- Consider using institutional stationary rather than WHI if you are affiliated with a locally prestigious institution
- Change from bulk to first class mail
- Sign with female rather than male investigators

4. Address commonly expressed concerns, misconceptions, and questions in the cover letter/invitation. For example, many women think they're ineligible because they're too healthy or unwilling to change their diet, go off of hormones, or replace their usual medical care.
5. Develop either in-house capabilities or contractual arrangements with a direct mailing service. Establish a "non-profit" bulk mail account and business reply account.
6. The mailing lists you use are very important. Potential sources for mailing lists are: purchased lists from professional mailing companies (e.g., AMPRO), Voter Registration mailings lists, Health Care Finance Administration (HCFA) lists, and Department of Motor Vehicles (DMV) lists. Some of these can be broken down by area/age/ethnicity. Some CCs have found that it is more cost-effective to contract out direct mailing services.
7. Be sure to use a tracking system to keep track of the yield from your mailing sources (that is, yield at each step: mail→ SV0→SV1→SV2→SV3). This is essential! This will help you plan and increase future mailings as needed, as well as help with clinic flow. Organize the number of mailings needed to keep a steady, but not overwhelming, flow of appointments.
8. Put your own address on letters or postcards for quality checks (to see if you get them).
9. Time mailings with ads in the paper, PSAs on television and radio, ads in local community newspapers, community festivals and fairs, etc.
10. Mail by zip code and coordinate mailings with community activities. Zip code mailings also help with the formation of DM groups.
11. Expand the catchment area for mailings and use mailings for outlying areas for HRT recruitment for which women do not need to come to the CC as frequently as with DM.
12. If you use a direct mailing service, check with them periodically to make sure that the GPO has delivered the correct clinic version of the study-wide WHI brochure. Do other periodic quality checks and become knowledgeable about their system.
    - When doing bulk mailings, check your local post office's regulations (regulations can vary).
    - Do regular (weekly or bi-weekly) mailings rather than bolus (all at once) mailings. Be sure that for whatever mailing method you use, you're staffed to receive responses.
13. If you are using HCFA data and the FRED recruitment data base, you may find the following information useful: The "Beneficiary Mailing Contact Address" field does not split out the city and state from the street address, which is a problem when you import the data into FRED. To ease the manipulation of this data, the following information was provided by a HCFA programmer: The Beneficiary Mailing Contact Address, positions 35-166 have the following subdivisions, all of which are 22 positions in length. This information is useful to parse the city and state from the mailing address and to sort the data.

    35-56
    57-78
    79-100
    101-122
    123-145
    146-167

G.2.4.3 Participant Materials

1. Make all materials attractive, clear, short, and simple.
2. Always use at least a 12-point font and lots of white space. Don't overwhelm participants with too much information.
3. Always do a spell-check.
4. In all recruitment materials, define and promote more clearly the benefits/advantages of participation in the WHI.
5. Consider establishing a WHI newsletter to use as a recruitment tool - available at community locations and events - as well as an item for participants. Student interns from local journalism programs can be useful in getting something like this started. Include personal profiles on WHI participants (with their permission) and clinic staff. Newsletters can go to all enrollees as well as to community areas where WHI staff go (use for recruitment, at libraries, doctors' offices, etc.).
6. Tie your cover letters and other materials in with national and local events and work in information about your population. For example, mention that it is "National Heart Disease Month", that heart disease affects all women, that it affects Black women by ... etc.
7. Here are a few of the national observances that may relate to WHI (this is not an exhaustive list - there are many other observances you may be aware of):

   American Heart Month - February
   National Nutrition Month - March
   Volunteer Week - April
   National Minority Cancer Awareness Week - April 14-20, 1996
   Older Americans Month - May
   Mother's Day - May 12th, 1996
   National High Blood Pressure Month - May
   National Osteoporosis Prevention Week - May 12-18, 1996
   National Senior Health and Fitness Day - May 31
   National Breast Cancer Awareness Month - October.

G.2.4.4 HRT/CaD Recruitment

HRT

1. Invite women who are not on hormones, even those who don't think they're interested in HRT, to a special SV0 session. Sometimes it is fear of the unknown that keep them from participating and a small amount of educating helps. It helps to have a clinician there to answer specific concerns.
2. Ask women why they are taking hormones. Older women who were originally prescribed hormones only for menopausal symptoms would be ideal candidates for a washout. Women who don't know why they are taking hormones are good candidates for washout and potential participation.
3. Increase the intensity of HRT-specific recruitment locally, by stressing the HRT component of the trial in materials and presentations.
4. Clinical Centers are encouraged to try the idea of HRT-specific recruitment in more outlying areas, since the travel demands are less for this component than for DM. Extend HRT recruitment to more rural areas. Women in rural areas are less likely to be taking HRT, and less likely to be bonded with a physician who might be giving specific advice re: whether or not to take HRT. One CC began using this strategy in June 1995 and has increased cumulative HRT recruitment from 61% (through August 1995) to 72% of goal.
5. Conduct HRT-only recruitment. Given the current discrepancies between DM and HRT recruitment, there will be an extension of HRT-only recruitment for VCCs without enhanced recruitment. It may be preferable to start this now, to gain experience in targeted HRT recruitment. Some CCs may wish to consider an HRT-only strategy for some target populations.

6. Increase knowledge of local providers. One barrier to recruitment to HRT is the prevalent opinion in the medical community, particularly among gynecologists, that the benefits of HRT outweigh risks and that virtually all women should use HRT. Clinic PIs and physicians, particularly gynecologists, might present at local physicians' organizations to get more balanced information about HRT to community providers. The S/C is circulating opinion pieces and an electronic version of slides to assist in this educational effort. Contact participant physicians who recommend their patients not take HRT to foster a working relationship with those physicians.
7. Learn women's perceptions of HRT. Several CCs have held focus groups of women who are choosing not to join the HRT. They have identified 2 groups of disinterested women: those who are on HRT and do not want to stop, and those who do not want to start because of cancer fears. There is an additional group of women who simply do not like taking pills. Encourage women to talk about their fears — by vocalizing them they may become less fearful. Don't encourage discussion in a mixed group (i.e., one where one woman's fears may create fears in others).
8. Revise recruitment materials. The studywide brochures and many CC brochures and recruitment materials are not optimal for gaining women's interest and attention specifically to the HRT. You may wish to revise your cover letter to place more emphasis on HRT. Do not re-invent the wheel - contact successful CCs for their materials.
9. Review CC staff success in interesting women in HRT. PMC and QA visitors to CCs have noticed differences in how various CC staff present the HRT to women. While there should be careful attention to honestly presenting the known benefits and risks, the staff presenting HRT should do so in an enthusiastic and knowledgeable manner. They should give potential participants the feeling that joining the HRT is a good thing overall. However, don't forget the importance of screening out women likely to be poor adherers.
10. Pitch recruitment messages to be more specific as to who should be considering the HRT program. In particular, put out a clear message that we are primarily looking for women who are not currently receiving HRT. Women who are currently on HRT and want to enter the trial need to make a decision up front that they are willing to go off HRT permanently (randomized to placebo). CCs should look at their local materials and presentation content to make sure that these messages get out very prominently. These steps will not necessarily increase HRT recruitment, but will avoid fruitless screening of large numbers who will not be interested or eligible.
11. Steps can be taken nationally and locally to change medical opinion away from misplaced enthusiasm for HRT towards more support for a trial. CCs should use doctors as message deliverers regarding HRT (most have done this already, but another round of physician education in recruitment areas to inform doctors of the study and ask for their support may be needed). In the CC, the message deliverer on HRT should also be a doctor or CP, since they will have more credibility.
12. HRT randomization yields can be improved within some CCs by looking carefully at how much and what information women are getting as they go through the screening process, and how it is delivered.
13. Use the newly-available HRT brochure during the early screening process to keep women interested in HRT until they can talk to a clinician.
14. During screening visits, deal with the myths about HRT. Consider having a knowledgeable medical professional give the SV0 presentation on risks and benefits, reasons why the HRT arm of WHI is important, and how closely they'll be monitored. Or, target SV1s to those interested in HRT and have a clinic practitioner talk to them early. Examples of information to cover:
    - We're looking at hard endpoints (coronary heart disease) rather than the surrogate endpoints (lipid levels) used at in other studies.
    - We need more information about the effect of taking estrogen combined with progestin - most other studies have looked at estrogen only.
    - Observational studies compare healthy women with less healthy women.
    - No data are available for women starting hormone replacement therapy at older ages.
    - We need more information about the risks and benefits of long-term hormone use.

- Stress the importance of HRT, the lack of conclusive research in the area, and helping future generations of women.
- Deal with misconceptions about risks.

15. As much as possible, try to offer one on one time with women to explain what they might expect (e.g., bleeding, breast tenderness, etc.). Many don't understand blinding, are afraid of risks, or are afraid of side effects; have materials ready to counter these concerns.
16. Wash-outs: consider whether HRT washouts are worth the time and effort. They may have a very low yield to eventual HRT randomization. To help screen out women, you can run a report to find out who is on HRT:
    - If you use *Form 3*:
    - Are you currently taking female hormones?
      Version 1 - field order 38, Question number 18.2
      Version 2 - field order 22, Question number 17.1
      Version 3 - field order 18, Question 17.1
    - If you use *Form 2*:
    - Are you currently taking female hormones?
      Version 3 - filed order 18, Question number 17.1
      Have you ever taken female hormones?
      Version 3 - field order 17, Question number 17
    - The information about how to do a batch extract can be found in: *WHI Manuals, Volume 5 - Data System.*

CaD

1. Briefly discuss the CaD trial as early as the SV0 so women will be aware of the study when it is offered at AV1.
2. Be prepared to take additional time when recruiting older participants for the CaD trial.
3. Apply the information learned from HRT "good adherers" to recruitment for the CaD trial.
4. In the AV1 packet mailed to participants, include the model "Invitation to Join the Calcium and Vitamin D Program of the WHI" (*Volume 2, Section E5.11*) and the CaD consent. Include information in this packet about reading the CaD consent before the scheduled clinic visit
5. Consider a session similar to SV0 for CaD. Invite women, even those who don't think they're interested.
6. To relieve any stress the participant may be experiencing during the AV1, draw the blood sample and give the snack before offering her participation in the CaD trial.
7. Present the CaD trial in a positive manner.
8. Emphasize the scientific need for the study (e.g., to gain answers about the effects of calcium and vitamin D on fractures and colorectal cancer, which are major concerns in women's health.
9. Emphasize how each participant can help to contribute to the goal by participating in the CaD trial.
10. Be aware of trends in your area for incidence of osteoporosis, hip fractures, and colorectal cancers, particularly in women. You can use these data to further stress the need for the CaD trial in your area.
11. Spend a lot of time on the presentation of the CaD consent.
12. Discuss the possibility of gastrointestinal (GI) symptoms to inform and screen women before they agree to participate in the CaD trial. [In discussing these issues, one CC reports that a high percentage of women stop their CaD trial pills because of GI symptoms. At this CC, if a participant reports already having GI symptoms, CaD participation is not offered (for example, if a woman says she is frequently constipated, it is suggested that she not join the CaD trial). Other reasons for declining randomization or stopping study pills include: not liking to take pills, not liking the taste, not remembering to take the pills—The new swallowable formulation should help with these issues.]
13. Stress to a participant that they do not have to stop taking their own supplements to join the CaD trial.
14. Always offer the taste test. ***It helps!***

15. If a participant feels the CaD study pills are too big, give her the feedback that she can break or crush the chewable pills or cut the new swallowable pills to reduce their size (as long as the "whole" pill is taken).
16. Show the participant the size of the CaD chewable **bottle(s)** before she makes the decision about joining the CaD trial.
17. Give the participant plenty of time to ask questions and discuss concerns about CaD.
18. Use the "CaD Questions and Answers for CC Staff "in the WHI Procedures manual (*Volume 2, Section G1.1*) to guide answering questions the participant may have.
19. Provide a nice, heavy tote bag at the AV1. Explain to the participant that this bag can be used for storing her empty CaD bottles. Emphasize the importance of returning all used and unused CaD bottles to the CC.

G.2.4.5 Older Women

1. To recruit older women, use a shorter letter with larger font type for ease of readability.
2. Mailings are probably your best strategy for recruiting older women. Older women take mail more seriously than younger women who receive a lot of junk mail. Many older women like to read their mail and to fill in forms (if they are readable).
3. Try to use mailing lists that are age-sorted, so that you can concentrate your mailings on the older population. One advantage of using HCFA lists is that the women listed are all over 65. Some CCs have found that HCFA lists contain many names not found on purchased lists.
4. Older women may be reluctant to use phone machines; try to have a person answering the phone whenever possible. Do not have a complicated menu system that could confuse women.
5. One clinic found that adding a printed message (e.g., "Your reply is requested" or "Your response is important") to the outside of the mailed envelope prompted a better response.

G.2.4.6 Minorities

1. While mailings are the best recruitment tool in general for all populations, recruiting minorities usually requires additional efforts and a multi-faceted approach. This includes outreach activities (which are very labor intensive), a partnership with the minority community, and the need to reassure potential participants who have suspicions about research. Use a combination of approaches in concert, so that if a specific geographic area is targeted for recruitment, several approaches are directed to that area.
2. Time mailings with ads in papers, ads in local community newspapers, festivals, etc.
3. Blind mailings don't work as well in minority populations - target mailings to areas where you've already done presentations. Place ads in local community publications. Mailings should be used as a follow-up after a personal contact has been made. Only conduct mailings after you've established a presence in the community.
4. When you do direct mailing, use letterhead paper and/or accompany the mailing with an endorsement from a member of a respected community organization.
5. Tie in letters with existing events, like the "National" of the month (National Heart Disease Month, National Black History Month) and make it relevant for the population you are recruiting. For example, during "National Heart Disease Month", mention statistics about heart disease and African-American women in your cover letter to that population.
6. Purchased mailing lists and voter registration lists in some areas will show ethnicity by precinct, which can help target your activities.
7. Target special groups like alumni at Black or Hispanic women's colleges, members of sororities, community centers, and religious organizations. Work with leaders in the ethnic communities. Other potential partnerships - commissions for women, hospitals, AARP at the local level, radio shows, grocery stores, book stores, libraries, and the National Council on Aging.
8. Minority women are generally quite willing to participate. They often say "the reason I've never participated is that no one has ever asked", so stress the importance of their inclusion in this particular

study. Talk about the study as being inclusive - not separate, but equal. Mention that this is an important opportunity for us to learn about health issues in groups under-represented in previous research.

9. Attend community events and set up booths where individuals can meet and talk with you about the study.
10. Take advantage of current participants to recruit their peers (friends and relatives) after they have attended a successful WHI visit.
11. Keep in mind that minority does not mean low income or low education.
12. Develop a partnership with the community you're recruiting from. Look at the area and know the history - look at innovative approaches and other studies approaching minorities.
13. Churches in African-American communities have sometimes been saturated by other research studies and may feel used by the research community. It is important to be sensitive to this issue in minority communities and with related organizations.
14. Many African-American children live with grandparents - information can sometimes be sent through children.
15. Keep in mind that the Hispanic culture places a lot of importance on the family unit.
16. Consult with outside expertise and other studies targeting specific minorities.

G.2.4.7 Transportation

1. Transportation can be a big barrier to participation for some women, especially older women who may not want to drive themselves. Try to provide transportation if appropriate in your area. Examples of how this can be done: use volunteers, hire a van service to shuttle participants, work with churches and other community organizations to borrow their vans, or reimburse participants for mass transportation costs.
2. Don't make participants pay for their own parking - have a system of reimbursement.
3. One clinic came up with the "STAT - Saturn Transportation Assistance Team" program:
   - Saturn dealership partnership - working with the dealership, they recruited 40 retired recent Saturn car buyers to drive women back and forth to the clinic.
   - Volunteer drivers have their own liability insurance and pay for their own gas.
   - Drivers have a WHI training/orientation workshop.
   - Drivers are recruited by the Saturn dealership.
4. Provide clear, detailed maps and try following them yourself.
5. If mass transportation is available in your area, provide clear directions in terms of bus or subway numbers, timetables (if available), and other relevant information.

G.2.4.8 Incentives

1. Incentives can increase bonding, show appreciation, and make a participant feel important. Design incentives to celebrate milestones; advertise to the rest of the community; increase identification with the study; and increase awareness of the study in the community. While incentives are not the only answer to recruitment or retention, they do convey to the participant that she is valued and appreciated.
2. Work with local corporate sponsors. If you receive an endorsement from a company or product, NIH and WHI should not appear to endorse a company or product. Therefore, WHI incentives cannot bear both the WHI logo and a company name or logo, since this creates the appearance of endorsement. Use either the WHI logo or the company logo alone.
3. Many clinics have purchased small, inexpensive recruitment and/or retention incentives. Examples of these include:

   Bookmarks; Flower/vegetable seed packets; Gardening information; Magnifying rulers; Lapel pins (with the WHI logo to advertise the study to other potential participants); Perpetual calendars useful

for noting return visits, mammograms, BSE, gyn appointments, etc.; Lighted key chains; Tote bags; T-shirts; Recipe boxes; Pot holders; Jar grippers; Pill boxes; Fans; Shopping list pads; License plate frames; Pantiliners; Jewelry; Aprons; Wooden/plastic spoons; Scented soaps; Pens and pencils with WHI logo; Set of stickers for calendars to remind participants to do monthly breast exams, etc.

4. Whenever possible, try to include the WHI logo on incentives.

5. Market research shows that older women like to send and receive greeting cards. Send cards: birthday cards (provided by CCC), holiday cards, and sympathy cards. Also, try to send thank you cards after screening visits.
6. Design a chamber of commerce type packet that lists sites (e.g., museums, places to shop, etc.) near the clinic to visit.
7. Plan events as incentives: do fun things like luncheons, fashion shows, clinic "birthdays" or anniversaries. Send invitations and have a real celebration.
8. Develop a coupon book to coordinate with the participant ID cards women receive when they join the study. In the booklet, include places like the YWCA, Video Stores, bottled water companies, beauty parlors, restaurants, coffee or tea shops, etc. Some of the coupons could be used for discounts and others could "buy one get one free".
9. Organize a "Name-A-Friend" campaign and provide incentives (e.g., pins, gift certificates, etc.) to women who refer friends who are randomized.
10. Develop a gift catalogue with an array of inexpensive gifts for women to choose from.
11. Evaluate use of incentives. Some populations may prefer that research money be spent on research rather than something they perceive as a trinket.
12. Use the market research from P/N for incentive ideas. For example, their profile on older women shows that many women like to garden, visit museums, read, buy lottery tickets, volunteer, and send/receive greeting cards.

G.2.4.9 Volunteers/Spokespersons

1. Enlist participants to help in recruitment. Design and use materials and incentives to encourage peer recruitment, such as the "Name-A-Friend" program, in which a participant receives a gift or gift certificate for every friend she recommends who joins the study, and "Dear Friend" postcards to send to family and friends. Consider bringing an articulate participant to an SV0, so that she can give a personal testimonial of her decision (for example) to join the HRT.
2. Use volunteers from the community or set up an advisory board of diverse members, including business people.
3. Use volunteers, e.g., students, retired persons, employees from local businesses, members of the community, and study participants to help recruit, stuff mailings, sort and copy materials, etc. Involve current participants in follow-up activities, e.g., phone call reminders and possible carpooling of new and current recruits. Volunteers can also serve as participant advocates, guiding them through the screening process to the end of the study.
4. Set up a recognition program with commendations suitable for businesses, organizations, and participant recruiters. Hold parties to show appreciation. For participants, set up an Ambassador's Club and hold parties, women's breakfast health talks, etc.
5. Use current participants for testimonials and media quotes, photo opportunities and possible speaking engagements, and in SV0s/presentations, as appropriate. Also look at women in your recruitment pipeline: these women can be a gold mine (e.g., one clinic had their state representative's mother and their state's Attorney General's mother in their pipeline).
6. Take time to train volunteers!
7. Find out if your volunteers have special skills that can be put to use. For example, you may find someone with marketing and journalism experience to help create a local newsletter to keep other volunteers (and/or participants) updated.

G.2.4.10 Community Outreach

1. In addition to mailings, community outreach can be essential to recruitment, especially for minority clinics. As one RC put it, you can't have the attitude "build it and they will come".

2. Develop partnerships with local organizations like libraries, bookstores, greeting card shops, etc. They can be helpful in providing free items or donations. They may also allow you to place brochures and set up displays. Some ideas for brochure placement and outreach:

   Bookstores; libraries; pharmacies; grocery stores; hospital lobbies; doctors' offices; drug stores; government agencies; beauty shops; restaurants; senior centers; community activities centers; churches; community and local business health fairs.

3. When working to place brochures, consider working with the organization rather than individual locations. For example, one CC attended a pharmacists' association meeting and was able to place thousands of brochures by getting each pharmacist to take a bunch back to his/her individual pharmacy. Another CC had similar luck with placing brochures in all Walgreen's locations.
4. It is a worthwhile investment to purchase nice holders for the brochures you place in the community; it is easier to keep them stocked and hold them in place.
5. Prepare educational handouts for lay and professional meetings.
6. Obtain schedules of community events (health fairs, women's organizations, senior groups, clubs, etc.) to ensure getting on their planning calendars.
7. Work with major sororities and leaders in African-, Hispanic-, and Asian-American communities, church groups, health care professionals, hospitals, civic groups, and national senior organizations.
8. Work with organizations and chains at the local level - develop targeted messages for your own population.
9. Other ideas and sources for outreach and advertisement: community screenings, billboards, bus signs, park bench signs, newspapers, and fashion show lunches (e.g., get permission to place brochures on chairs beforehand).
10. Organize outreach efforts by setting up an advisory group; clarify roles for members. Try and get activities supported and sponsored by budgets of other organizations - advisory group members can be helpful with this. To help set up an advisory group, host a lunch for community leaders. Be sure to include business leaders (i.e., don't include only academic types). Choose people with connections who can network. Include influential people from your target populations (e.g., Hispanic) who can write letters of support.
11. List of organizations you may want to consider contacting for alliance building:
    Older Women's League
    National Women's Health Network
    National Council of Negro Women
    American Dietetic Association
    Cancer Care
    American Cancer Society
    Coalition of Hispanic Health and Human Services Organizations
    National Asian Women's Health Organization
    Society for the Advancement of Women's Health Research
    YWCA
    National Osteoporosis Foundation
    National Lesbian and Gay Health Association
    Women's League of Conservative Judaism
    National Black Nurses Association
    Women Veterans Health Programs
    Center for Women Policy Studies

G.2.4.11 Media

1. Establish relationships with your in-house marketing personnel to communicate with local media (TV, radio, print).

2. Work on local media relationships. Call the health writer/reporter at your paper.
3. Arrange for featured news stories (radio and television) and articles (newspapers/newsletters).
4. Meet with the editorial board of the local paper for editorial promotion.
5. Develop a local press release. Prepare media updates, news conferences, news briefings, and media advisories.
6. Take advantage of radio and television on a local level. Arrange for Public Service Announcements on television and radio. Establish personal contact and follow-up with television and radio PSA station representatives. Be sure to clearly identify any materials sent to stations.
7. Arrange for morning news show appearances (radio and television).
8. Some sites have been successful in getting spots on the "Home Shopping Network."

G.2.4.12 Health Care Providers

1. Health care providers can be useful for recruitment:
   - Credible source of health information for women
   - Focus group results show women want to hear about WHI from health professionals
   - Other studies show that women rely on their physicians to recommend mammograms and other health tests
   - Important source of referral for WHI
2. Health care professionals are a good referral source: physicians are influential with women 50+. Groups to target include: General/family practitioners, Internists, Gynecologists, Nurses, Nurse Practitioners, Physician Assistants, Gerontologists, minority health care providers, chiropractors, state/local health departments, and community health centers/clinics.
3. Strategies: Hold seminars or set-up exhibits at regional/local meetings; attend hospital grand rounds; maintain contact by distributing WHI Updates, "Dear Friend" postcards, recruitment and HRT brochures, recruitment and informed consent videotapes, posters, buttons, displays.
4. Work through local chapters of national health care professional organizations:

   American Academy of Family Physicians; American College of Physicians; American Medical Association; American College of Obstetricians and Gynecologists; American Medical Women's Association; American Osteopathic Association; American Society of Internal Medicine; National Rural Health Association; American Nurses Association; American Academy of Nurse practitioners; Association of Women's Health, Obstetric and Neonatal Nurses, American Academy of Physician Assistants.
5. Minority health groups:

   Association of American Indian Physicians; Association of Asian/Pacific Community Health Organization; National Medical Association; National Black Nurses Association; American Indian Health Care Association; InterAmerican College of Physicians and Surgeons; National Hispanic Nurses Association; National Coalition of Hispanic Health and Human Services Organizations.
6. Other professional associations:

   Association of State and Territorial Health Officials; National Association of Community Health Centers; National Association of County and City Health Officials; American Public Health Association; American Center Society; American Heart Association; American Dietetic Association; Gerontological Society of America; Nation Hispanic Council on Aging; National Association of Area Agencies on Aging.

G.2.5 Participant Scheduling

G.2.5.1 Clinic Hours and Staffing

1. Do what it takes to get the women in. Offer 7:30 A.M. appointments, Saturdays, evenings, etc. Saturday appointments can be important for working women who can't come in during the week. Having Saturday visits addresses child care issues as well as work issues.
2. To help Saturday appointment show rates, let participants know that these are prime appointment slots and that it's important to show up. Do reminder calls and reschedule in the event of a cancellation, keep a waiting list for those wanting appointments. Encourage participants to "make a day of it" - provide them with information about what's going on in the area.
3. To maximize scheduling for screening and follow-up visits, consider staffing your CC so there are some non-routine scheduling times available (e.g., one late evening available for women who may not be able to schedule during the 8:00 to 5:00 routine). Non-routine schedules would probably work better for those visits that require the most time, i.e., SV0, SV1.
4. Schedule SV1s early in the morning (e.g., between 7:00 - 9:00) so participants have the option of coming to the CC early to complete the required visit tasks and can still get to work on time.
5. Schedule screening and follow-up visits four days of the routine week (Monday through Friday). Use the fifth day for " catch-up" clinic activities, all-staff meetings, etc.
6. Keep in mind that it is easier to schedule appointments, process lab results, and have more routine communications with on-site than off-site Clinic Practitioners.
7. To accommodate Saturday visits, consider staggering the staff so that some work from Monday-Friday and some work Tuesday-Saturday.
8. To minimize the clinic burden on Saturday, conduct only one type of screening visit, unless you have the available staff to do more.

G.2.5.2 Making Appointments

1. When scheduling participants, offer the participant two to four predetermined (by CC staff) visit times, rather than asking participants what time is convenient for them.
2. Schedule follow-up semi-annual or annual visits when the participant is leaving the CC. Tell them that you will be reminding them of the upcoming visits and that they can change it then if necessary.
3. To help reduce the number of no-shows, emphasize the importance of keeping the appointment - do not over-emphasize that they can change the appointment at any time.
4. Schedule a block of SV1s at the same time and offer a group consent presentation.
5. To off-set cancellations, calculate your "no show" and "cancel" ratio and overbook SV0/SV1 screening visits accordingly.
6. Over-book clinic visits if your CC has a high no-show or reschedule rate. Review other CCs' strategies for coping with no-shows or reschedules. Pay attention to no-show rate and overbook by that much; if you don't get the cancellations, call and cancel the overbooked women. If you do this, you need the space and staff to accommodate this strategy (e.g., someone to take responsibility for overbooking and watching cancellations).
7. Stress to women that these slots are at a premium.
8. Always give potential CT participants priority over OS participants when scheduling screening visits (i.e., fill slots first with potential CT and remaining slots with OS.)

G.2.5.3 Message to Participants

1. Ensure that the reasons for unusual screening times are communicated directly to participants. For example, if you offer a Saturday screening visit to a participant, make sure she understands that she may not be offered the opportunity of scheduling her follow-up clinic visits on Saturday for the duration of the study.
2. Remind participants of a scheduled visit at least 48 hours before a scheduled visit or mail a reminder at least one week before a scheduled visit.
3. Instead of leaving a message on an answering machine as a reminder of a scheduled clinic visit, keep calling until a personal contact is made with the participant, if at all possible. Positive results using this system have been reported.
4. Remind women to drink lots of water during their 12 hours of fasting before their blood draw.
5. Promise and provide incentives for women making their follow-up visits.

G.2.5.4 Schedule Tracking

1. Establish a scheduling system, including checklists and sequences for different individuals that are to perform tasks at specified screening/follow-up visits (e.g., lab, ECG, medication inventory, etc.).
2. Establish manual or computer tracking or tickler system for maintaining the status of pending appointments, temporary ineligibles, and rescheduled appointments.
3. Ensure available slots for screening and follow-up visits are filled appropriately so available CC staff resources are maximally used.
4. Arrange for mammogram appointments and/or report gathering early (SV1) in the screening process. Delays and other situations (needing to provide more enrollment pills) may be avoided by knowing the results of the mammogram early.

G.2.6 Clinic Flow

1. Concentrate on CT participants, not OS participants. Do not bring in OS only women for SV1s unless you are at your cumulative goal for the CT or have a late cancellation.
2. Evaluate where loss of participants occurs during the screening process and take steps to reduce these or move reasons for ineligibility to earlier in the screening process, if possible, to minimize late (i.e., SV2, SV3) losses.
3. Perform only the required tasks on participants. For example, do not perform tasks on OS women that are only required for CT participants.
4. Use group visits where possible, for example, for SV0s, SV1s, and 4DFR instruction, to minimize staff time needed to complete tasks at these contacts.
5. Instead of one person performing multiple activities at a group SV1, “specialize” CC staff so one person is assigned one activity (e.g., one staff person performs all weight and height measurements, one staff person performing all the resting pulse and blood pressure measurements, etc.).
6. Lead staff should know the clinic process within their own clinic (e.g., flow between SV0, SV1, SV2, SV3).
7. Always think about ways to streamline screening and follow-up activities.
8. If an HRT or CaD participant is a compliant participant, consider dispensing a year’s worth of HRT pills, making the 6-month clinic visit optional after year 1. This will free up precious clinic slots for more SVs!
9. Watch for and handle bottlenecks with gynecological procedures at SV2. If you have an outside gynecologist performing pelvics, Pap smears, or endometrial aspirations, be sure they are available for a sufficient amount of time to keep screening visits flowing. If there is a bottleneck, ask your gynecologist to increase available slots, or consider getting additional gynecology assistance.
10. Cross-train staff so that more staff are available to do screening procedures.

11. Make detailed day-to-day plans for how you will handle the increased screening visits that will result from increased mailings. If you are trying to "catch-up", concentrate your recruitment efforts up front: don't spread mailings out over the remaining months of recruitment. Consider forward funding to increase staffing at this crucial time. You want to be sure to have enough SV slots to accommodate interested women, once you find them. Recalculate randomizations needed per month to catch up, and work back from there to calculate how many SV0s/SV1s you need, and how many mailings (or other recruitment activities) you need from now on.
12. Have a good follow-up system - avoid losing women at SV0s, SV1s, SV2s, etc. Check reports for women who don't show up for a visit.
13. Plan to end SV1s earlier than projected to accommodate holidays, bad weather, etc.

SV0:

14. Conduct SV0s. Many CCs have been finding the SV0 to be a useful tool for describing the HRT in full and answering women's' questions, which saves time at SV1s. If feasible, plan large-group SV0s (up to 100 women) to minimize recruitment staff hours. Be sure to provide clerical assistance to recruitment coordinators if large SV0s are held. Having a clinician available at the SV0 to answer HRT questions is very helpful.
15. Offer an SV0 on a scheduled Saturday each month or offer alternating Saturdays each month to maximize clinic availability.
16. If doing SV0s, you may want to send the FFQ ahead of time. You can screen for eligibility beforehand and go over incomplete forms during the SV0. If you do SV0s with large groups of women, keep in mind that large numbers of FFQs will then need to be scanned.
17. If the CC does not have available space for scheduling a large group of participants on-site for a SV0, consider securing available space off-site.
18. Start early planning for remote SV0s.

HRT:

- Ask women what their own health care provider would think about them joining the HRT and/or CaD. If they think that the provider would respond in a negative tone, ask if you can contact the provider.
- Ask prior to randomization how they would feel if they thought they had been randomized to placebo (or active) pill and had to take them for 10 years. Would they be disappointed and want to change?
- Ask the woman how she would cope with bleeding or spotting, given the likelihood that it will occur. Also ask how she will cope with chewing two tablets of CaD daily for 10 years.
- To avoid adherence problems during the enrollment period, remind women to call the CC to report a lost bottle, problem with the pills, or other situations that would prevent them from taking the required number of pills.

Gynecology Procedures:

- Have multiple types of equipment ready and available for endometrial aspirations (EA). Some useful equipment mentioned: Lacrimal duct probes, the Os Finder, Hegar dilators, nontraumatic tenacula, Hurricaine gel.
- Schedule a longer appointment time for older women. Exams and procedures generally take longer.
- If the pathology reports returns with "insufficient material" or "no endometrial material seen", and the recorded depth of sound is less than 4.5 cm, a repeat aspiration should be attempted.
- Have samples of panty liners and pads available for women after their EA and for their future use if they should bleed and need to buy pads on their own.
- Develop a good working relationship with your consulting gynecologist. Make sure that they are familiar with protocols and algorithms by reviewing the Consulting Gynecologists Handbook with them.
- Warm water or a small amount of KY lubricant on the tip of the speculum will help entry into the vagina.

- If you are using a paracervical anesthesia and need to use a tenaculum, raise a small bleb of anesthesia on the cervical surface where you can attach the tenaculum.
- Silver nitrate sticks can be helpful in stopping bleeding from tenacula tines.

DM:

1. Maximize efficiency of CC staff and schedule group 4DFR instruction for DM participants.
2. When scheduling participants into DM intervention groups, offer the participant two to four predetermined (by CC staff) group meeting times, rather than asking participants when it is convenient for them to be in a group.
3. Consider extending the required time for the screening visit and collapsing SV1/SV2 into one screening visit for DM participants.
4. Maximize CC staff efficiency when scheduling HRT+DM participants. For example, schedule two HRT/DM participants before two DM-only participants for SV2. First, perform the tasks for the two HRT SV2, then provide the 4DFR instruction for the HRT/DM and the DM-only participants as a group.
5. Administration of FFQ: Administer FFQ at SV0 and ask participants to complete FFQ at SV0. For FFQ review, certify students to review FFQs and phone participants for additional information as needed.
6. Include groups of 2-4 participants at a time for Four-Day Food Record Instruction at SV2 to conserve staff resources.
7. Have lead nutritionist for dietary assessment hold periodic meetings with the Nutrition Team to discuss how to identify and handle different types of problem participants during the screening program.
8. Have the lead nutritionist for dietary assessment review all DM SV2 screening notes before the participant's SV3. Identify any DM participant with potential problem areas. Have nutrition staff meet as a team on a weekly basis to discuss any DM participants identified at SV2 as having potential problems or unresolved issues. Develop a plan of action for each DM participant including dietary assessment staff members phoning participants before their SV3s for follow-up.

Follow-Up:

1. When you schedule annual follow-up visits, take into account that the SV1 and the annual follow-up visit slots cannot be used interchangeably. It is reported that annual follow-up visits generally take longer, particularly for conducting the activities for CaD participation and for allowing additional time for any clinic-specific activities.
2. When planning the clinic schedules for the semi-annual and annual follow-up visits, consider the clinic resources and the type of follow-up visit scheduled (e.g., will one PC suffice for all of the scheduled follow-up clinic visits that will include HRT and CaD dispensations).

G.2.7 Data Management

1. Cross-train other staff in data entry. Examples include nutritional data entry by LNs, medication and supplement entry by SV1 interviewer. Hold regular in-services for staff to train them in using WHILMA, reading reports, etc.
2. Train all key staff in sending and receiving e-mail and encourage its use. Try to avoid having one person responsible for checking others' e-mail. E-mail communication is less expensive than phone, fax or mail; it's free to the Clinical Centers.
3. Use WHILMA whenever possible for tracking purposes. Avoid secondary data systems that require duplicate entry. Consider using the (optional) WHILMA scheduling system.
4. Create a notebook with samples of all WHILMA reports for all staff to use as a reference.
5. Create a "report schedule" for your clinical center. Include reports that need to be run for tracking and QA purposes and indicate how often they should be run and to whom they should be given.
6. Set reports to run overnight whenever possible (especially those that take longer to run) so that work stations can be used for data entry during the day. Use the WHILMA batch reporting feature for visit plans, personal information update reports, and *Form 33* labels.

G.2.8 Outcomes

1. Organize a system to track multiple steps in the outcomes process—KEEP IT SIMPLE.
2. Establish a participant outcomes file. Keep it separate from the participant's routine clinic file.
3. Establish a rapport with hospital medical records personnel you will have contact with on a regular basis.
4. Develop a working relationship with your physician adjudicator(s).
5. Use CC staff expertise.
6. Delegate filing for outcomes files.
7. Recognize that adjudication case packets may only be assembled and completed by the outcomes specialist.
8. Emphasize that outcomes is a team activity.

G.2.9 Retention

1. Retention begins with the very first contact a woman has with the clinic.
2. To build identification with the study throughout recruitment and follow-up, use materials provided by the CCC: birthday cards, health brochures, BSE card, magnet, mugs, folders, bags, cups/spoons (DM intervention), pill holders (HRT/CaD), ID card, HRT handbook, "Welcome to" sheets.
3. Put together a retention package to encourage women to stay with the study and to show our appreciation. The packet can include the CCC-provided incentive, other health education materials, and local incentive materials, such as a certificate expressing appreciation. You may want to put together an incentive list and provide different incentives at specific milestones, such as 1 or 5 year anniversaries.
4. Ideas for retention incentives (for other ideas on specific incentive items, refer to "Incentives"):
   - If women make all of their appointments, put their name in for a prize drawing
   - Annual parties (keeping DM Intervention and Control women separate)
   - Greeting cards: sympathy, holiday, thank you, birthday
   - Certificates that are updated annually with stickers (perhaps with prizes at the end for X number of completed visits)
   - Drawings each month with the names of women who came in for visits that month
   - Sticker reminders about appointment times to place on calendar at home
   - Gift certificates for small items, like free lattes at local Starbuck's.
5. Keep in mind that sometimes women come back after dropping out (close-out). Keep names and labels of close-outs and plan for recontacts after suitable interval (see Section 17).
6. Wallet-size reminder cards can be very effective for helping participants remember annual visits and other appointments.
7. Have the participant fill out her own reminder postcard at the time of randomization. For example, have a postcard that the participant completes at randomization saying "Where I think I'll be in one year" or "What I hope to achieve in the next year", etc. and send that card to her in one year as her visit reminder.
8. Watch for early warning signs of a person who may not stay in the study. Red flags include: history of substance abuse or mental illness; cancellations or no-shows early in the screening process; minimal compliance; strong negative feelings about WHI or specific intervention (e.g., HRT); large distance between home and clinic (for DM particularly); family members against participation; lack of back-up transportation; history of stopping hormones in the past; non-adherence; women looking for free health care, medications, or for a weight loss program.

G.2.10 Adherence

General

- Designate an Adherence/Retention Specialist, preferably one who is very organized.

- Organize a retention committee (if you don't have one) and meet at least monthly.

HRT

- Provide a letter to the participant's primary care provider at baseline to help inform the provider about WHI and its goals, to define the patient's role and responsibilities in WHI, and to solicit support for encouraging his/her patient to stay with the study. In addition, chart stickers for the physician's file which remind the provider of the patient's participation could be sent with the letter. A set of model letters are available in Vol. 2, *Appendix E.1.1 - Model Letter to Community Health Care Provider, E.1.4 – Model Letter to HRT Participant Health Care Provider*, and *E.1.5 – Model Letter sent with Chart Labels to Health Care Providers*. Chart stickers can be ordered in the regular quarterly orders from the CCC. See *Appendix F.4.1 – Chart Labels* for examples of the chart labels.
- Provide annual letters to the participant's primary care provider (PCP) to remind the provider about her participation in WHI, the goals of the study, and ways to support the goals (as above). CC staff are also encouraged to confirm with the participant who her PCP is at each visit and to update the information as needed. When participants change their PCP, send letters with the participant chart labels to the new PCP.
- Use the neon study pill bottle labels to remind participant of the need to return study pill bottles at their next clinic visit. These can be ordered with the regular forms and supply orders.
- Use an appointment card/information sheet at each clinic visit to help prepare participants for what to expect at their next visit. See examples in Vol. 2, *Appendix E.3.2.8 - Model Appointment Card* and *Appendix E.3.4 – Model Follow-up Appointment Reminder Letter*.
- Have regular and updated discussions between staff and investigators regarding recent media "events" that may impact participants' attitudes toward WHI and the HRT study. At the meetings, ensure that an investigator knowledgeable about the media event is available to discuss the information with the staff. These discussions can be done at regular staff meetings.
- Educate CC staff on HRT and related matters to ensure concise and consistent information is given to participants. See the HRT Question and Answer script for CC staff (Vol. 2, *Appendix G.1.2*). This provides standard WHI answers to frequently asked questions, or potentially sensitive issues.
- Educate participants during screening and follow-up on potential side-effects, such as bleeding and breast tenderness, to prepare women for what to expect in the study and decrease drop-outs from fear and lack of knowledge. Include information about the incidence of these symptoms and that the CC has the ability to evaluate and ensure the safety of the woman and to work with her to help decrease these side-effects. See material in *Vol. 2, Sections 4.3 - SV2, 4.4 – SV3, 5.4.1.2 – Participant's Reporting of Minor Symptoms*, and *Appendix F.3.2 - HRT Handbook*.
- Provide participants in need of care with a list of resources in a variety of fields. If a participant does not have her own primary care provider, it is helpful for the CC to have a list of providers the participant could see. Requirements for immediate and urgent referrals for a variety of physical measurements, tests, and conditions are listed in Vol. 1, *Section 5.5.5 – Notifications*. Other conditions and symptoms referral suggestions can be found in Vol. 2, *Section 5.4 – Managing Symptoms*.

CaD

1. One CC reports using a case management approach. This means CC staff take "ownership" of a CaD participant and any problems that may arise during the course of the study. One CC ensures the same staff person that randomizes the CaD participant is the same staff person that completes her follow-up contacts, including the 4-week phone call.
2. Promptly return phone messages from a participant. Be VERY attentive to a participant's problems when you talk with her.
3. Let the participant know you are interested in problems she might experience when taking the CaD trial pills and that there are options to help her continue to take study pills.

4. Make it a high priority to complete all 4-week CaD phone calls ON TIME.
5. Have a designated staff person do all of the 4-week CaD phone calls.
6. Give pill dispensers freely and include a full discussion of how they can help.
7. Emphasize the importance of keeping track of the CaD bottles and returning them at the next clinic visit (for example, point out the label on the bottle and the need to scan it in using the computer's scan gun). In annual visit reminder letters, emphasize the importance of returning the CaD bottle to the visit.
8. Give the participant a pre-stamped envelope to use for mailing the CaD bottles to the CC if she is not coming for a routine contact.
9. When assessing a participant's low adherence, inquire if either the AM or PM dose is a problem for her to remember. Resolve problem accordingly (e.g., suggest keeping the AM/PM doses in separate pill dispensers).
10. For women who forget to routinely take their study pills, let them know they can take the two CaD trial pills at the same time.
11. If a participant is experiencing an illness or crisis in her family and wants to stop study pills or drop out because of the life event, offer her the option of temporarily (e.g., one to three months) discontinuing study pills.
12. For addressing reported side effects, try using the "step-down" approach. Offer a step down to one pill per day, and if necessary, to a short time (e.g., one month) off study pills. Since relief from CaD side effects is usually fast, you can often get women to go back on their CaD trial pills. When adherence issues begin to resolve, encourage the participant to gradually step back to the standard CaD regimen if possible (e.g., take only one pill per day initially and, over time, increase the dose to two pills a day. Maintain a consistent tracking schedule for checking on the participant to see how she is doing during a symptom management period.
13. If side effects are experienced, one CC reports asking the participant to cut down on her own CaD intake versus reducing her intake of CaD intake for WHI.
14. Offer the swallowable formulation (when it becomes available) if a participant is having problems with the chewable formulation.
15. Offer the swallowable formulation (when it becomes available) to participants that may travel a lot. The swallowable pills will be easier to carry around as they and the pill bottles will be smaller.
16. Assess staff attitudes towards and questions about the CaD trial. Frustrations about individual participant's adherence rates may show through to other staff or participants. Talk enthusiastically to staff about the importance of the CaD trial.
17. Consider some CaD adherence efforts targeted specifically to HRT, DM intervention or DM comparison group participant issues. The nutrition staff at one CC is working on a handout for DM intervention participants to explain the study pill regimen (e.g., appropriate foods to take with their pills). [Note: All locally developed CC materials must be sent to the CCC for approval prior to their distribution to participants.]
18. If your CC promotes regional events, consider having the Clinic Practitioner attend to further bond with the CT participants, including the CaD participants.

DM

Self-Monitoring

A. Methods to encourage women to use the self-monitoring tools in their own self-management:

- Establish a need: emphasize to participants how self-monitoring serves them.
  - Explain that self-monitoring is a method to insure success. Using a self-monitoring tool is the only way to assess one's progress and to validate successful changes. Those who monitor more often do the best at reaching and maintaining goals.
  - Review the principles of behavior change using the "Circle of Self-Management." (See attached.)

- Encourage the self-test of record keeping as a personal challenge. Show how it empowers them.
- Explain the importance of self-monitoring in terms of learning how one can continue to eat favorite foods by budgeting.
- Have participants review their original purpose for joining the study. Discuss how records document putting their purpose into action and help them avoid drifting back to old eating habits.

- Use metaphors.
  - Money budgeting/financial records.
  - Thermometer metaphor.
- Use illustrations to present the advantages of budgeting.
  - Show the math.
  - Ask the group for examples.
- Promote group discussion and problem solving:
  - Call on and reinforce participants who are successful at self-monitoring. Use group members who have done well as spokespersons.
  - Ask participants if they would like to peer review one another's food diaries as a means of learning new ways to keep records or accomplish goals. (Be careful - some may object.)
  - Ask participants why they think self-monitoring has an impact on lowering fat intake.
  - Give feedback on self-monitoring tools. Many participants comment that feedback is very helpful and are eager to get records back. (See *Section G.*)
  - Use your system for collecting food records to reinforce self-management. (See *Section F below*.)

B. Methods to encourage women to self-monitor more often:

- Set an expectation of self-monitoring.
- Share nutrition research which shows the more frequently women self-monitor, the better they do at reaching and maintaining goals.
- Strongly encourage participants to use abbreviations. At Session 2, have participants add the following to the abbreviations found on page 9 in the *Fat Counter*:
  - L = label
  - R = recipe
  - LF = low fat
  - FF = fat free
  - NFA = no fat added
  - ? = best guess, am I on the right track?
  - w and w/o = with and without
  - FC = fat counter
- Offer reminder options.

  - Mention the importance of self-monitoring frequently at group and individual sessions. Emphasize that it is the only way to track progress and assess additional attempts to change eating patterns.
  - Provide reminder notices. Include a word about keeping food records and bringing them to class in the reminder postcard or phone call for the next session.
  - Recommend that women designate self-monitoring days on their personal calendars. This is especially important to working women for whom time is at a premium.
  - Alternatively, the Group Nutritionist may elect to assign days to self-monitor on a pre-printed calendar.

- If a participant misses a session, send her blank diaries.
- If a participant has overlooked self-monitoring for a session, ask her to fill out "Eating Pattern Changes" before she leaves class.
- Encourage women who are already self-monitoring more frequently than required to speak to the group about why they find it helpful.
  - Highlight the successes regular record keepers have with the group.
  - Enthusiastically agree it's the best way to stay on track.
  - Let participants know that women who self-monitor daily feel like they know where they are in terms of their goals and thus have a better sense of when/how to budget fat grams.
- Offer flexibility.
  - Communicate that frequency of record-keeping is much more important than neatness.
  - If self-monitoring lags, encourage the participant to try a new tool. Offer the full range of tools available to support a woman in finding the one best suited to her.
  - Give a participant more freedom to use her own tool or mix and match, e.g., keep a record in her own notebook, notepad, etc.
  - Absolve a participant of guilt if she hasn't been keeping records. Allow a fresh start.
  - Encourage women to self-monitor not only when they are doing well, but also when they are off track.
  - If woman finds herself falling short in one area (e.g., F/V or grain), encourage her to self-monitor just that area for an entire week.
- Support participants in self-monitoring by helping them see how the data is used. Share WHILMA reports of fat, F/V and grain intake with the group on a regular basis.
  - Highlight the numbers.
  - Emphasize the positive: show where the group is doing well.
  - Stress that self-monitoring data is beneficial for the success of the study. For participants who insist that they are meeting goals even without regular record-keeping, remind them the data is important to the study.
  - Give each group feedback on their overall self-monitoring performance to promote group cohesiveness. Prepare picture graphs or charts. Consider holding a competition between groups for the highest level of self-monitoring.
- Offer incentives.
  - At the end of a session, collect food records. Draw one out and give a prize.
  - Give out small tokens (candy cane, pencil) for everyone who kept a food record.

- Give an award for the highest number of days recorded.
- Establish a lottery for a prize. Give participants a lottery ticket for each day they self-monitor.

- Implement a system of "WHI Points" as a motivator for "prizes." (See attached.)
  - Assign "prize" value to points.
  - Assign point value to activities.
  - Create "prizes" or have them donated and clearly mark them with the point value.
  - Invite participants to look over the "prizes" to get them excited and give them an idea of how many points they need.
  - Have prizes in a full range of point categories. (Nevada's prizes start at 15 points for hand-dipped taper candles and range to 130 points for basket with wine, bubble bath, wine glasses and candles.)
- Thank participants for their contribution to the study by keeping food records.

C. Methods for Successful Introduction of the Fat Scan

- When introducing the *Fat Scan*, really "market" it. Participants' positive expectations of success and happiness with the scan are crucial.
  - Let women know: it's fast. It's easier than carrying around a diary and a Fat Counter. It gives more information to direct change. It's immediate. It helps you make choices on the spot. It encourages variety throughout the day. It focuses on the big picture, rather than on individual foods.
  - Point out the benefit of food categories in evaluating fat sources and overall nutrition.
  - Tell participants the aim of the *Fat Scan* is to make record keeping easier (if not now, then in the future).
  - Promote it as a *time-saving* self-monitoring tool.
  - Describe the Scan as a "Brain Exerciser" (the 'use it or lose it' kind).
- Lay a good foundation for the use of a variety of self-monitoring tools throughout the study. Prepare participants early for the introduction of new tools.
  - At screening visits, tell participants they will be using a variety of tools to self-monitor during the study.
  - When women begin to use the *Food Diary*, hint at the later appearance of a second tool to prevent surprises.
- Introduce the Fat Scan and monitoring of fruits, vegetables and grains in stages.
  - Introduce monitoring of fruits, vegetables and grains with the green *Food Diary* at Session 5 or 6. Give extensive feedback in the diaries.
  - Give participants a sample *Fat Scan* at Session 6 to take home. Ask them to look it over and read the directions before Session 7.
  - Allow participants to "dabble" at first and experience a learning curve.
- Communicate "tricks" for increasing the effectiveness of Fat Scan use.
  - To improve memory and tracking, encourage women to use different shapes around fat grams to denote different meals. For example, a circle = breakfast, a square = lunch, and a triangle = dinner.

- Point out that the blank space on the back flap can be used to record their meals right in the scan rather than using another sheet of paper.
- Encourage women to keep 2 scans between Sessions 7 and 8.
- Call on successful participants to help others. Pull out the positive comments. The group's feedback has some influence on an individual woman's choice of a tool.
- Request a "fair shake" for the *Fat Scan*. Ask women to use it for long enough to see if it will work for them. Encourage them to use it for 3 or 4 sessions, then choose the tool they prefer. If they are really having trouble with the scan, discuss it with them at their Individual Session.

- After an adequate test period, let participants know that people vary in their preferences for self-monitoring tools. Emphasize the high correlation between self-monitoring and meeting WHI DM goals as the important point. Reassure women they can self-monitor with whatever tool is most comfortable for them.
  - Some women like a "visually worded" picture of what they've eaten during day, so they prefer the *Food Diary*.
  - Working women often prefer the *Fat Scan* because of the speed of recording.
  - Remind participants they can always switch from the scan back to the green diary or return to scan from other methods. Variety helps.

D. Shortcuts to checking the math on self-monitoring tools and means to assist the participants with self-monitoring calculations:

- Encourage and reinforce accuracy on the part of participants.
  - Discuss common errors at the beginning or ending of a session.
  - Offer incentives for accurate diaries.
  - Write comments, corrections, and step by step calculations, if needed, on records. Identify the page # in the *Fat Counter* if there is a correction.
  - On the cover of a record, alert a participant to notes inside. Use a highlighter for areas of question.
  - Return the previous set of food records to participants at the beginning of a session. Ask participants to review their latest records in light of feedback, progress or changes in the interim before handing them in to the LN.
- Arrange for well-trained assistants to do an initial review of diaries and scans: Use students (CUP, interns, paid or unpaid), diet techs, or volunteers. Then as GN, review the records quickly and add your comments before returning them to the participants.
- When group members have completed their initial learning curve, spot check records. Let participants know reviewers will not be checking each day of each record.
  - Check records thoroughly during the early sessions and at 8, 12, and 16.
  - Look for outliers, i.e., unusual values.
  - Have participants highlight fat gram values they are uncertain about for reviewers.
  - Note participant ability in progress notes. Spend less time spent with the records of those who consistently make few errors.
  - Make comments on only 1 or 2 books or generalize comments to the entire reporting period.

- Speak individually with participants who are having difficulty. Give 'private lessons' after a session or at the Individual Session.
- After tools have been reviewed and corrected, mail them back to participants instead of keeping them until the next quarterly session.

E. Successful offering of the alternative self-monitoring tools

- Offer alternative self-monitoring tools toward end of first year of intervention or during maintenance.
- Offer alternative tools when you see indications of struggle with the process of self-monitoring. Many participants have voiced a favorable response to the expanded options these tools provide.
  - Offer them individually to a participant who is not doing well with the scan or diary or indicates boredom or discontent with her current tool.
  - Offer them to a participant who is not self-monitoring.
  - Suggest their use after a holiday or stressful weekend.
  - Suggest their use by anyone who wants to do more self-monitoring.
  - Be prepared for a whole group to want at least a look if a member is using a 'new' tool.
  - Introduce them during a maintenance session if the group discussion reflects frustration with the scan or diary.
- Suggest that participants keep scans or diaries on hand, also. They may wish to switch back from time to time. Most participants mention they like the increased amount of information the regular tools provide.

F. Collecting self-monitoring tools

- Most CCs collect and return self-monitoring tools at the same point during a session. Options include:
  - Collect records at the beginning of a session. Include a brief discussion of self-monitoring in the group's review of progress since the last meeting.
  - Ask participants to turn in them in after the Review of Home Activity. General feedback can often be given to the group about self-monitoring records, e.g., around the holidays.
  - Collect them at end of each session.
  - Make it easy for a participant who didn't bring records to a session to turn them in another way.
    - ♦ Provide a postage-paid envelope for mailing.
    - ♦ Have her call in her scores to the nutritionist's voice mail.
    - ♦ Have her fax in the last page of totals/scores.
- Options for where and how to collect records:
  - Have participants place completed tools in a basket or tray:
    - ♦ At the entrance to the classroom.
    - ♦ In the middle of the conference table.
  - Have a participant hostess assigned to collect diaries.
  - Use table tent name tags. Ask participants to set out the tools by their name tags.

G. Kinds of feedback given women who self-monitor

- Participants value feedback immensely! Make comments encouraging, positive, directive, and designed to help participants analyze their own records and set goals for the next session.
- Phrase suggestions as open-ended questions to promote self-management.
- Include something encouraging of participants as they reach toward goals:
  - Dutch pretzel in baggie clipped to front of the record.
  - A cartoon.
  - A low-fat recipe.
  - The menu from a restaurant they frequent with best choices circled.
  - A pertinent article.
  - Mini boxes of raisins.
- Use colorful stickers or stamps, e.g. color-coded stars for reaching their goals: gold = fat; green = F/V; red = grain.
- Use colored pens, e.g., green or purple for comments and corrections, pink to circle significant sources of fat. Avoid use of red pens.
- During the early intervention sessions provide lots of comments on:
  - Products participants could use as substitutes for regular items.
  - Calculating recipes and mixed dishes.
  - Major sources of fat by food group.
  - Where to find food information.
  - Obvious nutrition concerns.
  - Fat grams saved per suggestion.
  - "You can do it!"
  - A woman's effort, improvement, and achievement of goals.
- During later intervention sessions, provide:
  - Brief, simple, positive statements.
  - A shorter note either inside the front cover or on the back page next to scores. Write encouraging phrases such as:
    - "Great fruit and vegetable scores. Keep it up!"
    - "You're doing everything right."
    - "Your scores have really improved."
    - "Continue to set goals around increasing your grains. What are your favorites?"

H. Responding to a woman who does not turn in <u>any</u> self-monitoring tools.

- Probe to find out why an individual is not self-monitoring. Not feeling successful? Afraid of failure? Doesn't understand tool or using incorrectly? Non-compliant? Mixed dishes confusion?
- Look for what the participant IS doing well and build on that. For example, ask her to keep records on her fabulous fruit consumption or routine breakfasts.
- Have a woman "buddy-up" with another participant from her group who does well with self-monitoring.

- During maintenance, ask her to try one of the alternative self-monitoring tools available. Continue the positive feedback.
- Ask her to develop her own system of recording and totaling that works for her.
- Negotiate fewer days of record-keeping.
- Encourage members of a peer group to promote the importance of self-monitoring with one another.
- Ask her to calculate the previous day's intake and turn that in for at least one day's score.

Attendance

A. Methods to encourage women to attend their intervention group

- Set an expectation for group attendance. (See section G.)
- Maintain a good system to remind participants about their next group meeting. Mention the session topic on reminder postcards. Include the recipe that will be served. (See section F.)
- Send frequent mailings in addition to reminder cards, e.g.:
  - a postcard midway between classes — "We're thinking of you — have you done your self-monitoring yet?"
  - a letter that previews the session topic. Include a word about what to bring to the session.
- Use strategies to increase participants' involvement in promoting attendance. (See section B.)
- Enhance social cohesiveness. (See section C.)
- Continuously praise participants for their commitment to coming to group (even if they don't have records to turn in), especially if the weather is bad or you know they have a lot going on.
- Ask participants to write down what motivated them to join WHI and what motivates them now. Be aware of the short-term motivations participants name most frequently.
- Offer incentives for attendance. (See section E.)
- Do cooking demonstrations.
- Schedule seasonal celebration potlucks. December holiday parties have been especially successful.
- Reinforce participants' commitment by sharing progress reports:
  - Run the DM Session Adherence Summary report (*WHIP 0419*).
  - Use the Session 4 Winter format to discuss session attendance. Provide participants with information about how they are doing as a group, clinic and study-wide.
- At session 9, focus on the importance of attending sessions now that the group will meet only once a month.
- Encourage women to make up missed sessions in another group. Distribute a master calendar of the session schedule (Year 1 or maintenance) for make-up possibilities. Follow up with a letter of available group make-up dates to those who have been absent.

B. Use strategies to increase participants' involvement in promoting attendance

- Encourage group members to contact one another to increase social bonding and support.

  - Organize lists of women by zip code or neighborhood to promote carpooling and peer association.
  - Have women call other members of their group for session reminders.
- Assign buddies to do callbacks for absentees. Ask the participant who attended to give a brief summary of the session to the one who missed.
- Ask for volunteers to follow up on those suddenly missing from the group.
- Use "we missed you at the meeting" cards — signed by all members and mailed right away.
- Circulate a group condolence card to send to an absent member.
- Send a round-robin newsletter to those who are absent.
- Hold a "Show, Tell and Taste" activity: a participant brings a low-fat recipe or product label and tells how to prepare the dish and how it fits into WHI. Then samples are tasted.
- Use a mentoring or buddy system to:
  - pair those with complementary skills.
  - pair those with a common challenge — limited mobility; difficulty when eating out, etc.
- Develop support groups within groups. Break an intervention group into smaller groups, who are responsible to look out for one another if someone is absent. Participants appreciate hearing from their peers as well as from the GN - and it's often more effective.
- Encourage women to meet for peer group meetings.

C. Enhance social cohesiveness

- Serve tea and cookies to at the beginning of a session.
- Give time in group to share; invite participants to bring a photo or other "show and tell" item.
- Acknowledge participants' birthdays at the beginning of the session.
- Encourage participants to call each other between sessions. Group members may find it useful to compile a group phone directory. (Insure that women who prefer not to publish their phone number have a graceful opportunity to decline.)
- Put together a group photo calendar.
- Have some group members come early to set up, bring in food, and stay to clean up. Working on shared tasks promotes closeness.
- Alternatively, have a hostess for each DM session who gets the group ready to begin: makes coffee, sets out materials, collects fat scans, and greets women as they arrive. Women can rotate through this role, or the same participant can fill it all year.
- Keep a notebook with newspaper clippings about participants.
- Have each participant write a short autobiography to share with the members of her group.
- Encourage women to write about themselves for the DM newsletter.
- If there is a natural "motivator" in the group — someone who other participants look up to and admire — support her in an informal role as keeper of kin and organizer. (She may or may not be a peer leader.)

D. Strategies to overcome problems in DM groups with low attendance

For a group with low attendance:

- Decrease avoidance based on guilt — offer "amnesty" if women have not been self-monitoring or meeting goals. You may find it helpful to speak with participants individually or to the group as a whole.
- Enlist the aid of group members: create an atmosphere for frank discussion and ask the group why they think their attendance is low and what they recommend to improve it.
- Invite a "good participant" to be a guest at that group.
- Send a special letter to that group.
- Send a "Pep-Me-Up" packet with motivational items tailored to the members of the group: a letter, a "round tuit", a visual reminder (e.g., calendar), etc.

For an individual participant with low attendance:

- Be sensitive to the needs and issues that are preventing a participant from attending her group - illness (self or family member), depression, work or family crisis, behavioral issues, or lack of confidence in her reading or math skills. Design a strategy specific to the problem.
  - Give space, respite.
  - Set up a peer contact.
  - Adjust her level of participation.
- Target participants who report they are willing to change, but haven't yet focused on a particular goal.
- Target for individual help those who present individual concerns, e.g., inability to be satisfied after eating. Use notes in the food diary to communicate problems and suggestions. Women in these situations really seem to appreciate the individual touch.
- If a participant is assigned to a group that is not a good match for her, recommend that she try a more convenient group or one that she may relate to better.

E. Offer incentives for attendance

- Hold a drawing for door prizes that relate to the session in some way:
  - Cooking Light magazine
  - kitchen utensils
  - scented candles
  - dry beans, soup mix
  - a potted plant
  - discounts from local businesses
  - t-shirts
- Serve a special "theme" meal at quarterly sessions - low fat, but different than the WHI session recipes.
- Send each participant home with a small gift:
  - Give carnations, unannounced, to those present. The word will spread and encourage attendance at future sessions in anticipation of receiving flowers.

- Give fat-free candy on Valentine's day.

F. Use scheduling reminders

- Provide a printed calendar of the group schedule for the year.
- Mail pink (or other vibrant color) reminder postcards stating the day and time of the session.
  - Use one color consistently.
  - Include the session topic and the recipe that will be served.
- Make reminder phone calls a day or two before the session.
  - Design a system that identifies who makes the calls. Options include:
    - one participant who calls all the others in her group; the responsibility rotates. (She may or may not be the hostess for the session.)
    - a permanent phone committee.
    - "phone squads."
    - a student volunteer or work study student.
    - a diet tech or diet aide (non-blinded staff).
- Change the GN's voice mail message to notify participants of last-minute schedule changes due to bad weather.

G. Strategies for setting an expectation of group attendance

During screening:

- Emphasize — verbally and in writing — the importance of session attendance at each screening visit.
  - Let each woman know that consistent group attendance is essential should she be randomized into DM intervention. Assess her willingness to attend group sessions.
  - Ask each woman about her motivation for joining DM.
  - Review the schedule of group sessions — number of meetings and frequency — for Year 1 and maintenance. Assess each woman's availability. Inquire about her long-term travel plans and transportation to the CC.
  - Evaluate how she felt about completing the 4DFR with an eye to retention.
  - Emphasize the importance of make-ups should she miss a meeting. Assess each woman's willingness to make up missed group sessions.

During sessions 1-6

- Emphasize the impact of group support on personal success and achievement of study goals.
- Hold participants accountable:
  - Establish an expectation that session attendance is the norm.
  - Set a policy that participants will phone if they know ahead they must miss a session.
  - Establish a procedure for participants to schedule and accomplish session make-ups; follow up consistently.
- Do a roll call, with explanation and concern expressed for absentees.
- Make a point of welcoming absentees back at the next session.

- If a participant misses three or more of the first six sessions, encourage her to begin again with a new group.
- Anticipate times when participants may feel like dropping out; create an atmosphere where they feel comfortable discussing it.

During Sessions 10-18

- remind participants that attending their group is important to the study results and to women's health. Use a graph to illustrate the correlation between attendance and adherence to study goals.
- Tell participants that attendance is tracked separately from self-monitoring. Encourage them to attend even if they don't have records to turn in. Refer to the other areas to work on listed on the Home Activity worksheet.
- Discuss and promote peer groups. Encourage group members to brainstorm peer meeting topics and things to do – aloud or on paper. Categorize the ideas by type of activity. In this way groups have successfully planned peer activities for women with disparate interests. You may find the Thinking Ahead survey (distributed at the AGM) useful.

During Maintenance

- Emphasize that attendance is just as important — if not more so — than during Year 1.
- Publish a quarterly session schedule of make-up opportunities.
- Mail a "missed you" letter to absentees; personalize it when possible.
- Promote group cohesion via peer meetings:
  - Schedule the first peer group meeting one month after Session 18 to get them started.
  - Allow time at the end of each quarterly session for group members to plan and schedule their next peer group meeting.
  - Offer additional ideas for meeting topics if you have them.

G.2.11 Appendix – Examples of Successful Recruitment Strategies

G.2.11.1 Memphis - Recruitment Steps

1. Select age range and zip codes for mailings (who and where).
2. Select mailing lists - currently using DMV (in past have used voter registration for Mississippi, purchased lists for Arkansas, and HCFA lists for all sites).
3. Mail 5,000 pieces at a time, on average. Plan for a steady flow of cards returned and phone calls coming in so that SV0s can be done 2-3 weeks after mailing (SV0s are done weekly).
4. Direct mailing service inserts cover letter and brochure in pre-addressed envelopes and prepares bulk mail for post office.
5. Phone screen - Form 3 is completed and women are scheduled for an SV0 at the end of the screen.
6. SV0 packets are mailed, including FFQ, Form 20, and appointment confirmation letter and reminder (with information about what will take place at SV0).
7. SV0s take place once a week at each site (satellite and East clinic). 30-35 women are invited and 15-20 women show up at each site (33% no show rate).
8. SV0 - FFQ is reviewed by nutrition staff and presentation is done by staff describing CT process, WHI, dietary program, HRT and OS. SV0s are about 1 1/2 hours long with a break for refreshments.
9. At the end of the SV0, women are debriefed individually by staff. The FFQ has already been scanned for eligibility and women are told their eligibility for study arms. Non-eligible are given an OS packet (forms). SV1s are scheduled for CT and women are given written fasting instructions and written confirmation letter describing the first visit. CT women are given Forms 30, 31 and 32 (medical

10. history)to bring back to their first visit (they fill these out at home where it easier to ponder over and recall details). *Form 37 - Thoughts and Feelings* is given out and discussed at SV1 due to sensitive nature of questions and regional issues.
11. Recruitment staff call SV0 no-shows to reschedule/also reschedule SV1 no-shows.
12. Crucial for women to receive appointment reminder card/calls shortly before appointments - 3 days before. (Although if scheduling is spaced close enough to appointment, this isn't always necessary. If it is longer than two weeks from the time when staff talks to a women, then reminder cards and phone call should be done.)

G.2.11.2 Madison - Recruitment Steps

1. Main mailing list used is from driver's license records since they can target the right age range.
2. Send brochure with no cover letter (women send postcards back and they are checked off a tracking list as they respond).
3. When phone calls are made, *Form 3* is done. If a woman is interested and eligible for CT, then she is scheduled for an SV0. Only CT eligible women are invited to SV0s (not OS). It is important to this clinic to make this personal contact (Form 3) over the phone because they are asking a lot of women to drive a long way to the clinic and they form a connection with women this way.
4. 2-4,000 piece mailings are done each week. They plan for a steady flow of response which allows their staff to "keep up."
5. 2-3 SV0s are done each week. 25-27 women are scheduled and 15-20 show up at an SV0.
6. SV0s last two hours. Women are shown the consent video, slide show, and are given a presentation on HRT and other WHI issues. They allow special time for HRT discussion and questions. This clinic also does HRT washouts with good success. The CM/RC goes over the initial consent in a group (consents everyone at once). Women fill out FFQs at the SV0 visit. Women are told that they will receive a call in two weeks with their eligibility status. Women are also given interest forms so they can indicate which arm of the study they are interested in.
7. FFQs are scanned and eligibility is determined.
8. Women receive call about eligibility and SV1s are scheduled (this clinic designates types of SV1s based on goals and needs).
9. They try to do consent at end of SV1 if arm of study is chosen.
10. Madison has an outreach person who continually helps think of retention ideas for people in study (these are also used for recruitment).
11. Tracking - they use the FRED recruitment database to manage mailings.
12. They use a mailhouse to print labels and send out pieces bulk mail.
13. They are starting second mailings. They have started using the "invitation" to women over age 70.
14. They can't rely on mailings alone - community outreach, coalition building and referrals are important. Trust is an issue in small rural towns - referrals from friends are helpful with this issue.

G.2.11.3 Iowa - Recruitment Steps

1. Currently use driver's license registration lists for mailings (have used Blue Cross/Blue Shield lists, University of Iowa Hospital lists, U of I retiree/employee lists and nurses lists in the past). They have completed 200,000 mailings to date.
2. Send mailings that include the invitation.
3. Follow up invitation one week later with a letter and brochure.

4. Women who return the postcard receive a call that includes the phone screen (and questions are answered). Through this phone contact, they are able to weed out people who might not be good candidates for the study.
5. Women can leave messages on a phone machine (if they don't return card).
6. DM or HRT eligible women are scheduled for an SV0.
7. They try not to phone screen OS women and try not to schedule OS women for an SV0. They may try and set up OS SV0s in the future.
8. The SV0 takes place about 3-4 weeks after this contact. Women receive a letter and instructions one week before their SV0 appointment.
9. 18-20 women are invited to SV0s and 15-16 women attend (70-77% show rate).
10. No-shows are called to be rescheduled. After three no-shows, they are dropped from the study.
11. The SV0 in Iowa City is 1 1/2 hours long. Women watch a video and WHI slide show. They also fill out the FFQ. The SV0 in Davenport is 1 hour (they don't have women watch the slide show).
12. FFQs are scanned after SV0s, and women are contacted for SV1 appointments after eligibility is determined. In Davenport, they are seeing six women at a time for SV1s.

Tracking: They track mailing response using recruitment strategy calls. They also track incoming calls (for women who don't return a postcard, they keep information sheets on outcome). They track number of women scheduled, screened, and attending SV0s (these are split out by HRT, DM and OS). They track methods women use to contact WHI - phone, postcard, answering machine, etc.

G.2.12 Appendix – Hot Tips for Adherence and Retention Booklet

G.3 WHI Press Materials

G.3.1 Backgrounder

Backgrounder

WHAT IS THE WOMEN'S HEALTH INITIATIVE?

The Women's Health Initiative (WHI) is a long-term national health study that focuses on strategies for preventing heart disease, breast and colorectal cancer, and osteoporosis in postmenopausal women. These chronic diseases are the major causes of death, disability, and frailty in older women of all races and socioeconomic backgrounds.

This $628 million, 15-year project, sponsored by the National Institutes of Health (NIH), will involve 164,500 women aged 50-79, and is one of the most definitive, far reaching clinical trials of women's health ever undertaken in the U.S. The WHI will attempt to redress many of the inequities in women's health research and provide practical information to women and their physicians about hormone replacement therapy, dietary patterns, and calcium/vitamin D supplements, and their effects on the prevention of heart disease, cancer, and osteoporosis.

THE HISTORY OF WOMEN'S HEALTH RESEARCH

Women have long been underrepresented in medical research. Historically, women's health research focused on diseases affecting fertility and reproduction. Other disease research has focused disproportionately on men.

Despite this imbalance, new drug therapies tested on men, once approved, are often prescribed to women without comparable trials of clinical safety or efficacy. For example, a few years ago a study revealed that aspirin helps prevent heart attacks in men. Women were not included in this study even though heart disease is the number one killer of U.S. women. Yet, aspirin is now recommended to both men and women as a preventive measure for heart attacks.

Women have been excluded from medical research for at least two reasons: 1) concerns about pregnancy during a trial and 2) concerns that women's changing hormone levels during menstrual cycles might skew test results.

We now know that there are no significant reasons to exclude women in medical research. In most cases both sexes respond similarly to many therapies; however, there may be exceptions. For example, women may need lower dosages and some therapies may be specific to women.

A NEW ERA IN WOMEN'S HEALTH: THE WOMEN'S HEALTH INITIATIVE

To respond to the crucial need for the involvement of women in medical research, the NIH in 1990 established the Office of Research on Women's Health (ORWH). The earliest undertakings of the ORWH included the development of a research agenda to identify and address gaps in the biomedical community's knowledge of women's health and the strengthening and revitalization of already existing NIH guidelines and policies for the inclusion of women and minorities in clinical studies.

With the growing scientific interest in research on women's health, Dr. Bernadine Healy, former director of the NIH, launched the WHI in April 1991.

HOW IS THE WHI BEING CONDUCTED?

The WHI study has three components: a randomized clinical trial, an observational study, and a community prevention study.

The **randomized controlled clinical trial** will enroll about 64,500 postmenopausal women between the ages of 50-79. The clinical trial has three study components. If eligible, women can choose to enroll in one, two or all three of the components. The components are:

- Hormone Replacement Therapy (HRT): This component will examine the effect of HRT on the prevention of heart disease and osteoporosis, and any associated risk for breast cancer. Women participating in this component take hormone pills or a placebo (inactive pill).
- Dietary Modification: The Dietary Modification component will evaluate the effect of a low-fat, high fruit, vegetable and grain diet on the prevention of breast and colorectal cancer and heart disease. Study participants follow either their usual eating pattern or a low-fat eating program.
- Calcium/Vitamin D: This component starts one year after a woman joins one or both of the other studies. It will evaluate the effect of calcium and vitamin D supplementation on the prevention of osteoporosis and colorectal cancer. Women in this component take calcium and vitamin D pills or a placebo.

The **observational study** will examine the relationship between lifestyle, health and risk factors, and specific disease outcomes. This component will track the medical history and health habits of approximately 100,000 women.

Recruitment for the randomized clinical trial and the observational study will last four years and participants will be followed for 8 to 12 years.

The **community prevention study** is a unique collaborative venture between the Centers for Disease Control and Prevention (CDC), the National Center for Chronic Disease Prevention and Health Promotion, and the NIH. Eight CDC University-based Prevention Centers will conduct and evaluate health programs that encourage women of all races and socioeconomic backgrounds to adopt healthful behaviors such as improved diet, nutritional supplementation, smoking cessation, exercise, and early detection of treatable health problems. The goal of the community prevention study is to develop carefully evaluated, model programs that can be implemented in a wide range of communities throughout the U.S.

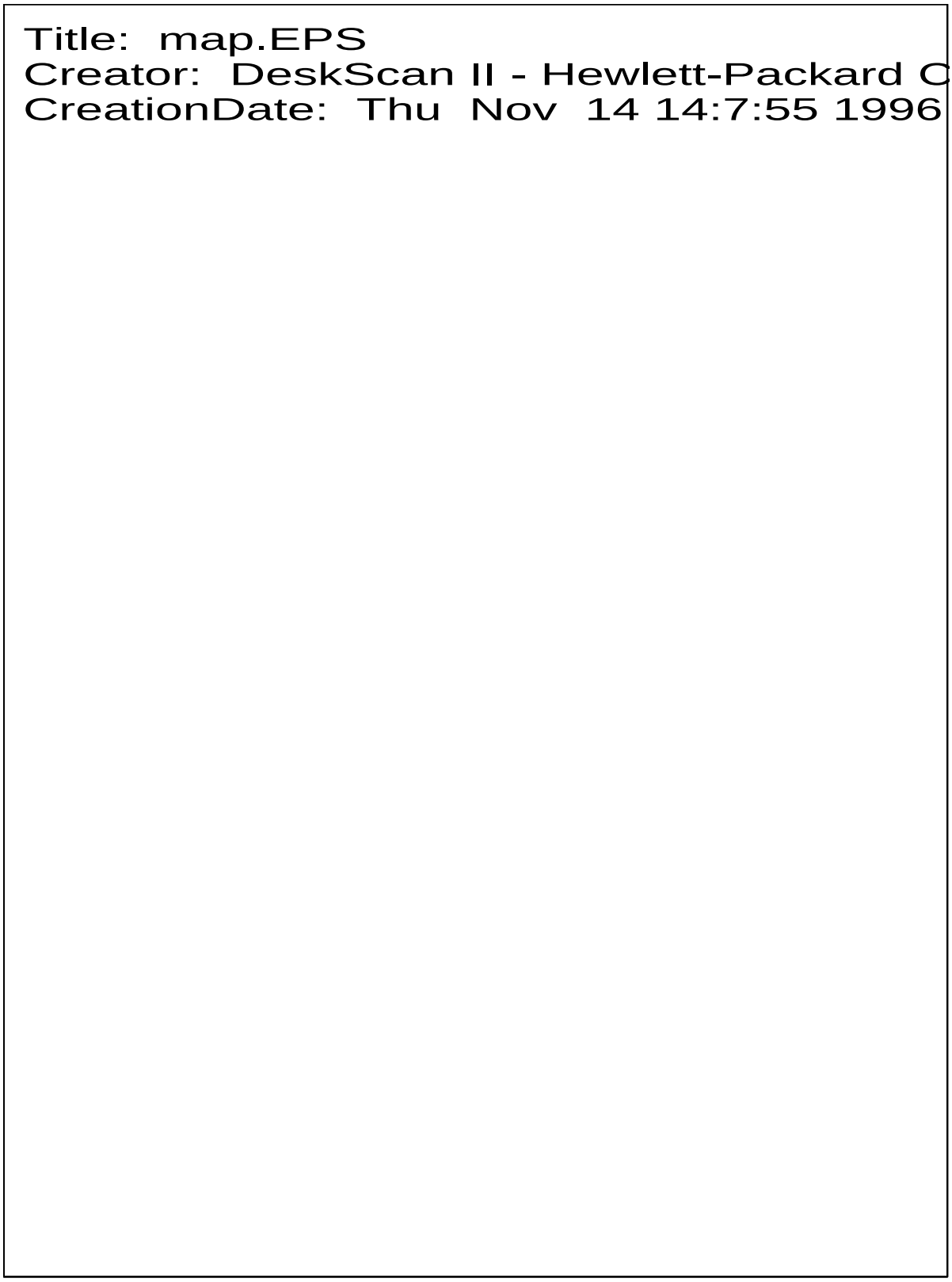
WHERE IS THE WHI TAKING PLACE?

The WHI clinical trial and observational study are being conducted at 40 clinical centers nationwide. The Fred Hutchinson Cancer Research Center in Seattle, WA serves as the WHI Clinical Coordinating Center for data collection, management and analysis. A total of 16 vanguard clinical centers began recruitment in September 1993. The remaining 24 centers were announced in September 1994 and began recruitment in February 1995. Recruitment of women who choose to "be part of the answer" will continue through January 1998.

WHO IS ELIGIBLE TO PARTICIPATE IN THE WHI?

The WHI encourages women of all socioeconomic backgrounds and ethnicity between the ages of 50-79 to participate in the clinical trials or observational study. Study participants get the personal satisfaction of knowing that they are contributing to their own health and the health of women for generations to come. Women interested in participating in the WHI can call 1-800-54-WOMEN to be connected to a WHI clinical center in their area.

G.3.2 Women's Health Initiative Clinical Centers (Map)



G.3.3 Hormone Replacement Therapy Study Fact Sheet

Hormone Replacement Therapy Study

Fact Sheet

WHAT IS THE PURPOSE OF THE HORMONE REPLACEMENT THERAPY (HRT) CLINICAL TRIAL?

The HRT component of the Women's Health Initiative (WHI) will study the effects of HRT on heart disease, osteoporosis-related bone fractures, and breast and endometrial cancer. This trial will enable scientists to assess both the benefits and risks of HRT.

HOW WILL THE HRT STUDY BE CONDUCTED?

About 27,500 women aged 50-79 will participate in the HRT study. Women with a uterus will be randomized to receive either estrogen plus progestin or a placebo (inactive pill). Progestin is added to protect women with a uterus from endometrial cancer. Women who have had a hysterectomy will be randomized to receive either estrogen alone or a placebo. Randomization is the computer procedure by which women are placed into the hormone group or the placebo group. Placement with either group is by chance; this ensures that the groups are comparable. HRT study participants will be followed for 8 to 12 years and have clinic contacts every six months to assure safety and assess their health.

This study component tests whether long-term HRT reduces coronary heart disease and fractures without increasing breast cancer risk. Study results will help women and medical providers make informed decisions as to whether long-term HRT should be routinely prescribed to postmenopausal women.

HAVEN'T NUMEROUS STUDIES ALREADY REVEALED THAT HRT DECREASES HEART DISEASE AND OSTEOPOROSIS?

No study has <u>proven</u> that HRT will reduce heart attacks. Numerous studies have been conducted on the effects of HRT on heart disease and have suggested that HRT decreases heart disease risk or heart disease risk factors such as LDL levels (bad cholesterol). However, these studies were mostly observational studies where women themselves (or their physicians) chose HRT and were followed over time. Such studies are not reliable. They were not controlled enough to offer definitive answers.

HRT appears to lower the risk of osteoporosis. The WHI HRT study component will attempt to demonstrate that HRT not only slows bone loss, but also prevents actual bone fractures.

A particular feature of WHI is that it will track the long-term use of HRT. If hormones are to be used to prevent heart disease, they will need to be prescribed for a long time, perhaps decades.

WHAT ABOUT HRT AND ITS RELATIONSHIP TO BREAST CANCER?

Research on HRT and its relationship to breast cancer is inconclusive. The more than 30 observational studies on breast cancer and HRT have not yielded consistent results. These studies suggest a reduced risk, no risk, or increased risk of breast cancer. As in the studies analyzing heart disease and HRT, many of the studies completed to date have been observational in nature and, therefore, not as reliable as information that will be learned from WHI, a randomized, controlled, long-term clinical trial.

The physicians who designed WHI studied all the scientific data about breast cancer and HRT and took this information into consideration when planning this component of the study. As a result, study participants are as well-protected as possible from any potential risk of breast cancer. They will be regularly screened to detect any cancers at an early stage. In addition, potential study participants are thoroughly briefed on the potential risks and benefits of HRT so they can make an informed decision about joining the study. WHI will provide important information about whether HRT actually does (or does not) increase breast cancer risk.

G.3.4 Dietary Modification Study Fact Sheet

Dietary Modification Study

Fact Sheet

WHAT IS THE PURPOSE OF THE DIETARY MODIFICATION CLINICAL TRIAL?

The dietary modification (DM) clinical trial will study the effect of a low-fat, high fruit, vegetable, and grain diet on breast cancer, colorectal cancer, and heart disease in postmenopausal women.

HOW WILL THE DM STUDY BE CONDUCTED?

About 48,000 women aged 50-79 will participate in the DM component of WHI. Participants will either be randomized to a comparison group or a dietary change group. DM study participants will be followed for 8 to 12 years. Participants' health will be assessed every six months by their clinical center.

WHAT IS REQUIRED OF THE COMPARISON GROUP?

Comparison group participants will maintain their usual eating habits and receive standard information on nutrition guidelines. They may be asked to keep a food diary occasionally and will fill out health forms every six months.

WHAT IS REQUIRED OF THE DIETARY CHANGE GROUP?

Women in the dietary change group will decrease their fat intake to 20 percent of their total daily calories; increase fruit and vegetable consumption to five or more servings per day; and increase grains to six or more servings per day. They will monitor their food intake and attend nutrition group meetings to learn about changing their eating habits. These meetings are led by registered dietitians or nutritionists.

WHAT ABOUT RECENT STUDIES QUESTIONING THE LINK BETWEEN DIET AND BREAST CANCER?

An analysis of seven cohort studies published in the *New England Journal of Medicine*[1] was unable to identify a link between dietary fat intake and incidence of breast cancer. This cohort study analysis used recall of recent food intakes to calculate an estimate of total fat, which was then related to the incidence of breast cancer. This study "pooled" data from seven studies in which women were observed for several years. The validity of data from observational studies such as these depends directly on long-term accurate dietary measurements--a practical impossibility. Additionally, these studies did not attempt to alter eating patterns, thus they cannot directly assess the health benefits that may follow adoption of a low-fat eating pattern.

In contrast, the WHI DM study will compare the health outcomes of women randomly assigned to one of the two study groups. Randomization eliminates the possibility that other personal characteristics or exposures may interfere with results concerning the health benefits and risks that follow the undertaking of a low-fat eating pattern.

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[1] D.J. Hunter, et al. "Cohort Studies of Fat Intake and the Risk of Breast Cancer -- A Pooled Analysis," *New England Journal of Medicine*, Feb. 8, 1996: pgs 356 - 361.

G.3.5 Calcium/Vitamin D Supplementation Study

Calcium/Vitamin D Supplementation Study

Fact Sheet

WHAT IS THE PURPOSE OF THE CALCIUM/VITAMIN D (CAD) SUPPLEMENTATION STUDY?

Previous research on calcium/vitamin D and its effect on bone fractures is limited. Past research in this area is observational and focused more on bone mass than the frequency of bone fractures. Observational studies also suggest that increased calcium and vitamin D intake may decrease the risk of colorectal cancer.

The calcium/vitamin D study will test whether these supplements reduce the risk of colorectal cancer and the frequency of hip and other bone fractures in postmenopausal women.

HOW WILL THE CAD STUDY BE CONDUCTED?

Women in the hormone replacement therapy and/or the dietary modification clinical trials will be encouraged to also join the CaD study at their first annual visit.

About 45,000 postmenopausal women aged 50-79 will be randomized into one of two study groups. One group will take 1,000 mg of calcium carbonate and 400 International Units of vitamin D daily. The second group will take a placebo. Women who already take calcium supplements can continue to take them. Participants will be followed for 8 to 11 years and contacted by their clinical center every six months to assure their safety and assess their health.

G.3.6 Observational Study

Observational Study

Fact Sheet

WHAT IS THE PURPOSE OF THE OBSERVATIONAL STUDY?

The WHI observational study (OS) has several goals. These goals include:

- To give reliable estimates of the extent to which known risk factors predict heart disease, cancers and fractures;
- To identify "new" risk factors for these and other diseases in women;
- To compare risk factors, presence of disease at the start of the study, and new occurrences of disease during the WHI in all study components; and
- To create a future resource to identify biological indicators of disease, especially substances and factors found in blood.

HOW WILL THE OBSERVATIONAL STUDY BE CONDUCTED?

The observational study will enlist 100,000 postmenopausal women between the ages of 50 to 79. The health of OS participants will be tracked over an average of nine years.

Women who join this study will fill out periodic health forms and also visit the clinic three years after enrollment. OS participants are not required to take any medication or change their health habits. The OS does, however, follow a woman's health over a long period of time.

G.3.7 Women and Heart Disease

Women and Heart Disease

- Coronary heart disease is the number one killer of women in the U.S.; it kills 250,000 women a year.
- More than 500,000 women have heart attacks each year.
- Approximately 90 percent of all heart disease deaths among women occur after menopause.
- Studies have shown that heart disease in women often goes undetected and untreated until the disease has become severe. As a result, 39 percent of women who have heart attacks die within one year compared to 31 percent of men.
- Women are twice as likely as men to die within 60 days of a heart attack.
- Nearly two million women are hospitalized for heart disease each year.
- African American women are almost four times more likely to die of coronary heart disease than white women.
- In 1989, an estimated $23 billion was spent on hospital care for women who had cardiovascular disease. An additional $6.6 billion was spent on physicians' fees over 32 million office visits by women with cardiovascular disease.
- Eleven of 15 prospective observational studies suggest a 40 percent decreased risk of heart disease in women on hormone replacement therapy (HRT).
- Dietary factors are associated with five of the top 10 causes of death in the U.S., including coronary heart disease.

G.3.8 Women and Breast and Colorectal Cancer

Women and Breast and Colorectal Cancer

Breast:

- One in 8 women can now expect to develop breast cancer in her lifetime. In 1960 this ratio was 1 in 20 women.
- More women are struck with breast cancer than any other cancer. It is second only to lung cancer in the number of cancer deaths among women.
- The breast cancer death rate increased 24 percent between 1979 and 1986.
- A woman dies of breast cancer every 12 minutes.
- Although white women experience breast cancer more often than minority women, African American women die more frequently from the disease.

Colorectal:

- Colorectal cancer is the third leading cause of cancer death among women.
- In 1991, 78,000 new cases of colorectal cancer were diagnosed in women and about 31,000 deaths were reported.

G.3.9 Women and Osteoporosis

Women and Osteoporosis

- Osteoporosis accounts for 1.5 million fractures annually, including more than 90 percent of all hip fractures.
- Osteoporosis (weak or porous bones) leads to more than 300,000 hip fractures annually.
- Osteoporotic fractures, while not a leading cause of mortality in women, account for much disability and decreased quality of life in older women.
- It is estimated that a 50-year-old woman has a 50 percent chance of suffering an osteoporosis-related fracture during the remainder of her life.
- Approximately 25 million Americans suffer from osteoporosis; 80 percent of those affected are older women.
- A woman's risk for hip fracture is equal to the combined risk of developing breast, uterine, *and* ovarian cancer.
- Approximately 50 percent of people who suffer a hip fracture lose their ability to walk independently, and up to a third become totally dependent.
- Osteoporosis-related fractures costs $10-12 billion annually in medical, nursing home, and societal costs.

G.4 Position Statements

G.4.1 WHI Olestra Position Statement

The Women's Health Initiative

May 14, 1996, position approved by the WHI Council

Olestra is a zero-calorie fat replacement approved in January 1996 by the Food and Drug Administration. Olestra was approved for use as an ingredient in savory snacks, such as potato chips, and crackers. Food products with olestra could be available in late 1996. Olestra is made by Proctor and Gamble. The tradename of olestra is Olean.

Based on FDA approval, the Women's Health Initiative allows the use of olestra-containing foods in moderation, as an option, for participants in the Dietary Change part of the Dietary Modification study. Eaten in moderate amounts on occasion, olestra-containing foods offer Dietary Change participants an increased variety of low-fat or fat-free food choices. As with other foods labeled, "fat-free", participants are to record 1 gram of fat for three servings of olestra-containing foods eaten during one day. Participants should note that olestra-containing foods themselves are not calorie-free, only the olestra is calorie-free.

Olestra reduces the absorption of fat-soluble vitamins, such as vitamins A, D, E, K, and related nutrients such as beta-carotene, when the nutrients are consumed at the same time as olestra. The FDA requires that olestra-containing foods be so labeled and have vitamins A, D, E, and K added.

Olestra may cause gastrointestinal distress, such as cramping and loose stools. This information, too, is required to be on the label. People that experience these symptoms are advised to stop or decrease their consumption of olestra.

Procter and Gamble, the makers of olestra, must study how much olestra people eat and do more studies on long-term effects. The Food and Drug Administration (FDA) will be reviewing olestra again within 30 months from the original approval date of January 24, 1996.

G.4.2 Press Release from FDA and Proctor and Gamble about Olestra

G.4.2.1 Press Release from FDA (January 24, 1996):

The Food and Drug Administration today approved olestra — a fat-based substitute for conventional fats developed by Proctor & Gamble Co. — for use in certain snack foods and required all products containing olestra be labeled.

Because of its unique chemical composition, olestra adds no fat or calories to food. Potato chips, crackers, tortilla chips or other snacks made with olestra will be lower in fat and calories than snacks made with traditional fats.

"Olestra may cause abdominal cramping and loose stools in some individuals, and inhibits the body's absorption of certain fat-soluble vitamins and nutrients," said Commissioner of Food and Drugs David A. Kessler, M.D. "FDA is requiring Proctor & Gamble and other manufacturers who use olestra to label all foods made with it, and, to protect the public health, to add essential vitamins — vitamins A, D, E, and K — to olestra."

As a condition of approval, Proctor & Gamble will conduct studies to monitor consumption as well as studies on olestra's long-term effects. The FDA will formally review these studies in a public meeting of the Foods [sic] Advisory Committee within 30 months.

The approval today means that FDA has determined that the available data and information establish that olestra is safe for use in savory snacks.

The following labeling statement will be required on all products made with olestra: "This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added."

Like all food additives, olestra's safety was the primary focus of FDA evaluation. For olestra, the safety evaluation focused not only on its toxicity, but also on the product's effects on the absorption of nutrients and on the gastrointestinal system.

Studies of olestra indicated it may cause intestinal cramps and loose stools in some individuals. These gastrointestinal effects do not have medical consequences. The required labeling will give consumers needed information to discontinue this product if appropriate.

Clinical testing also indicated that olestra absorbs fat-soluble vitamins (Vitamins A, D, E, and K) from foods eaten at the same time as olestra-containing products. Studies also demonstrated, however, that this effect could be compensated for by replacing these essential nutrients in olestra-containing snacks. This information will also be provided consumers in the product labeling.

In addition in inhibiting the absorption of essential vitamins, olestra reduces the absorption of some carotenoids — nutrients found in carrots, sweet potatoes, green leaf vegetables and some animal tissue. The company's post-marketing monitoring of olestra consumption levels and additional studies will provide FDA with further information about olestra's effects on the absorption of carotenoids. The role of carotenoids in human health is not fully understood. FDA will continue to monitor all available scientific research on the role of carotenoids in human health.

In addressing these questions, FDA evaluated more than 150,000 pages of data on olestra, drawn from more than 150 studies. Proctor & Gamble submitted these data in its original 1987 food additive petition, and in several amendments filed since then to that petition.

In addition, FDA sought advice from outside experts through its Food Advisory Committee. A special working group of the committee met in public in November 1995 to review and discuss the safety questions regarding olestra. After evaluating data presented by FDA, the company, and organizations and individuals both opposing and supporting olestra's approval, a clear majority of the working group agreed that all the major safety issues had been identified and addressed by the FDA review, and that the data provided reasonable certainty that the proposed use of olestra would be safe. A majority of the full Food Advisory Committee, which later reviewed the data in public, reaffirmed that judgement.

The company, based in Cincinnati, Ohio, plans to market the product soon under the trade name Olean.

G.4.2.2 Press Release from Proctor and Gamble (January 23, 1996):

CINCINNATI, January 24, 1996 — Procter & Gamble (P&G) (NYSE: PG) is launching Olean(TM) brand fat replacer, a breakthrough, calorie-free fat replacement ingredient that can fully replace the added fat and cut calories in salted snacks and crackers, without sacrificing great taste. This announcement immediately follows the U.S. Food and Drug Administration's (FDA) approval of olestra for use in salty snacks and crackers. Olean is P&G's brand name for olestra.

"Americans can get ready to taste history because snacks made with Olean eliminate the taste trade-off with many fat-free or reduced-fat snacks. With Olean, 'no fat' doesn't mean 'no taste'," said Procter & Gamble Chairman and Chief Executive John Pepper.

"Taste buds are tough critics, and fat-free chips made with Olean get rave reviews from consumers across the country who've compared them with regular chips fried in vegetable oil," Pepper added.

"This is great news for Americans, who eat an average of 22 pounds of salty snacks annually. By replacing the fat in snacks, Olean can help millions of Americans cut excess fat and move closer to achieving an important dietary health goal," Pepper said.

Procter & Gamble will sell Olean to snack and cracker makers for use in their products, so consumers can expect to find the ingredient in a broad range of snacks in the future. P&G will also use Olean in new versions of its own Pringles potato crisps. Test markets of snacks made with Olean are expected to begin over the next several months. P&G said it will still be some time before snacks made with Olean will positively impact earnings.

The FDA's approval of Olean follows an extensive and thorough review of nearly 270 volumes of data by the agency and confirms that Olean meets the tough federal safety standards for new food ingredients. Olean is the most thoroughly tested new food ingredient ever reviewed by the FDA. The safety assurance program for Olean includes more than 150 long- and short-term studies spanning nearly three decades.

The FDA's approval covers the use of Olean in snack chips and crackers, such as potato chips, tortilla chips, cheese puffs and club crackers. While Olean can be used in other types of foods, this would require additional FDA approvals.

Consumer surveys reveal that the way food tastes influences our food choices more than any other factor. Taking the fat out of foods is not easy to do because fat plays such a critical role in the taste and texture of many foods. As a result, consumers have come to expect a sacrifice in flavor and enjoyment with many of today's low-fat and fat- free foods. Not true with Olean. Snacks made with Olean have the great flavor of snacks fried in vegetable oil.

Marilyn Harris, cookbook author and culinary adviser, has put Olean through its culinary paces for eight years. "Olean does the glorious things fat does in all foods — it brings out the taste, the texture and the wonderful character that makes food delicious, but with no added fat or calories. Chips made with Olean and regular chips both taste great, have the same golden color and the same satisfying crunch," Harris said.

For those who enjoy snack foods, Olean will provide new options which have little or no fat and far fewer calories. For example, a one- ounce bag of potato chips made with Olean contains zero grams of fat and about 70 calories, compared to 10 grams of fat and about 150 calories for a one-ounce bag of regular potato chips.

John Foreyt, Ph.D., director of the Nutrition Research Clinic at Baylor College of Medicine, has conducted research with Olean and found choices are important to people trying to cut their fat intake. His study suggested that people find it easier to adopt a lower fat diet when they could choose Olean versions of some of their favorite foods compared with another group which did not have access to foods made with Olean.

"While Olean won't single-handedly solve our dietary fat problem, consumers can come out ahead on both fat and calories if they substitute fat-free snack chips and crackers made with Olean for their current snacks," Foreyt said. "Snacks made with Olean give us more choices and take us another step in the right direction."

Because taste powerfully influences our food choices, many people have found that cutting excess fat in the diet is easier said than done. Nutrition authorities, such as the American Dietetic Association (ADA), recognize that reaching the goal of cutting fat to 30 percent of total calories will take a variety of approaches and that fat replacers can play an important role. The ADA's position statement on fat replacers says:

"Fat replacements provide an opportunity for individuals to reduce intake of high-fat foods while preserving basic food selection factors. In addition, good tasting foods containing fat replacements may promote the gradual acquisition of a preference for lower-fat foods."

Olean Made From Common Ingredients, Performs Like Vegetable Oil

The basic building blocks of Olean are everyday ingredients found in virtually every kitchen — table sugar and vegetable oil. These ingredients are combined in such a way that the body cannot break them down. As a result, Olean contributes no fat or calories to foods.

Procter & Gamble has been an innovator and marketer of cooking fats for home and institutional use for 85 years, starting with the introduction of Crisco shortening in 1911. Crisco, the nation's first all-vegetable shortening, was soon used for cooking and baking by millions of consumers as a healthier alternative to lard and other highly-

saturated fats. P&G introduced Crisco Oil in the 1960s and in 1987 launched the first nationally marketed canola oil, now known as Crisco Puritan Oil.

As so often happens with inventions, Olean was discovered by accident. In the 1960s, P&G researchers were conducting research on fat digestion and discovered a fat-like ingredient that wasn't broken down or digested at all. Today, that discovery, Olean, opens up new possibilities for tasty, fat-free snack chips and crackers.

Olean is a registered trademark of The Procter & Gamble Company.

G.4.3 Common Questions & Answers About Olean (Written by Procter & Gamble)

Procter & Gamble
1 Procter & Gamble Plaza
Cincinnati, OH 45202

Common Questions & Answers About Olean®

Introduction

Leading health organizations, including the American Heart Association, the American Dietetic Association, and the American Cancer Society, recommend limiting fat to no more than 30 percent of the calories in the total diet. Reducing fat in the diet is one of the most important steps people can take to reduce their risk of heart disease, some types of cancer and other health problems.

The FDA recently approved Olean (Proctor & Gamble's brand name for olestra) the new fat replacer that gives snacks like potato chips and corn chips the rich taste of snacks made from fat. Snacks made with Olean provide patients with a unique new tool to help manage fat and calorie intake without giving up their favorite foods.

Q: What is Olean?

A: Olean is a no-calorie fat replacer made starting with everyday ingredients – table sugar and vegetable oil. Olean's molecular structure is similar to triglycerides. Where triglycerides have three fatty acids attached to a glyucerol core, Olean has six, seven or eight fatty acids on a sucrose core. The extra fatty acids on Olean make it too large to be digested or absorbed, which is why it adds no fat or calories. This means a one-ounce bag of potato chips made with Olean contains 0 grams of fat and about 70 calories, compared to 10 grams of fat and 150 calories for a one-ounce bag of full-fat potato chips.

Q: How will Olean be available?

A: The FDA approved Olean for use in snacks such as potato, corn, and tortilla chips; extruded snacks (cheese puffs for example); and crackers. It is the first approved fat replacer that is heat-stable at high temperatures, allowing snacks made with Olean to have the great taste of full snacks. Olean can also replace the fat in many other foods including shortening and oil, ice cream, salad dressings and cheese, but any use beyond snack chips and crackers requires separate FDA review and approval.

Q: When will snacks made with Olestra be available?

A: Great-tasting, fat-free snacks made with Olean should be available in limited test markets in 1996.

Q: Is Olean safe?

A: Olean is the most thoroughly tested new food ingredient ever approved by the FDA. More than 25 years of research, including more than 150 long and short term studies, confirm that foods made with Olean can be safely consumed by adults and children.

Q: Will Olean have any effects on GI structure?

A: Since Olean is not absorbed, the gastrointestinal tract is the only part of the body that comes in contact with Olean. Extensive research has shown that Olean does not adversely affect the structure or function of the GI tract. Studies in animals and humans support that Olean will not exacerbate disease in people with disorders of the GI tract such as ulcerative colitis and Crohn's disease.

Q: Will Olean cause GI effects?

A: With typical patterns of consumption, most people will experience no different gastrointestinal effects from snack foods made with Olean than from full-fat snacks. Some people, especially if they ingest large amounts of snack foods made with Olean, may experience GI effects such as abdominal cramping and loose stools. Any digestive effects end once Olean passes through the body. A statement informing consumers about these effects will be included on the package. As with any food, moderation is the key. Olean is a replacement for fat, not for common sense.

Q: Does Olean affect the absorption of vitamins and carotenoids?

A: A comprehensive human and animal nutrition program confirmed that Olean's use in snack foods will not affect availability of carbohydrates, protein, fat, water-soluble vitamins and minerals from other foods. Olean can cause a decrease in the absorption of carotenoids and fat-soluble vitamins A, D, E, and K from other foods eaten at the same time as snacks made with Olean. A statement informing consumers about these effects will be included on the package. With typical patterns of snack food consumption, the effect of Olean on carotenoid levels in the body should remain within the range of normal variations. To offset any effect on the essential fat-soluble vitamins A, D, E, and K, manufacturers will add specific amounts of these essential vitamins to snacks made with Olean.

Q: Does Olean affect absorption of drugs?

A: Animal and human clinical studies verified that Olean does not affect the absorption of orally dosed drugs that are widely used or lipid-soluble such as ethinyl estradiol or norethindrone (oral contraceptives), diazepam (tranquilizer), or propranolol (cardiovascular medication). Olean will not adversely affect patients onanticoagulant drugs (e.g., Coumadin®).

Q: How will foods made with Olean be labeled?

A: The brand name Olean will appear on the front label of products containing this ingredient. "Olestra," the ingredient name for Olean, will appear in the ingredient listing on the back label. There will also be a statement informing consumers about potential GI effects and potential for absorption of vitamins and carotenoids.

Q: How does Olean taste?

A: Olean looks like fat, cooks like fat and gives snack foods such as potato chips and corn chips the rich taste and texture that people love. In fact, in taste tests across the country, consumers have found that snacks made with Olestra have the great taste of full-fat snacks.

For additional information write:

Procter & Gamble Professional Affairs
P.O. Box 5544
Cincinnati, OH 45202

G.5 Motivation Enhancement

G.5.1 Motivation Enhancement Training August 1999, WHI Intensive Intervention Protocol

Motivation Enhancement Training

August 1999

Women's Health Initiative

Intensive Intervention Protocol

Training materials and curriculum created by:

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We would like to acknowledge the following:

William R. Miller, Ph.D., and Stephen Rollnick, Ph.D., for their seminal work in motivational interviewing that was the inspiration for this work.

Victor J. Stevens, Ph.D., for gathering the resources and providing support to allow the trainers to accomplish the work.

The many members of the Women's Health Initiative team who reviewed materials, shared experiences, and contributed to the quality of the product.

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Women's Health Initiative Intensive Intervention Protocol (IIP): A Rationale and Overview

A pilot study with WHI DM change participants at three clinical centers demonstrated that an intensive intervention program of three individual contacts based on a motivational interviewing style of counseling was effective in further lowering dietary fat intake, beyond that achieved with the standard WHI DM intervention. The WHI Steering Committee approved implementation of the IIP at each clinical center, as part of the study-wide effort to increase the C–I (control minus intervention percent calories from fat intake).

The pilot as well as the IIP use a collaborative, participant-centered method for increasing participants' motivation to consider eating behavior change and to negotiate the best course of action. The nutritionist does not assume an authoritarian role and attempts to draw on and enhance participants' internal motivation to make health behavior changes based on their own decisions and choices. The focus shifts from giving information, advice, and behavior change prescriptions to helping participants explore concerns, ambivalence, reasons for change, and ideas and strategies for change. The health care professional utilizes a variety of negotiating strategies based on a participant's readiness to consider change.

Fundamental Belief

The capacity and potential for making health behavior change is in every one of us.

Goals

1. Establish rapport by using an empathic, non-judgmental style.
2. Emphasize participants' freedom of choice to make decisions regarding their health.
3. Understand and accept participants' feelings and thoughts about their health condition and/or health behavior change issue.
4. Collaborate with participants to explore motivation and confidence about health behavior change.
5. Create an environment that encourages participants to think and speak about their concerns, ambivalence, reasons for change, and ideas and strategies for health behavior change.
6. Individualize the negotiating strategies based on a participant's readiness to consider change.
7. Minimize participant resistance by not confronting, pushing, persuading, etc.
8. Enhance participants' self-confidence by expressing your confidence in their ability to change when ready.
9. Offer clear, professional advice.
10. Provide clear, brief education.

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What Motivates Change?

1. If you are told what to do, there is a good chance that you will do the opposite.
2. Values and beliefs. The more central or core to you the value is, the more long-lasting and pervasive the change is likely to be.
3. Your beliefs are more influenced by what you hear yourself say than by what others say to you.
4. Ambivalence is a normal and natural part of the change process.
5. Knowledge about how likely you are to incur harm or reap a benefit is an important element in deciding to change. Also important is the magnitude of the perceived harm or benefit.
6. Before you can decide to change, you need to believe that there is something you can do that will effect the change.
7. Decision making can be facilitated by the weighing of pros and cons of any choice.
8. The interaction between therapist and client powerfully influences client resistance, compliance, and change.
9. Brief interventions have the potential to produce similar outcomes to longer, more intensive interventions.

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Conceptual Models of Motivation

Reactance

The Brehms' (1981) **reactance** theory posits that perceived threats to personal freedom and choice will elicit behaviors designed to demonstrate and restore that freedom. When behavioral freedom and autonomy are threatened, the probability and the perceived desirability of the to-be-lost behavior will increase. This is consistent with the effects of more aggressive confrontational strategies, which tend to elicit resistance and are associated with lack of long-term behavior change (Miller, Benefield, & Tonigan, 1993; Brehm & Brehm 1981).

Self-Perception Theory

Daryl Bem proposed **self-perception theory** as an alternative conceptual explanation for many of the empirical findings from cognitive dissonance research. Rather than postulating, as Festinger did, that there is an inherent Hullian drive to be internally consistent (cognitive dissonance), Bem proposed that people learn what they believe in the same way that others do: by hearing them (selves) talk. When people publicly take a position, their commitment to that position increases. The more a person argues on behalf of a position, the more committed she becomes to it. This is a way of understanding the countertherapeutic nature of the confrontation/denial trap, in which the therapist argues for change and the client argues against it.

Self-Regulation Theory

Yet another way of understanding what triggers change is found in **self-regulation** theory, originally described by Kanfer (for a recent review see Miller & Brown, 1991). In this view, behavior is regulated by cycles involving the monitoring of one's own status, comparison of status with expectations, and "course correction" when status does not match goal or expectancy. To trigger change, one would seek to increase the discrepancy between status and goal, which could be accomplished either by increasing awareness of status (e.g., through feedback such as self-monitoring) or by affecting goal states (see the work of Miles Cox on goals in motivational counseling, chapter 19 in MI).

Conflict and Ambivalence

Animals, including people, tend to be immobilized by conflict. **Approach-avoidance** conflict seems to be particularly potent in its ability to hold people in repetitive cycles, with **double approach-avoidance** conflicts being still more tenacious (e.g., vacillating between a marital partner and an affair). In conflict situations, **ambivalence** (feeling at least two different ways about something, or wanting mutually exclusive goals) is a normal and defining condition of the state and is a key obstacle to change.

Rokeach's Value Theory

Most recently, the New Mexico group has been studying people who have undergone sudden transformations in personality (see Miller & C'de Baca paper on quantum change). We have been seeking conceptual models to understand why such dramatic shifts in behavior and identity (the fictional model is Ebenezer Scrooge) occur and endure. One promising model is found in Milton Rokeach's 1973 classic volume on *The Nature of Human Values.* He conceptualized personality as hierarchically organized, with immediate behaviors and cognitions at the most peripheral level. An individual's attitudes, which number in the thousand, represent on organizational step inward. More central are beliefs, and behind these a set of a few dozen **core personal values**. Beyond these, Rokeach alluded to a most central sense of personal identity. The further "in" the shift occurs, the more sweeping will be the resulting change.

Health Beliefs

Health beliefs models have emerged primarily from the public health field. An example is Ronald Rogers' protection motivational theory. Such models typically include two elements: (1) **degree of perceived risk**, often the cross-product of perceived probability and perceived severity, and (2) **self-efficacy**, the perceived availability of personally efficacious action. Motivation for change depends upon the presence of a sufficient degree of perceived risk, in combination with sufficient self-efficacy. Perceived risk without self-efficacy tends to result in defensive cognitive coping (e.g., denial, rationalization, projection) rather than behavior change. The first element of this change model can easily be converted to **degree of perceived promise** (for a positive goal), being the cross-product of perceived probability of reward and perceived values of reward.

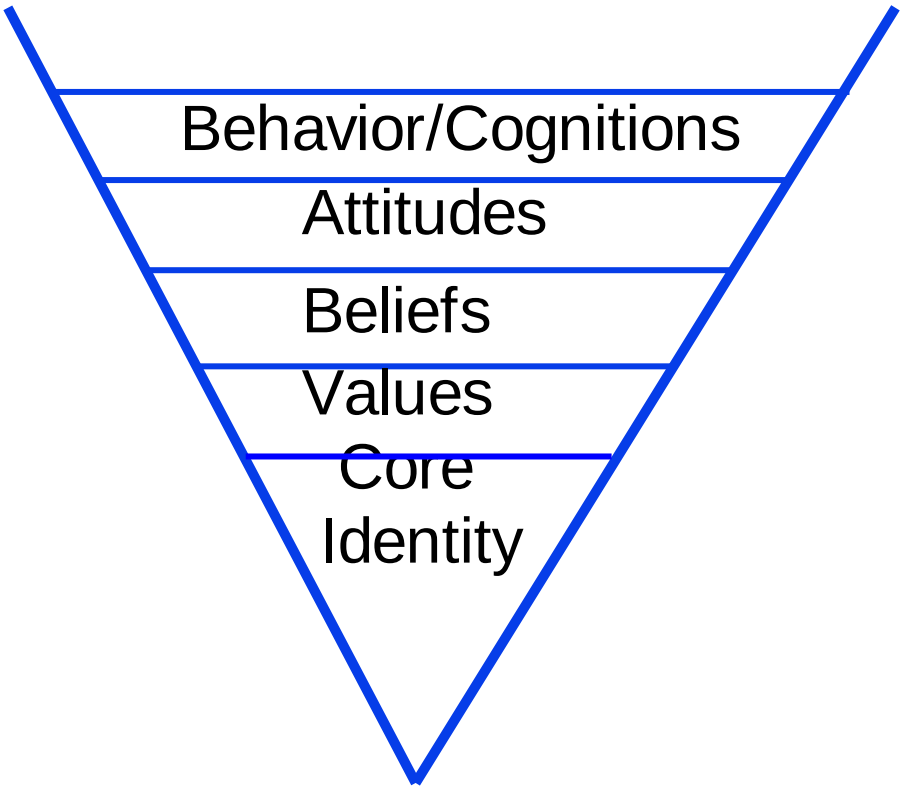
Decisional Balance

The classic Janis and Mann (1977) **decisional balance** is a rational view, describing decision as a process of weighing cognitively the pros and cons of change. Change here depends on the pros (of change) outweighing the cons.

Interaction

According to Miller and Rollnick, motivation can be thought of not as a client trait, but as an **interpersonal process** between therapist and client. Research clearly demonstrates that the interaction between therapist and client powerfully influences client resistance, compliance, and change.

Rokeach's Value Theory



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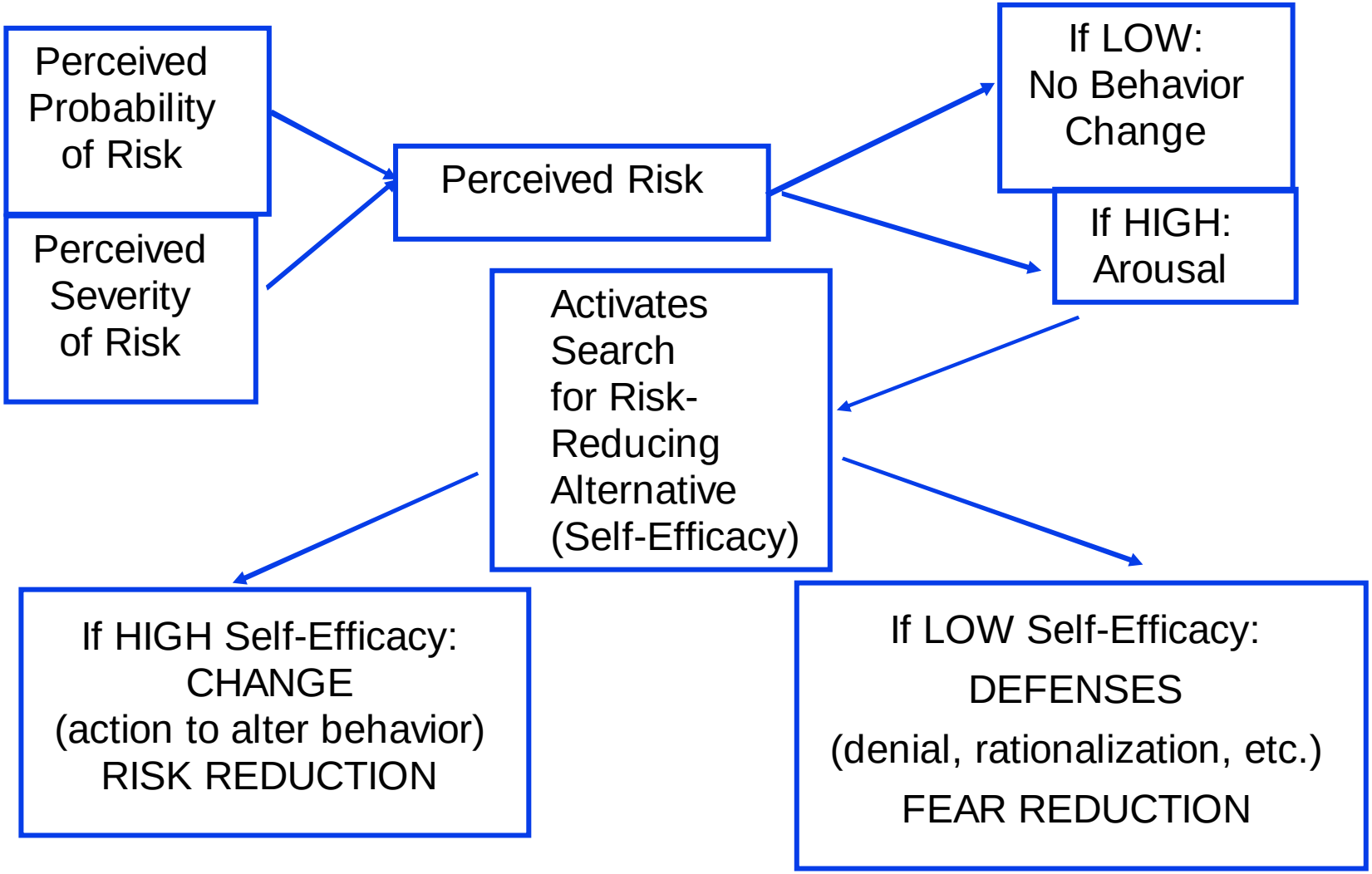
Rogers' Protection Motivation Theory



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Stages of Change

Precontemplation is the state in which people are not considering changing or initiating a behavior. They may be unaware that a problem exists.

Contemplation is the stage characterized by ambivalence about changing or initiating a behavior.

Preparation is the stage characterized by reduced ambivalence and exploration of options for change.

Action is the stage characterized by the taking of action in order to achieve change.

Maintenance is the stage characterized by seeking to integrate and maintain a behavior that has been successfully changed or initiated.

Relapse is the stage characterized by a recurrence of the undesired behavior or elimination of a desired behavior.

Implications

1. Behavior change or initiation is a process.
2. Ambivalence is a normal and healthy aspect of the process and is a major obstacle to change.
3. Tailoring an intervention to match the stage of change is critical.
4. A "successful" intervention may not produce the desired change in behavior but may be reflected in movement in that direction.

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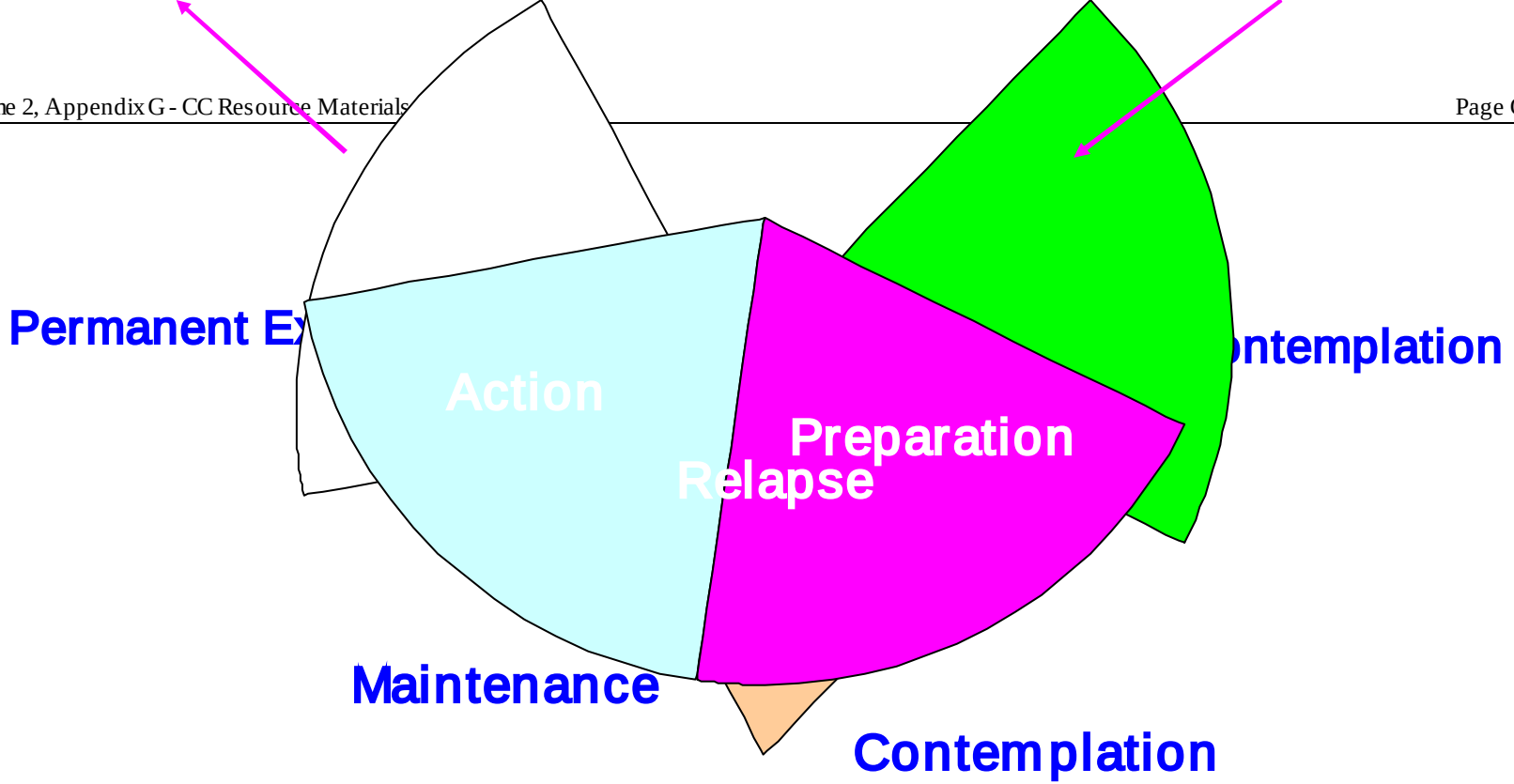

Stages of Change

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Effective Brief Intervention (FRAMES)

Feedback. Provide participants with *personal* feedback regarding their individual status and where they stand in relationship to the norms and standards.

Responsibility. Emphasize the individual's freedom of choice and personal responsibility for their choices.

Advice. Provide clear recommendations or advice in a supportive, non-threatening manner.

Menu. Provide options for participants to choose from.

Empathy. Express empathy; accurate reflective listening, warm and genuine manner, non-judgmental approach.

Self-Efficacy. Reinforce the participant's sense of self-efficacy regarding their ability to make changes, modify behavior, or participate fully.

Implications

1. Brief (even 30 seconds) intervention is effective.
2. Of all the FRAMES elements, empathy is the most powerful.

Sample Script

"In reviewing your records I noticed that I don't have any completed self-monitoring tools for the past three months. I understand that keeping the records is challenging and often painful. From the study's perspective, I would like to encourage you to do the self-monitoring. It is the way we can track our own progress as well as yours. Of course, it is up to you. As you know, there are a variety of self-monitoring tools you can choose from if you decide to do it. I would be happy to help in whatever way I can. And I'm confident that should you decide to start again, that you will be able to do it."

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A Motivation-Enhancing Interpersonal "Style"

Key Elements

1. Understanding
   - ♦ Empathic, careful listening, attentive, non-judgmental, warm, and supportive.
   - ♦ Seeking to see things from the participant's perspective.

2. Participant-centered
   - ♦ Encouraging participants to be as active as possible in making decisions about health behavior change.
   - ♦ Eliciting motivation to change from the participant, not imposing it from without.
   - ♦ Encouraging participants to do most of the talking.

3. Collaborative
   - ♦ Pursuing common goals.
   - ♦ Sharing of agendas and responsibility.
   - ♦ Working together in partnership to determine the best course of action (a meeting between "experts").

4. Individualized
   - ♦ Tailoring intervention approaches to match the participant's personal 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").

6. Respectful/accepting
   - ♦ Conveying respect by accepting whatever decisions a participant makes about health behavior change.

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Skills That Bring the Motivation-Enhancing "Style" to Life

A. Listening

Goals

1. To establish rapport.
2. To create a supportive environment for the participant to think and talk about change ("change talk").
3. To let the participant know you are listening and understand.
4. To tap into the "natural change potential" of the participant.

Key Elements

1. Demonstrate open and receptive non-verbal behaviors.
2. Let the participant talk without interruption.
3. Employ minimal encouragers.
    - Mm-hmm
    - I see
    - Go on
    - For instance
    - Oh?
    - And?
    - Tell me more
    - Really?
    - What else?
4. Use attentive silence to allow the participant to think and process.
5. Listen without judgment or rebuttal.

Avoid

Employing the roadblocks to effective listening (see following handout)

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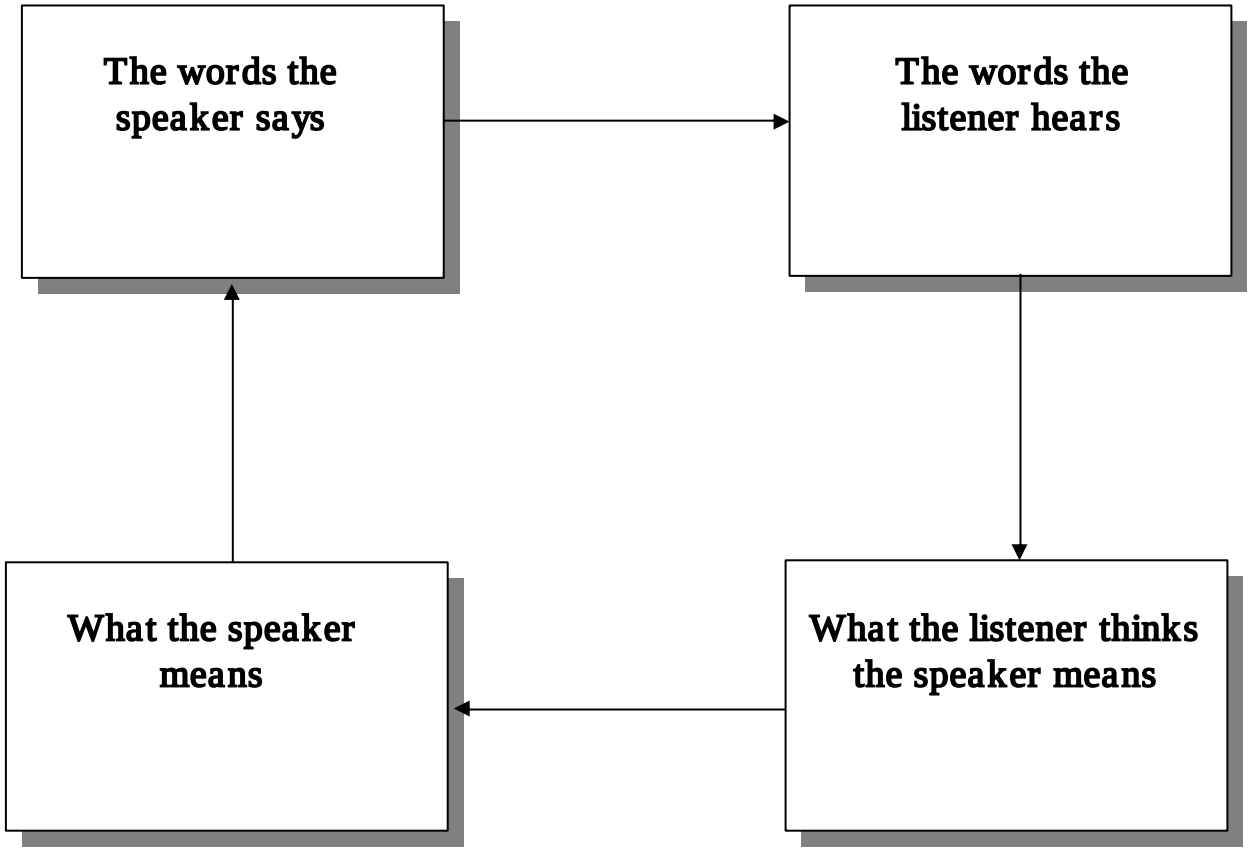
Roadblocks to Effective Listening

1. Ordering, directing, or commanding
2. Warning or threatening
3. Giving advice, making suggestions, or providing solutions
4. Persuading with logic, arguing, or lecturing
5. Moralizing, preaching, or telling participants what they "should" do
6. Disagreeing, judging, criticizing, or blaming
7. Agreeing, approving, or praising
8. Shaming, ridiculing, or labeling
9. Interpreting or analyzing
10. Reassuring, sympathizing, or consoling
11. Questioning or probing
12. Withdrawing, distracting, humoring, or changing the subject

Gordon's Model of Communication



- Communication can go wrong because:
  1. The speaker does not say exactly what is meant
  2. The listener does not hear the words correctly
  3. The listener gives a different interpretation to what the words mean
- The process of reflective listening is meant to connect the bottom two boxes, to check whether "what the listener thinks the speaker means" is the same as "what the speaker means."

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Skills That Bring the Motivation-Enhancing "Style" to Life

B. Summarizing

Goals

1. To reinforce what the participant has said, especially self-motivational statements.
2. To show that you have been listening.
3. To provide a mirror for the participant to see themselves (to show the "big picture").
4. To allow the participant to hear her "change talk."
5. To tie together what has been said, to provide a transition link, and/or to bring closure to a conversation.

Key Elements

1. Summarize in a brief, concise manner.
2. Preface a summary statement with an introduction (ex: "let me see if I understand what you've told me so far").
3. If a participant has expressed ambivalence, it is useful to capture both sides of the ambivalence in the summary statement ("On the one hand ... on the other ...").
4. End a summary statement with an invitation for the participant to respond, such as: "How did I do? What have I missed?"

Avoid

1. A rambling summary.
2. Interpreting the meaning of what a participant has said.

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Skills That Bring the Motivation-Enhancing "Style" to Life

C. Asking Open-Ended Questions

Goal

To encourage the participant to think and talk about change.

Key Elements

1. Ask the participant specific open-ended questions to elicit "change talk":
   - Recognition of a problem
   - Concerns about a perceived problem
   - Reasons and arguments for change
   - Intentions for change
   - Ambivalence about change
   - Confidence in ability to change
   - Ideas and options for change
   - Roadblocks in making a change
2. Ask questions in a way that is open and inviting.

Avoid

Asking closed-ended questions. This type of question typically elicits a "yes" or "no" response or a short answer.

Sample Questions

"In what ways has the WHI eating pattern been a challenge for you?"
"How do you feel about your fat gram goal?"
"Is this information summarizing your diet scores surprising to you?"
"What makes you think that you need to change your current eating habits?"
"What would need to be different for you to eat less fat?"
"What are some things you like about your current eating habits?" "What are some things you dislike about your current eating habits?"
"What would be some of the good things about making a change?"
"Let's suppose you decided to cut back on fat." "How would your life be different?"
"What do you think has to change?"
"What's going to happen now? Where do we go from here?"
"What could you do?" "What are your options?"
"What might get in your way of eating lower-fat meals?"

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Skills That Bring the Motivation-Enhancing "Style" to Life

D. Supporting Self-Efficacy

Goal

To increase the participant's belief in her ability to successfully make a behavior change.

Key Elements

1. Provide supportive messages that emphasize your confidence in the participant's ability to change.
2. Seek out opportunities to affirm, compliment, and reinforce the participant sincerely.
3. Emphasize the many different options and pathways to change. Failure to change can be viewed as not yet having found the right approach.
4. Provide information about the "cycle of change." Helping a participant understand the process of change can provide hope.
5. Emphasize that most people who make a firm decision to change eventually succeed.
6. Focus on successes and efforts. Have participants talk about their past and current successes.
7. Stay positive! The provider's belief in the participant's ability to change can also significantly influence outcome.

Avoid

1. Insincerity.
2. Discounting concerns or the difficulty in changing.

Sample Statements

"I'm confident that you can do it once you decide the time is right."

"I applaud your efforts, and I know you can do it."

"Keep it up; you're doing great."

"You really have some good ideas for how you might change."

Skills That Bring the Motivation-Enhancing "Style" to Life

E. Eliciting Self-Motivational Statements ("Change Talk")

Definition: a *self-motivational statement* (SMS) is one in which the participant expresses a thought supporting a change in current behavior. This participant "change talk" may be evidenced in various ways such as: problem recognition; concern; intention to change; and optimism.

Goal

To use a variety of strategies to help participants resolve their ambivalence and present their own arguments for change.

Key Elements

1. The skills practiced and learned previously are fundamental to eliciting participant change talk.
2. Strategies seen in the WHI IIP road map and further detailed in the following pages have all been designed to elicit participant change talk.
3. Asking evocative questions is very useful in helping participants to think differently. We will be practicing the use of these to bring out participant change talk throughout the course.
4. Participant self-motivational statements vary and fall into four general categories.
   - Problem Recognition: *"I guess the way I've been eating lately really isn't that good*."
   - Concern: *"I'm concerned that the study may not be able to answer the question*."
   - Intention to Change: *"It was so useful to self-monitor. I am going to start again!"*
   - Optimism: *"You know, I know I can reduce my daily fat grams. I did it before*."

Avoid

Rushing the participant at first mention of SMS or "change talk."

Sample Evocative Questions

"What things make you think that this is a problem?"

"What is there about _____ that you or other people might see as reasons for concern?"

"What makes you think that you may need to make a change?"

"What makes you think that if you did decide to make a change, you could do it?"

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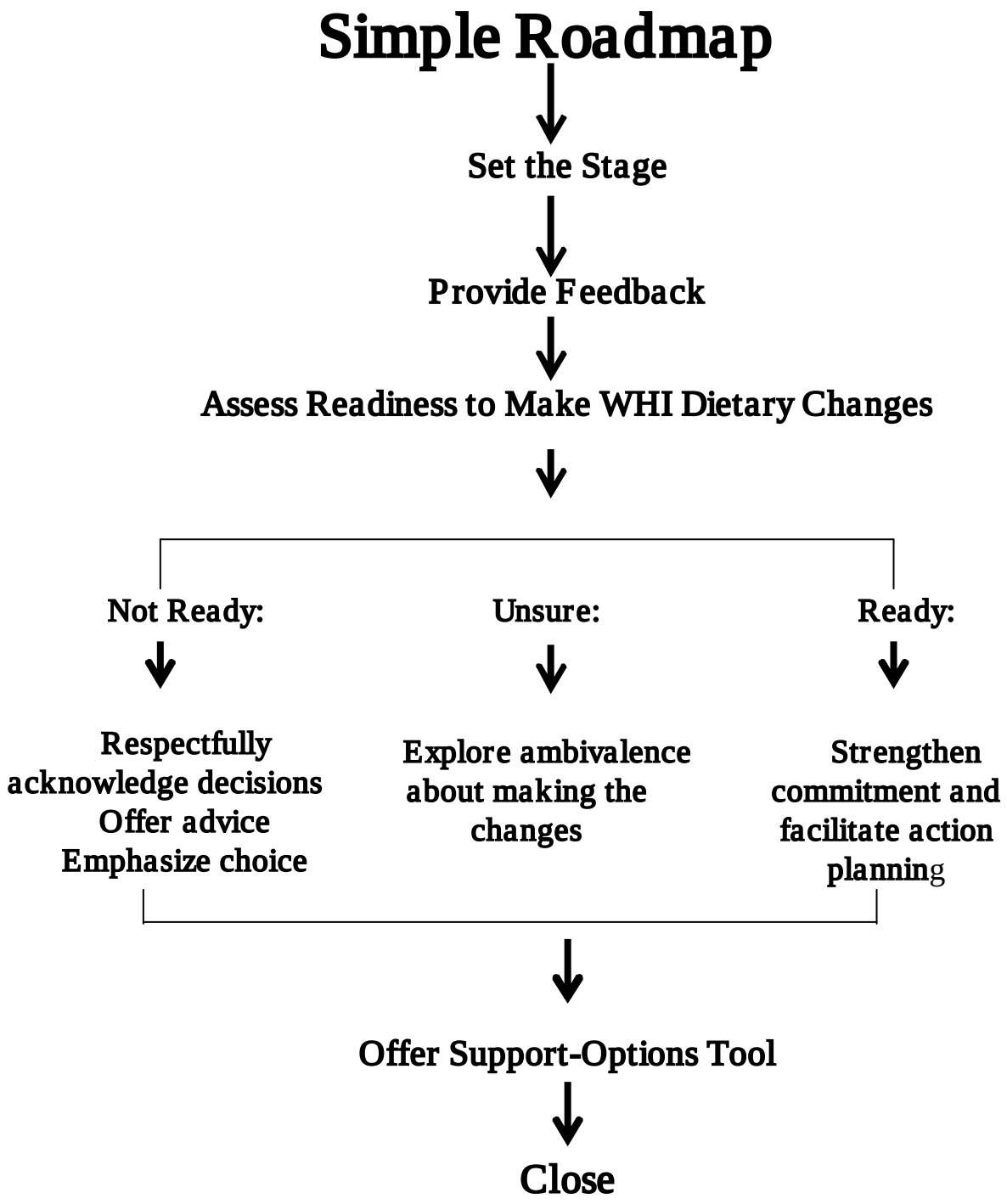

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Setting the Stage

Goal

To establish rapport with the participant by setting the parameters of the interaction.

Key Elements

1. Open with a statement that tells the participant who you are, why you are there, and how much time you have.
2. Seek permission to discuss a specific behavior in a non-judgmental, gentle, respectful way.
3. Emphasize the participant's responsibility and freedom of choice about the behavior.
4. Proceed with an open-ended question designed to encourage the participant to express their thoughts and feelings about the behavior, disease, or medical condition.
5. Allow the participant ample opportunity to tell their story; listen, don't interrupt.

Avoid

1. Leaving the purpose and time vague.
2. Interrupting their story.
3. "Shoulding," wagging your finger, judgmental tone of voice, and beating around the bush.

Sample Script

"Hello, Mrs. _____. I'm _____ with the Women's' Health Initiative (introduce yourself if participant is new). Thank you for taking the time to meet with me. We have 45 minutes today that I'd like to spend reviewing the WHI diet. Does this sound okay to you? Is there anything else that you'd like to talk about? I want to make it clear that I'm not here to tell you what to do. Any decisions about your diet are, of course, yours. So how are you feeling about the WHI diet?"

Key Questions/Statements

1. Prior to discussing topic: *"Would you be willing to discuss _____?"*
2. After receiving permission: *"Tell me about your _____."* or *"Tell me how _____ fits into your life."*

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Assessing Readiness to Change

Goal

To determine a participant's readiness to change or initiate a behavior.

Key Elements

1. Show the participant the readiness-to-change ruler and ask her to indicate where she is in relation to the particular behavior.
2. Acknowledge and accept the participant's position on the ruler.
3. Ask specific open-ended questions to elicit "change talk."

Avoid

1. Showing bias or judging the participant's position on the ruler.
2. Rushing this process, as it is crucial to decision making.

Key Questions/Statements

"On a scale of 0-12, how ready are you right now to make any of the dietary changes that WHI has asked you to make?" (0 = not at all ready; 12 = very ready)

"On a scale of 0-12, how ready are you to lower your daily fat intake from where it is right now?" (0 = not at all ready; 12 = very ready)

Key Follow-up Questions

Straight Question: "*Why did you pick a ____?"*

Backwards Question: "*Why did you pick a 4 and not a 1?"*

Forwards Question: "*What would need to be different for you to move from a 2 to an 8?"*

Future Question: "*Let's suppose you decided to _____." "Why would you want to do it?" "What would you want to do?"*

Tools/Strategies

Ruler

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Exploring Ambivalence

Goals

1. To help the participant verbalize all the conflicting thoughts and feelings about the behavior(s) or the project.
2. To convey to the participant a complete verbal picture of her uncertainty and ambivalence.

Key Elements

1. Ask permission.
2. Begin the exploration by asking the participant her reasons for not changing the behavior; then ask the participant about her reasons to change.
3. Summarize the reasons for not changing first, followed by the reasons for change.
4. Ask if you got it all.
5. Ask about the next step (e.g., "Where does this leave you now?")

Avoid

1. Using the words "problem" or "concern" unless the participant uses them.
2. Telling the participant your perceptions of the reasons to change.
3. Arguing with the participant about the validity of their thoughts and feelings.

Key Questions

"What are some of the things you like about your current eating habits?"

"What are some of the things you dislike about your current eating habits?"

"What are some of the reasons why you would want things to stay just the way they are?"

"What are some of the reasons for making a change?"

"What are the advantages/disadvantages of being in WHI?"

"What are advantages/disadvantages of decreasing fat in your diet?"

Tools/Strategies

Pros and Cons

Deciding-to-Change Worksheet

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Exchanging Information

Goals

1. To share personalized feedback with the participant in a neutral manner.
2. To offer your professional advice and opinions in a motivation-enhancing manner.
3. To offer new information to help support the participant's decision-making process.

Key Elements

1. Ask permission.
2. Be clear, succinct, and non-judgmental.
3. Elicit participant's response.

Strategies

1. Giving Feedback
   - ♦ Give the facts, leave the initial interpretation to the participant.
   - ♦ Compare participant's feedback to norms, standards, historical data, and/or other clinical centers, etc.

   Example: *"Taking a look a your IPR, the percentage of calories you were eating from fat at Session Three was 30. At Session Two it was 27, and at Session One it was 26. To give you a reference point—a point of comparison—the average percentage of fat for all the women at our clinic at Session Three was 24."*

   - ♦ Elicit participant's interpretation of the feedback.

   Examples:

   "What do you think about this information?"

   "Is this information surprising to you?"

   "Are these numbers where you thought you might be?"
2. Offering Advice
   - ♦ Emphasize freedom of choice and personal responsibility.

     Example: *"This is what we recommend, but the final decision is yours."*
   - ♦ Voice confidence in the participant's ability to change/adhere.

     Example: *"I'm confident that if you make a firm decision and commitment to eat more fruits and vegetables, you'll find a way to do it."*

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- Elicit participant's thoughts and feelings in response to advice.

  Example: *"What do you think about my recommendation?"*

- "FRAMES" is a useful guide for constructing advice statements.

  "As a W.H.I. nutritionist, I strongly encourage you to self-monitor on most days of the week. As you already know, self-monitoring is one of the most important things a person can do for keeping her fat grams down. But of course, the decision is yours. I know from experience, however, that self-monitoring is not necessarily easy. But I'm very confident that if in fact you decide to do it on a regular basis, you'll find a way to do it. The good news—from my perspective—is that there are a number of different things that a person might do to make self-monitoring easier."

3. Providing Education

- Education is important but not sufficient for health behavior change!
- Ask participant what she already knows.
- Avoid overwhelming participants with too much information.
- Check in frequently for understanding.

  Example:

  "Does this make sense?"

  "Any questions?"

  "How is this information relevant to you?"

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Facilitating Action Planning

Goal

To help the participant decide a specific course of action to take.

Key Elements

1. Strengthen participant commitment to change.
2. Encourage the participant to identify potential areas of focus, behaviors, options, resources, ideas, strategies, etc.
3. Provide additional options, etc., only after the participant has exhausted her ideas or has asked.
4. Affirm that change is process, with many ways to accomplish goals a person sets, and that you are confident that the participant will find a way that will work for them.
5. Participate in an exploration of the pros and cons of options, etc., as well as problem-solving around potential barriers and challenges.
6. When the participant has decided on a course of action, help her articulate a specific plan, including when, how, and what her plans are. The more specific the plan, the better. Encourage the participant to write it down and make a copy for you for follow-up. Be sure the next step is clear.
7. Summarize participant's decision and ask if it is what she intends to do.
8. Affirm participant's ability to take action and your confidence in her success.

Key Follow-up Questions

1. *"What are your main reasons for wanting to make this change?"*
2. *"What could you do? What are your options? What are some of your ideas?"*
3. *"What might get in the way of you making this change?"*
4. *"Where will your support come from? What resources do you need?"*
5. *"How will you reward yourself?"*

Tool/Strategies

Options tool

Offer Support (Optional Additional Strategies)

Goal

To provide nutritionists with additional optional strategies to use when there is time in the visit and the participant is interested. To provide the participant with an opportunity to further explore an area of interest related to WHI.

Key Elements

1. Offer the options as something potentially useful when thinking about WHI.

- **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 options 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. (show WHI How Can We Support You options tool) Are any of these of interest to you or is there something else you would like to do with this time?"*

2. Allow for the participant to decide what to focus on.
3. Using open-ended questions and reflective listening, work to understand in depth where the participant is.
4. Summarize, and ask about the next step or what it all means to the participant, or where the discussion leaves her.

Avoid

1. Action planning unless specifically indicated by the participant.
2. Problem solving for the participant.
3. Giving advice.
4. Being a cheerleader for change
5. Being judgmental about where she is.

Options

1. Assess Current Eating Behavior

Purpose: Allows the participant to do an honest, self-evaluation of her current eating behavior.

Allows the participant time to reflect on her own habits and how it effects her life.

How to present it: *"Some people find it useful, when thinking about dietary change, to really look at what is happening right now with your dietary patterns. We would spend some time looking in depth at those. What do you think?"*

Key Questions:

Tell me about a typical day with regard to food.

What do you see as ideal eating habits? Where would you like to be?

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

Purpose: Allows participant to explore their thoughts about the WHI dietary goals.

Allows the participant to think about past successes and what she would like to do.

How to present it: *"It might be useful to look at the whole range of dietary changes that WHI is focusing on. Something might stand out to spend more time discussing. What do you think?"*

Key Questions:

Here are the WHI dietary goals. What do you think about them?

Which of these goals might you be interested in talking about right now?

What successes with change have you had in the past?

What do you think would work for you?

Where would you like to be?

3. Explore study activities (WHI Study Activities options tool)

Purpose: Allows participant to think about her role in WHI and how it has changed.

Allows the participant to focus on study activities and her commitment.

How to present it: *"WHI is a big study with lots of activities to be involved in. We could look at those activities and see if any look particularly interesting and worth exploring. What do you think?"*

Key Questions:

"Here are some of the WHI activities. What do you think about them?"

"What were your reasons for taking on these activities initially?"

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"What has changed for you since the beginning?"

"What makes sense for you given your circumstances?"

"Where would you like to be in relation to the study goals or activities?"

4. Explore self-monitoring

Purpose: Allows participant to reflect on the value and challenges of self-monitoring.

Allows participant to explore options for self-monitoring.

How to present it: *"WHI has focused a lot on the value of self-monitoring. It might be interesting to explore what that has been like for you. What do you think?"*

Key Questions:

What are your thoughts about self-monitoring?

What are the advantages/disadvantages of self-monitoring?

How has it been helpful in the past?

What did you learn about yourself from the monitoring?

If the participant is interested in talking about specific forms of self-monitoring use the WHI Self-Monitoring Tools options tool. *"Here are the suggested forms of self-monitoring? What do you think about them?"*

5. Explore barriers to change

Purpose: Allows participant to explore barriers to change that she has overcome.

Allows participant to reflect on what it would take to change at this time.

How to present it: *"Some people find it useful to spend some time looking at the barriers and challenges that come with change. You have a wealth of experience to draw on about what works for you. What do you think?"*

Key Questions:

What do you see as your greatest barriers to change?

What kinds of strategies have you used to overcome barriers?

How do other people help/hinder your efforts?

6. Dreaming

Purpose: Allows participant to reflect on the value of WHI and what it will mean to future generations.

Allows participant to remember her motivation to participate in WHI.

How to present it: *"Sometimes it is fun to look at the future and examine how, if at all, our actions today impact it. What do you think?"*

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Key Questions:

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 heart disease and cancer. You personally were able for the most part to meet your fat gram goals. There were many difficulties along the way and times when it was impossible to do, but you stuck with it. What is your life like? How is it different from the past? How has the world changed for yourself and other women because of what the study was able to accomplish? What do you tell your grandkids/friends/co-workers/family about WHI?

Using an Options Tool

Goal

To work together with the participant in deciding what to focus on.

Key Elements

1. Options tools consist of a group of several circles that list the options for discussion from the study's perspective. These circles are separated from two blank circles by a heavy line. The blank circles may be used to include options suggested by the participant. It is important to have the blank circles. Options tools for WHI IIP have been created for WHI Support Strategies, WHI Dietary Goals, WHI Self-Monitoring Tools, and WHI Study Activities. Nutritionists may create additional options tools if these are useful.
2. Show the participant the appropriate options tool and ask if any of these behaviors/topics/issues might be of interest to her to discuss or if there is something else that she would like to focus on that might be impacting her participation in WHI.
3. Be honest and up-front about your own agenda.
4. Invite the participant to express her views on the subject.
5. Honor the participant's choice of behavior/topic/issue.

Avoid

Setting the agenda on your own and/or pushing the participant into premature focus on any one behavior of your choosing before she is ready.

Sample Scripts

"This diagram shows all the dietary changes that WHI is encouraging participants to make. What, if any, of these would you be interested in spending some time on? It could be one that you are considering making some changes on at this time. From my perspective, meeting the daily fat gram goal is the most important. However, it is up to you. Or maybe there is something else related to your participation that you consider more important to discuss at this time. What do you think?"

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Closing a Session

Goal

To maximize what happened in the interaction, to build a bridge to further interactions, and to tie it all together.

Key Elements

1. Summarize the encounter in a brief, concise manner. Check with the participant to make sure that you got it all.
2. Express your confidence in the participant's ability to make good decisions for herself, that when she decides to change there will be something that works for her.
3. Acknowledge and appreciate the participant's willingness to engage in a discussion about change.
4. If possible, schedule follow-up.

Avoid

1. A rambling summary or one that emphasizes only the points you want to make.
2. Non-genuine expression of hope or confidence.
3. Minimizing the challenges required by change.

Sample Script

Let me see if I can summarize what we've discussed today. You have concerns about being able to meet your fat gram goal, especially when you travel. You're struggling a bit with self-monitoring and feel like you're letting the study down. On the other hand you really enjoy the group sessions and want to continue to participate and share with the others. Did I get it all? I understand that meeting the study goals may be difficult, but I'm confident that if and when you should decide to make any further changes in your diet, you'll find a way that will work for you. Would it be okay if I called you in a couple of weeks to follow up on our conversation today?

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Rolling with Resistance

Goal

To minimize and manage participant resistance.

Key Elements

1. Recognize resistant behaviors as a signal to change strategies.
2. The health care provider can generate resistance by:
   - Using a judgmental or confrontational approach.
   - Jumping ahead of where the participant actually is on the readiness-to-change continuum.
   - Mis-assessing the participant's readiness to change.
   - Discounting the participant's feelings and thoughts.
3. When you encounter resistance, step back, listen, and try to understand things from the participant's perspective.

Avoid

1. Arguing.
2. Confronting.
3. Persuading.
4. Telling the participant what to do and how to do it.
5. Judging.

Tools/Strategies

Listen, listen, listen...

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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 find some ways to help our participants and the study move closer to the goal."

"What are your thoughts and feelings 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'm 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.**

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

Forward 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.	**Explore ambivalence about making changes.**	**Strengthen commitment. Facilitate action planning.**
Key Questions:	**Key questions:**	**Key Questions:**
"I wonder what would have to be different for you to consider making any changes?"	*What are the advantages/disadvantages of making dietary changes?"*	*"What are your reasons for wanting to make or maintain these changes?"*
Listen and summarize:	*"What do you like/dislike about the WHI dietary changes?"*	*"What are you thinking about doing?"*
Offer advice and emphasize choice:	**Listen and summarize.**	*"What have been your successes with this in the past?"*
"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 choose to make any changes you can find a way to be successful in the long	*"Where does that leave you?"*	*"What works for you when making changes?"*
	"What do you see as the next step?"	**Listen and summarize. Help participant set a reasonable plan of action**

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?

Explore barriers to change.

What do you se as your greatest barriers to change?
What kind 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 the making dietary changes reduced the risk of cancer and heart disease. What is you life like?

Closing

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

Guiding Principles for Individualizing Each Encounter

Each IIP encounter will have a life of its own. A participant's readiness to change may shift in either direction. The art of this counseling style requires clinicians to be flexible and to respond to what the participant offers. The following is a series of principles that will help guide your approach as you move through the general structure.

1. If the participant gives you a clear indication of readiness to change prior to a formal assessment, move to the appropriate strategy.
2. **Don't jump on the first self-motivational statement (SMS) and start action planning.** Sometimes in our eagerness to move toward change, we are more likely to hear the SMS than the equally important reasons not to change. Even when you begin to hear multiple SMS the best policy is to "hold the reins" and probe further for commitment. *"It seems like you are really thinking more about making this change. Is that right? You haven't convinced me yet. Are you sure that is what you want to do?"*
3. If you are confused about where the participant is, ask and seek clarification and understanding. Often the participant is still trying to figure things out. There is no reason why you should be able to figure it out before she does. Your confusion is okay.
4. Often when a participant is in transition between ambivalence and the decision to change, she begins to express strong feelings such as anxiety, anger, frustration, fear, sadness. These feelings are a normal and important part of the decision making. Let the participant have her feelings.
5. If you encounter resistance, this is a strong signal to change strategies and your behavior. Resistance is typically a result of not meeting the participant where she is. If it happens stop, back up, and listen.
6. It is appropriate that you give feedback on individual progress in the study to the participant. This can be used as part of the process to enhance motivation. The timing of delivering the feedback and the extent to which you discuss it depends on the participant's readiness to change.
7. If you have one minute or less, offer advice in a non-judgmental manner, emphasize personal choice, voice your confidence in the participant's ability to take action, and offer informational materials if available.

Participants Who Are Not Ready

Goal

To offer respect for the participant's decisions and leave the door open for further interactions.

Key Elements

1. Respectfully acknowledge the participant's decision.
2. Ask simple open-ended questions to help participant articulate possible reasons or arguments for change and/or what would need to be different to move forward. (see samples below.)
3. Being not ready could end the discussion immediately.
4. Offer professional advice, if appropriate. Briefly express your concerns and reasons for wishing the participant to change.
5. Explore pros and cons if the participant is not at the far end of the readiness-to-change continuum.
6. Ask the participant if she would like information and/or be interested in learning more about a specific topic.
7. Let the participant know that you're available to provide support and guidance in the future.
8. Express your hope and confidence in the participant's ability to make change in the future when she is ready.
9. End the session on a positive note.

Avoid

1. Pushing, persuading, confronting, coaxing, or telling.
2. Expecting the participant to be ready to do something. According to change research, most people make decisions to change on their own and at their own pace. Change most often occurs outside the office.

Sample Questions

"If you did start to think about changing, what would be your main concern?"

"What would need to be different in your life for you to consider changing?"

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Sample Scripts

"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 choose to make any changes you can find a way to be successful in the long term. I'm always available to help. In the meantime, I'd like to stay in touch. How does that sound?"

"From what you've told me, self-monitoring is not possible right now. I respect that. As you might guess, I encourage you to consider self-monitoring again in the future. From my experience with dietary change, it is a very useful tool for most people. In addition, it is the way that the study is able to monitor progress toward the overall goals. I know that it can be difficult to do and is even painful at times. There are many options available, some substantially easier than others, and I would be happy to discuss those with you should you decide in the future that you would like to start again. It really is your choice. In the meantime, keep up the good work."

Participants Who Are Unsure

Goal

To facilitate the participant's exploration and resolution of her ambivalence.

Key Elements

1. Ask about the pros and cons.
2. Explore concerns about the behavior, participation, or dietary changes (e.g., what concerns do you have about _____?).
3. Ask if there is any information the participant would like.
4 If time is limited, encourage the participant to continue to think about change (e.g., "*You say you're unsure about what to do. I do not want to push you into a decision. It's really up to you. I suggest that you take your time to think about it. Let me know if you want to talk about it again. I have met other people who have felt just like you do, and then managed to do something about it. You will be the best judge of when is the right time to consider change.*" [Rollnick, Mason, and Butler, 1996]).
5. Encourage a "look into the future." *"I can see why you're unsure about making a change. Let's take a step back for a moment and imagine that you decided to change. What would it be like? What would you want to do?"*
6. Ask about the next step. *"Where does this leave you now? Or, is there anything you'd like to do between now and our next visit?"* The question of action, if the participant is ready for this, often arises naturally out of this discussion.
7. Ask about motivation and confidence, using ruler strategies.

Avoid

1. Jumping ahead - assuming the participant is ready to change when she in fact is not.
2. Giving advice about change.
3. Expecting the participant to agree to change.

Sample Questions

"What are some of the things you like and dislike about _____?"

" What concerns do you have about_____?"

"You say you are a 3 on the ruler. Why did you not give yourself a 1 or a 2?"

"You indicated you are here (say a 4). What would help you get to a 7 or 8?"

"What would have to happen before you seriously considered change?"

Participants Who Are Ready

Goal

To collaborate with the participant to make a plan of action, resolve potential barriers to change, and enhance her sense of self-efficacy.

Key Elements

1. **Hold the reins on the action-planning and problem-solving**. Ask open-ended questions to help the participant explore her own ideas for change and to strengthen the commitment to change. Questions might include: *"What are your reasons for wanting to make this change?" "What do you think you will do?" "What could you do?" How would you like things to turn out?" "Let's take things one step at a time. What do you think is the first step?"*
2. Emphasize options, other's successes, and *"you're the best judge of what to do."*
3. Explore in detail the participant's plan of action. Open-ended questions might include: *"Where will your support come from?" "In what ways can other people help?" "What resources do you need?" "What barriers or roadblocks might you run up against?" "How will you know if your action plan is working?"*
4. Establish realism-change is gradual and takes time; and if things don't work out, there will be other options that might work.
5. Talk in terms of whether the "plan" succeeds or not. Emphasize that if the behavior doesn't change, the plan was inadequate – not the person; in the process of changing, "slips" are a normal occurrence and a valuable opportunity to learn.
6. Express optimism in the participant's ability to change.

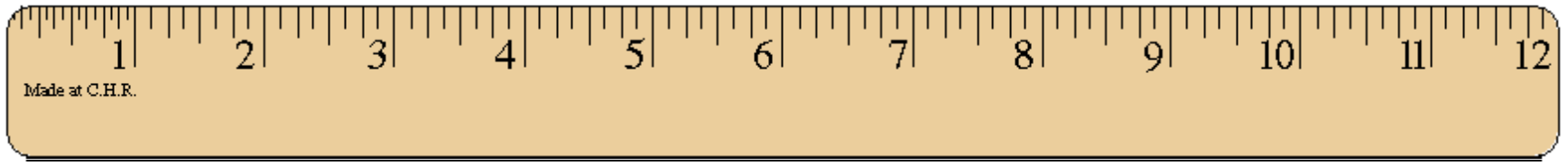
Avoid

Telling the participant what to do. Instead, help her decide what is best for her.

Sample Questions

"There is probably a number of things you could do, but what do you think will work for you?" "I can tell you about what has worked for other people in your situation, but what will be best for you?"

Ruler



Bibliography: Motivational Interviewing

Annis HM, Schober R, Kelly E (in press). Matching addiction outpatient counseling to client readiness for change: The role of structured relapse prevention counseling. *Experimental and Clinical Psychology*.

Berg-Smith SM, Stevens VJ, Brown KM, Van Horn L, Gernhofer N, Peters E, Greenberg R, Snetselaar L, Ahrens L, Smith K, for the Dietary Intervention Study in Children (DISC Research Group). A brief motivational intervention to improve dietary adherence in adolescents. *Health Education Research*; 14(3):101-112.

Brehm SS, Brehm JW (1981). Psychological reactance: *A Theory of Freedom and Control*. New York: Academic Press.

Butler C, Rollnick S (1996). Missing the meaning and provoking resistance: A Case Of Myalgic Encephalomyelitis. *Family Practice*; 13:106-109.

Butler C, Rollnick S, Stott N (1996). The doctor, the patient and resistance to change: Fresh ideas on compliance. *Canadian Medical Journal*; 154(9):1357-62.

Janis JL, Mann L (1977). Decision-making: *A Psychological Analysis of Conflict, Choice and Commitment*. New York: Free Press.

Keller VF, White MK (1997). Choices and changes: A new model for influencing patient health behavior. *Journal of Communications on Medicine*; 4(6):33-36.

Kushner PR, Levinson W, Miller WR (1998). Motivational interviewing: When, where and why. *Patient Care*; 32(14):55-72.

Miller WR (1983) Motivational interviewing. *Behavioral Psychotherapy*; 11:147-172.

Miller WR (1993). What I would most like to know: What really drives change? *Addiction*; 88:1479-1480.

Miller WR (1994). Motivational interviewing: On the ethics of motivational intervention. *Behavioral and Cognitive Psychotherapy*; 22:111-123.

Miller WR (1995) Increasing motivation for change. In RK Hester and WR Miller (eds) *Handbook of Alcoholism Treatment Approaches: Effective Alternatives* (2nd ed).

Miller WR (1996). Motivational interviewing: Research, practice and puzzles. *Addictive Behaviors*; 21:835-842.

Miller WR (1998). Enhancing motivation for change. In Miller WR and Heather N (eds) *Treating Addictive Behaviors: Processes of Change* (2nd ed), pp 121-132. New York: Plenum Press.

Miller WR (1998). Why do people change addictive behavior? The 1996 H. David Archibald Lecture. *Addiction*; 93:163-171.

Miller WR, Benefield RG, Tonigan JS (1993). Enhancing motivation for change in problem drinking: A controlled comparison of two therapist styles. *Journal of Consulting and Clinical Psychology*; 61(3):455-461.

Center for Health Research, Portland, Oregon, 1999

Miller WR, C'de Baca J (1994). Quantum change: Toward a psychology of transformation. In Heatherton T and Weinberger J (eds) *Can Personality Change?* Washington, DC: American Psychological Association.

Miller WR, Jackson KA (1995). "Not Listening" and "Listening" chapters in *Practical Psychology for Pastors.* Englewood Cliffs, New Jersey: Prentice Hall.

Miller WR, Rollnick S (1991). Motivational interviewing: *Preparing People to Change Addictive Behavior.* New York: Guilford Press.

Patterson GA, Forgatch MS (1985). Therapist behavior as a determinant for client noncompliance: A paradox for the behavior modifier. *Journal of Consulting and Clinical Psychology*;53:846-851.

Prochaska J, DiClemente CC (1986). Toward a comprehensive model of change, in: Miller WR, Heather N (eds) *Treating Addictive Behaviors: Processes of Change*, pp 3-27. New York, Plenum.

Prochaska J, DiClemente CC, Norcross J (1992). In search of how people change: Applications to addictive behaviors. *American Psychologist;* 47:1102-1114. Description of a model.

Project MATCH Research Group (in press). Therapist effects in three treatments for alcohol problems. *Psychotherapy Research*.

Rogers RW, Mewborn CR (1976) Fear appeals and attitude change: Effects of a threat's noxiousness, probability of occurrence, and the efficacy of coping responses. *Journal of Personality and Social Psychology*; 34:54-61.

Rokeach M (1973). *The Nature of Human Values.* New York: Free Press.

Rollnick S (1996). Behavior change in practice: Target individuals. *International Journal of Obesity*; 20 (supplement 1):522-526.

Rollnick S (1997). Whither motivational interviewing? *Journal of Substance Misuse*; 2:1-2.

Rollnick S (1998). Readiness, importance and confidence: Critical conditions of change in treatment. In Miller WR, Heather N (eds) *Treating Addictive Behaviors: Processes of Change* (2nd ed), pp 49-60. New York: Plenum Press.

Rollnick S, Heather N, Bell A (1992). Negotiating behavior change in medical setting: The development of brief motivational interviewing. *Journal of Mental Health*; 1:25-37.

Rollnick S, Kinnerly P, Stott N (1992). Methods of helping patients with behavior change. *British Medical Journal*; 307:188-190.

Rollnick S, Mason P, Butler C (in press). *Ready, willing and able: A Practitioner's Guide to Behavior Change*. Edinburgh: Churchill Livingston.

Rollnick S, Miller WR (1995). What is motivational interviewing? *Cognitive and Behavioral Psychotherapy*; 23:325-334.

Smith DE, Heckemeyer CM, Kratt PP, Mason DA (1997). Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM: A pilot study. *Diabetes Care*; 20:53-54.

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Woollard J, Beilin L, Lord T, Puddey I, MacAdam D, Rouse I (1995). A controlled trial of nurse counseling on lifestyle change for hypertensives treated in general practice: Preliminary results. *Clinical and Experimental Pharmacology and Physiology*; 22:466-468.

Yahne CE, Miller WR (in press). Enhancing motivation for treatment and change. In McCrady BS, Epstein EE (eds) *Addictions: A Comprehensive Guidebook for Practitioners*. Oxford University Press.

Zweben A, Bonner M, Chaim G, Santon P (1988). Facilitative strategies for retaining the alcohol-dependent client in outpatient treatment. *Alcoholism Treatment Quarterly*; 5:3-24.

Clinical Demonstration Videotapes

Miller WR (1989). ***Motivational Interviewing***. Available from the author at the Department of Psychology, University of New Mexico, Albuquerque, New Mexico 87131.

Motivation and Change (1990). Two training videotapes available from the Addiction Research Foundation, 33 Russell Street, Toronto M5S 2S1, Ontario, Canada.

Miller WR, Rollnick S, directed by TB Moyers (1998). ***Motivational Interviewing***. Series of six training tapes. Available from Delilah Yao, Department of Psychology, University of New Mexico, Albuquerque, New Mexico 87131-1161. Dyao@unm.edu. European format available from the European Addiction Training Institute, Stadhouderskade 125, 1074 AV Amsterdam, The Netherlands. Telephone: 31-20-675-2041; Fax: 31-20-675-4591. http://www.eati.org; info@eati.org.

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G.5.2 Working with Special Populations Using the Motivational Enhancement

This guideline is designed to assist nutritionists when working with a variety of diverse women, particularly minorities. The information provided focuses on special populations (SP), yet may apply to all women. It may also be used as a resource for other clinic staff who have experience with motivational enhancement techniques. Understanding the participant from a behavioral *and* cultural perspective is crucial in supporting her in the change process (Perez-Escamilla R et al., 2000; Campbell, MK et al., 2000;Resnicow et al., 2001 *in press*; Resnicow K et al., 1999;Harris JH et al., 1999). How does she currently handle her multiple roles of work, caring for elders, older children or grand-children? What type of a personality does the participant exhibit? Is she passive? Is she proactive? Does she ask for help when needed or does she feel overwhelmed by the daily demands? What role does spiritualism play in her life?

Motivational Enhancement (ME) is a technique that has primarily been used in a psychotherapeutic approach in the field of addiction behaviors. It has great potential for use among special populations because it allows for a tailored person-to-person counseling approach that deals with core values and intrinsic motivators. It is intended for use at a personal individual level. The counselor works with whatever situation may come up in the interview process. The counselor is engaged as a problem solving partner-not an aloof listener giving advice. This style of involvement is especially welcome with Special Populations (SP) because of its compassionate and personalized nature and its sensitivity to differences. It allows the participant to face ambivalence about behavior change and to come up with solutions that are acceptable to the participant. The counselor can tailor content to match needs and participant's readiness to change. Follow-up calls serve as cues/reminders to change behavior.

A query among investigators using ME indicated that use of ME in special populations is novel. It has been used to improve adherence to a weight control program for older obese with non-insulin dependent diabetes (Smith et al., 1997) and in a dietary intervention program conducted through Black churches to increase fruits and vegetable intake (Resnicow, *Am J Public Health*, 2001 in press). These contacts serve as cues or reminders to follow treatment or other adherence measures such as eating more fruits and vegetables, or to have altered the associated shopping and cooking behaviors.

In conducting ME, the nutritionist may encounter situations unique to special populations such as low socio-economic status (SES). Three commonly used indices of SES are education, occupation and income (Greenlund et al., 1996). Women with limited resources may be less likely to give priority to adhering to the dietary goals of the study. SES may affect risk factors for cardio-vascular mortality, morbidity in men and women of various ages, races/ethnicities and geographical locations (Stamler et al, 1995). Parental education, for example may influence body mass index (BMI) and BMI changes in young adulthood (Greenlund et al., 1996).

Since the nuclear and extended family may play a major role, the nutritionist needs to be sensitive to SP issues and be willing to explore these issues in a subtle manner without being intrusive. This balance is necessary in order to fully understand the participant's life while at the same time respecting boundaries. Issues such as spiritualism may be important, but not immediately come to the fore. The nutritionist can respectfully ask questions that allow the participant to share topics such as how spiritualism may play a role in her life. If the nutritionist is comfortable discussing spiritualism, it is also important to seek the participant's permission to discuss this topic. If the nutritionist is uncomfortable with discussing spiritualism, she may prefer to ask a colleague who is more experienced with this topic to work with the participant. In pursuing these angles, one should not lose sight of the fact that the goal is changing eating behavior and not necessarily solving every problem. Yet, it is crucial to understand cultural differences and how they play a role in changing eating behavior.

In dealing with SP, these situations may arise:

- Travel between host country (eg. Puerto Rico) and mainland may impact continuity of contact with participant
- Complex family obligations: SP participants may reside in extended households and care for family members; they may be more reluctant to leave family members in nursing homes compared to mainstream participants
- Inability to cope with stress and day-to-day difficulties due to limited emotional and financial resources

- SP participants may be generally more passive, particularly in marital relationships.
- Spiritualism may play an important role in a participant's life.
- SP participants may perceive that WHI dietary goals cannot be achieved on a limited budget

Asking questions that help both you and the participant are key to the process of change. Below are potential questions:

I. General Participant Understanding:

- What is important to you at this time in your life?

II. Family Issues

- On a scale of 0-10, how supportive is your family of your WHI efforts?
- What would need to be different for your family to be supportive?
- What can you do to gain the support of your family or friends?

G.6 Health News Discussion

G.6.1 Health News Discussion Guide

DM Health News Discussion Guide for dietary change group discussions

(Can be adapted for use with health guidelines and position statements, too. See comments in parentheses.)

- **Set the stage/assess interest/knowledge.**

  Study results (or health guidelines): *There's new research (or a new guideline) about* <<topic>>. *If you are interested, we can take time now to talk about this research (guideline). How does that sound?*

  Ask what the participants have heard or know about the study (guideline).

  Offer to share information.

- **Briefly describe the purpose and results of study (guideline).** (Refer to talking points, if available.)

  Consider finishing the description with: *This study (or guideline) suggests that eating* <<low fat, high fruit, vegetable, or grain>> <<does, does not>> decrease the risk of <<health outcome>>.

- **Solicit comments about how the study (guideline) challenges or supports existing beliefs.**

  Consider using this pair of questions (include both to bring out negative and positive comments).

  - *How does this study/guideline challenge our thinking or beliefs about diet and disease?*
  - *How does it support our thinking or beliefs about diet and disease?*

  Alternatively or additionally, ask:

  - *How does this study apply to you? Tell me more…Who else feels this way?*

- **Compare the study (or guideline) to the WHI dietary study. Seek participant input throughout.** (*Note*. Modify this section to be shorter or longer depending on participant interest and knowledge.)

  Study (or health guideline): *Let's look at how the study was done (or guideline) and compare it to the WHI dietary study. OK?*

  If participants are interested, describe the research methods, e.g., type of study (randomized controlled clinical trial? cohort observational study? case-control study? meta-analysis or pooled data analysis?), how long study lasted, how many people in the study.

  Compare exposure and outcome measures of the study to the WHI dietary study.

  - Was the exposure dietary fat? Fruits or vegetables? Grains? Other?
    Was the outcome breast cancer? Colon cancer? Heart disease? Blood cholesterol? Other?
  - Compare to the WHI dietary study exposures of low-fat, high fruit, vegetable and grain intake on the outcomes of breast and colorectal cancers and heart disease.

  Ask for input and describe (if necessary) the pros and cons of the type of study. (Refer to Fall Year 3 session, Making Sense of Health News.)

  For a health guideline: Look at the guideline (or position statements) and compare them to the WHI dietary study low-fat eating pattern.

  Ask for input and describe (if necessary) how the guideline is compatible (or not) with the WHI eating pattern.

  Ask for input and describe (if necessary) the target population for the guideline.

- **Summarize and close.**

  Use open-ended questions and summarizing reflections to bring discussion to an end.

  - Potential questions: *Where does that leave us? What thoughts do you have now?*

  Close with the following points (also may be brought up during the discussion):

  I'd like to add that,

  - *WHI does have a data and safety monitoring board that meets every six months. The members look at WHI data and data from recent studies (or health guidelines) to decide whether to continue or stop WHI. This group watches out for your safety.*
  - *The WHI dietary study is a randomized controlled clinical study – the strongest research design that there is. The WHI dietary study is designed to give us answers about the effect of a low-fat high fruit, vegetable, and grain dietary pattern on breast and colorectal cancers and heart disease in postmenopausal women.*

    For a health guideline, add one of these two possibilities (or modify to fit your situation):

    The WHI dietary pattern is compatible with the guideline.

    OR

    It can be challenging for persons who have (or at risk for or are concerned about) <<health state>> to follow the WHI dietary pattern and the guideline. We can work with you individually to see how you can follow the WHI dietary pattern as much as possible and the guideline, too. Your health and comfort with the WHI eating pattern are important to us.

  - All the staff and investigators appreciate your involvement with WHI. Please contact us whenever you have questions. Thank you!

G.7 Personalized Evaluation of Fat Intake (PEFI)

G.7.1 PEFI-Q Adjustment Questions

This appendix provides information about the adjustment questions used in the PEFI-Q. The information includes: the types of adjustment questions and how they work; the defaults used when adjustment questions are missing or inconsistent with the associated line item; and a table providing the specific adjustment questions used for lines on the questionnaire. This information is OPTIONAL READING. This appendix provides information that some nutritionists may find helpful for their understanding of how the PEFI-Q works. This information is provided for nutritionist use only. Specifically, the fat gram information shown in *Table G.3 – PEFI-Q Line Item Information: Adjustment Questions Associated with Specific Lines & Fat Grams Associated with a Medium Serving Size* should not be used to guide and/or determine how participants mark responses on the questionnaire. Giving participants this level of information is unnecessary (i.e., the PEFI-Q is not a precise measure of fat intake) and potentially confusing for the participant. Refer to *Vol. 2, Section 6.15.2.1 – Personalized Evaluation of Fat Intake Self-Assessment Questionnaire (PEFI-Q)* for a complete description of the PEFI-Q.

A. Types of Adjustment Questions and How They Work

Types of Adjustment Questions:

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.
- Type of Food: These questions ask about the type of food the participant usually ate.

Refer to *Vol. 2, Section 6.15.2.1.1, Table 6.6 – Types of Adjustment Questions Used in the PEFI-Q* for examples.

How the Adjustment Questions Work:

Frequency of Use:

'Frequency of use' adjustment questions have two different levels of fat associated with the question: a fat-free/low-fat version and a full-fat version. The computer uses the participant's response to the adjustment question to average the two different versions and determine total fat grams for the food or mixed dish. *Table G.1 – Response Weighting for Frequency of Use Adjustments* shows the mix the computer uses to determine fat grams for different responses.

Table G.1 – Response Weighting for Frequency of Use Adjustments

Response	Weighting Used by Computer	
	Fat-Free/ Low-Fat Version	Full-Fat Version
Almost always =	100%	0%
Often =	75%	25%
Sometimes =	50%	50%
Rarely =	25%	75%
Never =	0%	100%

Example:

- Assume that on page 7, line 25, a participant marks that she ate a medium serving of '*Pancakes, waffles or French toast'* once a week.
- And for the Qx. 1a (pg. 2) – *When you ate these foods, how often were they fat-free or low-fat?,* she selects *'Sometimes'*.

- Then the computer would calculate the fat grams using a 50/50 mix between the fat-free/low-fat and the full-fat version of the food.
- Or, if the participant marked *'Almost always'* for Qx. 1a, the programming would calculate the fat grams using 100% of the fat-free/low-fat version.

Note: Adjustment questions 10 and 11 are also 'frequency of use' adjustment questions, but the weighting given for these questions is reversed from the weighting shown in Table G.2 (i.e., Almost always = 100% full-fat version and 0% low-fat). The weighting is reversed because the questions ask about the frequency with which a participant uses a high-fat choice (e.g., eat the fat on meat, or eat the skin on poultry) rather than a low-fat choice.

Type of Food:

For 'type of food' adjustment questions, there is a fat gram value associated with each response (e.g., regular, low-fat, and fat-free salad dressings). These adjustment questions provide an opportunity for a participant to select more than one response – *Mark all that apply*, if she desires. For example, if a participant routinely uses both regular and low-fat salad dressings she may mark both of these choices.

The computer calculates fat grams based on a participant's selection(s). If a participant marks more than one choice, an average is calculated based on her selected responses.

Example:

- Assume that on page 8, line 45, a participant marks that she ate a medium serving of *'All types of ground meat or ground poultry'* once a week.
- Then for the Qx. 9a (pg. 3) – *When you ate these foods, what type did you usually eat?*, she selects *'Ground chicken or turkey'* and *'Low-fat meatless burgers.'*
- The fat grams are calculated by averaging the fat grams for *'Ground chicken or turkey'* and *'Low-fat meatless burgers'*.

Adjustment Questions – Miscellaneous Information:

Fat Used in Cooking: Adjustment questions 22 and 23 on page 4 of the PEFI-Q work together to create a *Fats Used in Cooking* 'food item'. The *Fats Used in Cooking* 'food item' does not appear on the PEFI-Q, but may appear in a participant's list of top 10 foods (PEFI-F).

Adjustment questions 22, 22a, and 23 provide a way for a participant to account for the fat used in cooking. To calculate fat grams for this 'food item'(*Fats Used in Cooking*), the computer programming uses a standard serving size (2 teaspoons) and data from the participant's responses to questions 22, 22a, and 23.

- Qx. 22 & Qx. 22a (Type of food question) - "When you used fat for cooking, what kind of fat did you usually use?"
- Qx. 23 (Frequency of use question) - "How often did you eat foods that were pan-fried, deep-fried, or cooked in fat?"

Milk Adjustments: Two adjustment questions (Qx. 17 and 18) are used to 'adjust' the four milk-based lines on the questionnaire (lines 85, 100, 101 and 102).

Qx. 17: "Milk or cream on cereal":
Question 17 only asks about milk/cream on cereal (line 85), but information from this adjustment question is also used to 'adjust' line 102 (Milk, cream, or creamer added to coffee or tea).

Note: If a participant uses milk, cream or creamer in tea or coffee and she wants to know where to mark this food, direct her to Qx 17.

Qx. 18: "Milk or beverages made with milk":
Question 18 is used to 'adjust' information for lines 100 (milk as beverage) and 101 (latte, cappuccino, etc.). If a participant drinks milk at home, or away from home as part of a latte, hot chocolate or some other milk-based beverage, she uses Qx. 18 to indicate the type(s) of milk that she usually uses.

Note: Adjustment questions 17 and 18 focus on food sources that contribute large amounts of milk or cream to a participant's eating pattern (i.e., milk on cereal – ½ cup serving and milk as a beverage – 1 cup serving). Due to space limitations on the PEFI-Q, a separate adjustment question for "milk, cream or creamer added to tea or coffee" could not be added. However, for most WHI Dietary Change participants, it was thought that the amount of fat contributed by milk/cream in tea or coffee would not be a top 10 source of fat.

B. Adjustment Question Defaults

Defaults are used when responses to adjustment questions are missing or inconsistent with the associated line item. Refer to *Vol. 2, Section 6.15.2.1.2.1 – Defaults for Missing Information* for a description of the types of defaults and how they work.

The defaults used for specific adjustment questions are provided in *Table G.2 – Adjustment Questions: Type of Default and Specific Default Used*.

Table G.2 – Adjustment Questions: Type of Default and Specific Default Used

Adjust. Qx.	Adjustment Question	Type of Default	Default Used if Response Missing
1a	How often were pancakes, waffles or French toast fat-free or low-fat?	Frequency of use	Sometimes
2a	How often were biscuits, muffins or scones fat-free or low-fat?	Frequency of use	Sometimes
3a	How often were flour tortillas fat-free or low-fat?	Frequency of use	Sometimes
4a	How often were cornbread, corn muffins or polenta fat-free or low-fat?	Frequency of use	Sometimes
5a	How often were snack chips fat-free or low-fat?	Frequency of use	Sometimes
6a	How often were crackers fat-free or low-fat?	Frequency of use	Sometimes
7a	How often were breakfast meats fat-free or low-fat?	Frequency of use	Sometimes
8a	How often hot dogs or other sausages were fat-free or low-fat?	Frequency of use	Sometimes
9a	Type of ground meat, ground poultry or meatless burgers eaten?	Type of food	Extra lean
10a	How often ate the fat on beef, pork, ham or lamb.	Frequency of use	Rarely
11a	How often ate the skin on chicken, turkey or other poultry.	Frequency of use	Rarely
12a	How often were tofu or tempeh (soy products) fat-free or low-fat?	Frequency of use	Sometimes
13a	Kind of fat usually used at the table on breads, vegetables, potatoes, pasta or rice?	Type of food	Butter, margarine, olive, or other oil
14a	Type of salad dressing usually used?	Type of food	Low-fat
15a	Type of dressing(s) used for mayonnaise or oil-based salads?	Type of food	Light, low-fat or reduced-fat
16a	Type of mayonnaise or mayonnaise-type spread?	Type of food	Light, low-fat or reduced-fat
17a	Type of milk or cream used on cereal?	Type of food	Fat-free or ½%
18a	Type of milk drunk as beverage?	Type of food	Fat-free or ½%
19a	How often were frozen desserts fat-free or low-fat?	Frequency of use	Sometimes
20a	How often were puddings, custards or flans fat-free or low-fat?	Frequency of use	Sometimes
21a	How often cookies or cakes were fat-free or low-fat.	Frequency of use	Sometimes
22a	Type of fat used for cooking (frying foods or flavoring beans or vegetables)?	Type of food	Butter, margarine, olive, or other oil
23a	How often were foods pan-fried, deep-fried or cooked in fat?	Frequency of use	Never or less than once per week
24 (all)	How often were mixed dishes or soups prepared to be lower in fat?	Frequency of use	Sometimes low-fat

The specific adjustment questions used for specific food line items on the PEFI-Q are outlined in *Table G.3 – PEFI-Q Line Item Information: Adjustment Questions Associated with Specific Lines & Fat Grams Associated with a Medium Serving Size*.

Table G.3 – PEFI-Q Line Item Information:
Adjustment Questions Associated with Specific Lines &
Fat Grams Associated with a Medium Serving Size

PEFI Line #	Adjust. Qx.	Fat (g)	Food Line Item Name	Serving Size (medium)
GRAIN PRODUCTS/SALTY SNACKS				
25	**1**	6.4	Pancakes, waffles or French toast	2 pancakes or 1 waffle (7-inch)
		1.9	Low-fat/fat-free pancakes, waffles	
26	**2**	9.7	Biscuits, muffins, or scones	2 small or 1 medium muffin
		4.0	Low-fat/fat-free biscuits or muffins	
27	**3**	3.1	Flour tortillas	2 tortillas (8-inch)
		1.7	Low-fat/fat-free flour tortillas	
28		1.9	Breads, rolls, or corn tortillas	2 slices, 1 medium bagel or 2 tortillas
29		13.5	Fried breads such as hush puppies, Indian fry bread, or fritters	3 hush puppies or 1 medium fried bread
30	**4**	7.6	Cornbread, corn muffins or polenta	1 medium (3" sq) or 1/2 cup
		2.0	Low-fat/fat-free cornbread	
31	**5**	7.8	Snack chips	1 cup
		0.4	Low-fat/fat-free snack chips	
32	**6**	6.7	Crackers	5-8 crackers (about 1 oz)
		1.2	Low-fat/fat-free crackers	
33		1.0	Air-popped popcorn or fat-free microwave popcorn, no fat added	3 cups
34		6.7	Low-fat microwave popcorn, no fat added	3 cups
35		27.8	Oil popped or buttered regular microwave popcorn	3 cups
36		10.9	Soy nuts	1/4 cup
37		19.0	Peanuts or other nuts and seeds	1/4 cup
MEAT, POULTRY, FISH & EGGS				
38		0.0	Egg whites or fat-free egg substitutes	2 eggs or 1/2 cup
39		13.3	Eggs and egg substitutes with fat	2 eggs or 1/2 cup
40	**7**	9.1	Breakfast meats (bacon, sausage)	3 strips or 2 links
		2.4	Low-fat/fat-free breakfast meats	
41	**8**	24.3	Hot dogs and other sausages (includes soy)	2 hot dogs or 3 ounces
		10.8	Low-fat/fat-free hot dogs (includes soy)	
42		0.3	Fat-free lunchmeats (includes soy)	2 slices
43		5.7	Low-fat lunchmeats (includes soy)	2 slices
44		15.5	All other lunchmeats (includes soy)	2 slices
45	**9**		Ground meat or ground poultry	3 ounces
		19.2	Regular	
		16.8	Lean	
		12.7	Extra lean	
		11.5	Ground chicken or turkey	
		5.5	Rinsed ground beef (all types)	
		1.0	Low fat meatless burger	
		3.3	Regular meatless burger	
46	**10**		Beef, pork, ham or lamb	4 ounces
		24.9	Untrimmed (with fat)	
		8.5	Trimmed (without fat)	
47		8.5	Liver and organ meats	4 ounces
48	**11**		Chicken and other poultry, roasted	3 ounces

		9.7	With skin	
		4.8	Without skin	
PEFI Line #	**Adjust. Qx.**	**Fat (g)**	**Food Line Item Name**	**Serving Size (medium)**
MEAT, POULTRY, FISH & EGGS (continued)				
49		22.1	Fried chicken, w/skin	3 ounces
50		14.3	Fried fish	3 ounces or 1 sandwich
51		1.5	Shellfish, not fried	3 ounces or 1/2 cup
52		1.3	White fish, not fried	3 ounces
53		6.6	Dark fish, not fried	3 ounces
54		15.7	Laulau	1 medium
55		5.8	Dim sum, steamed or baked	3 pieces or 1 med.
56		7.7	Egg rolls, lumpia and fried dim sum	1 med. or 1 small cone
57	**12**	6.8	Tofu or tempeh	3 slices or 3 ounces
		1.2	Low-fat/fat-free tofu or tempeh	
FATS USED AT THE TABLE OR ADDED IN COOKING				
58	**13**		Butter/margarine on bread, pancakes, etc.	2 pats or 2 teaspoons
59	**13**		Butter/margarine/sour cream added to vegetables, potatoes, pasta, etc.	2 pats or 2 teaspoons
		8.1	Butter, margarine, olive or other oil	
		5.1	Whipped butter or whipped margarine	
		4.0	Low-fat margarine	
		0.0	Fat-free margarine	
		2.0	Sour cream	
		1.0	Low-fat sour cream	
		0.1	Fat-free sour cream	
60		12.0	Reduced-fat peanut butter	2 tablespoons
61		16.5	Peanut butter	2 tablespoons
62	**14**		Salad dressing	2 tablespoons
		13.8	Regular (includes vinegar & oil)	
		6.0	Low-fat	
		0.1	Fat-free	
63		6.9	Avocado or guacamole	1/4 medium or 1/4 cup
64		3.4	Low-fat cheese or low-fat cream sauce	1/4 cup
65		9.4	Cheese, cream or coconut sauces (high-fat)	1/4 cup
66		0.3	Low-fat meat gravies	1/4 cup
67		6.2	Meat gravies (high-fat)	1/4 cup
68	**15**		Mayonnaise or oil-based salads	1/2 cup
		12.1	Regular	
		6.0	Light, low-fat, or reduced-fat	
		0.8	Fat-free	
		0.8	No dressing or vinegar only	
69	**16**		Mayonnaise or mayo-type spreads	2 tablespoons
		18.1	Regular	
		9.8	Light, low-fat, or reduced fat	
		0.0	Fat-free	
70		9.7	Fried vegetables	3/4 cup
71		13.1	French fries or fried potatoes	3/4 cup
	22/23		Fat Used for Cooking	2 teaspoons
		6.7	Lard, bacon fat, or meat drippings, salt pork, ham hock, or chorizo sausage	

		8.1	Butter, margarine, oil, or shortening	
		5.1	Whipped butter or whipped margarine	
		4.0	Low-fat margarine	
		0.0	Fat-free margarine	
		0.0	Non-stick spray (such as PAM)	
PEFI Line #	**Adjust. Qx.**	**Fat (g)**	**Food Line Item Name**	**Serving Size (medium)**
MIXED DISHES AND SOUPS				
72	**24a**	18.1	Stews or casseroles	1 cup
		2.5	Low-fat stews and casseroles	
73	**24b**	14.9	Pasta or rice dishes with tomato sauce	1 cup
		1.6	Low-fat pasta or rice dishes with tomato sauce	
74	**24c**	20.6	Pasta or rice dishes with cheese or cream sauce	1 cup
		7.1	Low-fat pasta/rice dishes with cheese or cream sauce	
75	**24d**	25.5	Pizza	2 slices of a 12" pizza
		8.5	Low-fat pizza	
76	**24e**	9.4	Asian-style noodle/rice dishes	1 cup
		1.2	Low-fat Asian-style noodle/rice dishes	
77	**24f**	13.1	Asian-style stir-fried dishes (w/ meat & veg)	1 cup
		4.6	Low-fat Asian-style stir-fried dishes	
78	**24g**	19.9	Tortilla-based dishes	2 enchiladas or 1 medium
		5.8	Low-fat tortilla-based dishes	
79	**24h**	23.0	Tamales, chili rellenos, etc.	1 cup or 1 medium
		14.2	Low-fat tamales, chili rellenos, etc.	
80	**24i**	13.6	Beans or bean/rice dishes	1 cup
		1.7	Low-fat beans or bean/rice dishes	
81	**24j**	7.8	Ramen® noodles and Ramen® noodle soup	1 cup
		0.8	Low-fat Ramen ®noodles	
82		3.2	Vegetable and broth-based soups	1 cup
83	**24k**	8.7	Cream soups	1 cup
		1.8	Low-fat cream soups	
84	**24l**	5.1	Bean soups	1 cup
		1.1	Low-fat bean soups	
MILK, CHEESE, AND YOGURT				
85	**17**		Milk or cream on cereals	1/2 cup (4 fluid ounces)
		4.1	Whole	
		2.3	2%	
		1.3	1%	
		0.2	Fat-free or 1/2%	
		14.9	Cream or half and half	
		8.6	Nondairy liquid creamer	
		0.0	Fat-free creamer or fat-free half and half	
86		0.3	Fat-free cottage or fat-free ricotta cheese	1/2 cup
87		2.5	Low-fat cottage or low-fat ricotta cheese	1/2 cup
88		5.9	Cottage cheese or ricotta cheese	1/2 cup
89		0.4	Fat-free cheeses (include soy cheeses)	2 slices or 1/4 cup shredded
90		8.9	Low-fat cheeses (include low-fat soy cheeses)	2 slices or 1/4 cup shredded

91		18.2	All other cheese (include full-fat soy cheeses)	2 slices or 1/4 cup shredded
92		0.5	Fat-free yogurt (except frozen)	1 cup
93		2.9	All other yogurt (except frozen)	1 cup

PEFI Line #	Adjust. Qx.	Fat (g)	Food Line Item Name	Serving Size (medium)
SWEETS				
94	**19**	14.0	Frozen desserts	3/4 cup or 1 shake
		1.2	Low-fat/fat-free frozen desserts	
95	**20**	7.8	Puddings and custards	3/4 cup
		2.5	Low-fat/fat-free puddings	
96		23.4	Pies, donuts and fried pastries	1 medium slice or 1 piece
97	**21**	10.4	Cookies and cakes	3 small or 1 large cookie, 1 piece
		1.6	Low-fat/fat-free cookies and cakes	
98		4.6	Low-fat chocolate and candy bars	1 regular bar or 4 pieces
99		12.7	Chocolate, candy bars and toffee	1 regular bar or 4 pieces
MILK AS BEVERAGES				
100	**18**		Milk as a beverage	1 cup (8 fluid ounces)
101	**18**		Latte, cappuccino, mocha, or hot chocolate	1 cup (8 fluid ounces)
		8.2	Whole	
		4.6	2%	
		2.6	1%	
		0.4	Fat-free or 1/2%	
102	**17**		Milk, cream or creamer in coffee	1 Tbsp. (0.5 fluid ounces)
		0.5	Whole	
		0.3	2%	
		0.2	1%	
		0.03	Fat-free or 1/2%	
		1.9	Cream or half and half	
		1.1	Nondairy liquid creamer	
		0.0	Fat-free creamer or fat-free half and half	

G.7.2 Tailored Messages for Top 10 Foods on PEFI-F

This appendix provides an overview of the principles used to guide development of the tailored messages displayed for each of the top 10 foods listed on Page 3 of PEFI-F. The information includes the description and purpose of the messages, the types of messages, and how the messages and fat gram savings per week are determined. This information is OPTIONAL READING. Refer to *Vol. 2, Section 6.15.2.2 – Tailored Feedback (PEFI-F)* for a complete description of the tailored materials generated from the PEFI-Q.

Description and Purpose of the Tailored Messages

Each of the top 10 foods listed on Page 3 of PEFI-F has at least one corresponding message that is tailored for the participant based on her responses on the PEFI-Q. In general, the purpose of the tailored message is to: a) provide a suggestion for a lower-fat choice and to b) show potential fat gram savings per week if that choice were used instead of the higher-fat option marked on the questionnaire.

Types of Tailored Messages

There are two categories of tailored messages:

- Messages that provide a suggested change to reduce fat.
- Messages that provide a statement supporting current behavior.

Messages that provide a 'suggested change to reduce fat':

Overall, these messages have been designed to encourage a change that is large enough to make a difference in fat grams, but not so large that it would be behaviorally unrealistic.

Food Message: a suggestion to reduce the fat in the food.

In general, the food message suggests the 'lowest fat alternative'. For many foods, the lowest fat alternative is a fat-free choice (e.g., suggesting fat-free cottage cheese instead of regular or low-fat cottage cheese). For some foods, the lowest fat alternative is a low-fat choice (e.g., suggesting chicken without skin instead of chicken with skin).

> Note: A few fat-containing foods do not have a food message. These foods include those where: a) there is no lower-fat alternative (e.g., organ meats) or b) the food is 'low-fat cheese' (the DMWG made the decision to not suggest 'fat-free cheese' as an alternative for 'low-fat cheese' because fat-free cheese is often considered unacceptable). In these cases, the food message is bypassed and the frequency and serving messages come into play as outlined below.

Table G.4 – Food Messages shows the food message for each line item on the PEFI-Q.

Frequency Message: a suggestion to reduce how often the food is eaten.

In general, the frequency message suggests that the food be consumed half as often as reported on the PEFI-Q. For example, if the reported frequency was '2+ times per day', the frequency message would provide the following suggestion: 'reduce to once per day'.

> Note: To avoid suggesting unrealistic frequency reductions, no frequency message is provided when the reported frequency is '1 per month' or 'never or less than once per month'.
>
> Note: To avoid suggesting that dark fish (line item 53) be consumed less frequently than recommended, no frequency message is provided for dark fish when the frequency is '2-3 per month' or less.
>
> Note: To avoid suggesting that milk or milk beverages (lines 85 and 100-102) be consumed less frequently, there is no frequency message for milk or milk beverages.

Serving Size Message: a suggestion to reduce the serving size of the food.

In general, the serving size message suggests that a LARGE serving be reduced to MEDIUM.

Note: The serving size message suggests that a MEDIUM serving be reduced to SMALL only for foods in the 'Fats Added at the Table or Used in Cooking' group (see page 9 on the questionnaire). The suggestion to use a small serving in the 'Added Fats' group promotes the opportunity for a substantial fat reduction while remaining generally realistic.

Note: To avoid suggesting that milk or milk beverages (lines 85 and 100-102) have a reduced serving, there is no serving message for milk or milk beverages.

Messages that provide a 'statement supporting current behavior':

Healthy Choice Message: a statement that says 'Healthy choice'.

This message is used to give a positive health message when the following foods appear in the top 10 list: breads (line 28), fat-free popcorn (line 33), egg whites (line 33), fat-free lunchmeats (line 42), shellfish, not fried (line 51), white fish, not fried (line 52), fat-free cottage cheese (line 86), fat-free cheeses (line 89), fat-free yogurt (line 92).

Note: When the 'healthy choice' message is used, it is the only message given for the food; i.e., there is no frequency or serving size message.

Neutral Message: a statement that says 'This food may not contribute much fat to your eating pattern.'

This message is used when a food appears in the top 10 list and none of the four other types of messages apply. This could happen in the following situation: the food is not considered a 'healthy choice' (as defined above) and the participant eats the lowest fat option (i.e., no suggestion to change food), she eats the food infrequently (i.e., no suggestion to reduce frequency), and she eats a medium or small serving (i.e., no suggestion to reduce serving).

Determining Tailored Messages

The tailored messages for each of the top 10 foods are determined using the steps outlined below.

Step 1: Determine if the food is a 'healthy choice' as defined above.

- If yes: display the 'healthy choice' message.
- If no: continue to Step 2.

Step 2: Determine messages that provide a 'suggested change to reduce fat'.

- Priority 1: Food Message. Can the fat grams in this food be reduced by changing the food (i.e., by using a lower-fat alternative)? If yes, identify 'food' message. If no, go to Priority 2.
- Priority 2: Frequency Message. Can the fat grams in this food be reduced by changing the frequency that the food is eaten? If yes, identify 'frequency' message. If no, go to Priority 3.
- Priority 3: Serving Size Message. Can the fat grams in this food be reduced by changing the serving size for the food? If yes, identify 'serving size' message. If no, go to Step 3.

Exception: For the 'Fats Added at the Table or Used in Cooking' group (see page 9 on the questionnaire), the message hierarchy is: Priority 1 = Food Message, Priority 2 = Serving Size Message, Priority 3 = Frequency Message.

Step 3: Determine if fat reduction messages were identified in Step 2.

- If yes and three messages apply: display the top two priority messages.
- If yes and two messages apply: display these two messages.
- If yes and one message applies: display this one message.
- If no: display the 'neutral' message that says 'This food may not contribute much fat to your eating pattern.'

Determining Fat Gram Savings Per Week

In general, each tailored message has an associated fat gram value. This fat gram value is determined by the fat grams linked with a specific food, a different frequency of use, or a different serving size. The fat gram value associated with the tailored message is used to determine the 'fat gram savings per week' for the message.

Exception: the 'healthy choice' and 'neutral' message do not have an associated fat gram value; when these messages are used, a 'fat gram savings per week' value is not given for the food.

The fat gram saving per week for each message is determined as follows:

FAT GRAM SAVINGS PER WEEK = (Fat grams per week for the food reported on the PEFI-Q) - (Fat grams per week for the tailored message).

Table G.4 – Food Messages

Line #	Food Description for "Top 10 List"	Food Message
	GRAIN PRODUCTS and SALTY SNACKS	
25	Pancakes or waffles	Choose fat-free frozen waffles or use low-fat ingredients in mix.
26	Biscuits or muffins	Choose crumpets or bagels.
27	Flour tortillas	Choose fat-free flour or corn tortillas.
28	Breads	
29	Fried breads	
30	Cornbreads	Choose fat-free cornbread or other fat-free breads.
31	Snack chips	Choose fat-free chips or pretzels.
32	Crackers	Choose fat-free or low-fat crackers.
33	Air-popped popcorn	
34	Low-fat microwave popcorn	Choose fat-free or air-popped popcorn.
35	Regular microwave popcorn	Choose fat-free or air-popped popcorn.
36	Soy nuts	Choose pretzels.
37	Peanuts and other nuts	Choose soy nuts.
	MEAT, POULTRY, FISH and EGGS	
38	Egg whites or fat-free egg substitutes	
39	Eggs or egg substitutes with fat	Choose egg whites or fat-free egg substitutes.
40	Breakfast meats	Choose Canadian bacon or very lean ham.
41	Hot dogs or sausages	Choose low-fat varieties.
42	Fat-free lunchmeats	
43	Low-fat lunchmeats	Choose fat-free lunchmeat.
44	Regular-fat lunchmeats	Choose fat-free lunch meat.
45	Ground meat or ground poultry	Choose extra lean ground beef or ground turkey breast.
46	Beef, pork/ham or lamb	Trim meat or choose lean cuts.
47	Organ meats	
48	Chicken or turkey	Remove the skin.
49	Fried chicken	Choose roasted or baked chicken.
50	Fried fish	Bake, broil or steam fish.
51	Shellfish, not fried	
52	White fish	
53	Dark fish such as salmon	
54	Laulau	
55	Dim sum (steamed)	
56	Egg rolls or fried dim sum	Choose steamed or baked dim sum.
57	Tofu or tempeh	Choose fat-free soy/veggie products.

Table G.4 – Food Messages (cont.)

Line #	Food Description for "Top 10 List "	Food Message
	FATS USED AT THE TABLE OR ADDED IN COOKING	
58	Butter or margarine on breads	Choose fat-free margarine or fruit spreads.
59	Butter, margarine, or sour cream added to foods	Choose fat-free flavorings like chutneys and salsas.
60	Reduced-fat peanut butter	Choose fruit spreads.
61	Peanut butter	Choose reduced-fat peanut butter.
62	Salad dressings	Choose fat-free dressings.
63	Avocado or guacamole	Choose fat-free dips and salsas.
64	Low-fat sauces	
65	Cheese or cream sauces	Choose low-fat sauces.
66	Low-fat meat gravies	
67	Meat gravies	Choose low-fat gravies.
68	Mayonnaise or oil-based salads	Prepare with fat-free dressings.
69	Mayonnaise or mayo-type spreads	Choose fat-free mayonnaise or spreads.
70	Fried vegetables	Prepare with nonstick sprays or broths.
71	French fries or fried potatoes	Choose oven-baked fries or a baked potato.
	Fats used in cooking	Use non-stick pans or fat-free cooking spray all the time.
	MIXED DISHES and SOUPS	
72	Stews or casseroles	Prepare with less fat and low-fat ingredients.
73	Pasta or rice dishes with tomato sauce	Prepare with less fat and low-fat ingredients.
74	Pasta or rice dishes with cream or cheese sauce	Prepare with less fat and low-fat ingredients.
75	Pizza	Use less cheese; order vegetarian pizza.
76	Asian-style noodle/rice dishes	Prepare with less fat and low-fat ingredients.
77	Asian-style stir-fried dishes	Prepare with less fat and low-fat ingredients.
78	Tortilla-based mixed dishes	Prepare with less fat and low-fat ingredients.
79	Tamales, chili rellenos	Prepare with less fat and low-fat ingredients.
80	Beans or bean/rice dishes	Prepare with less fat and low-fat ingredients.
81	Ramen noodles	Choose lower-fat noodle and vegetable soups.
82	Broth-based soups	
83	Cream soups	Prepare with less fat and low-fat ingredients.
84	Bean soups	Prepare with less fat and low-fat ingredients.
	MILK, CHEESE, and YOGURT	
85	Milk or cream on cereal	Choose fat-free milk.
86	Fat-free cottage cheese	
87	Low-fat cottage cheese	Choose fat-free cottage or ricotta cheeses.
88	Regular cottage cheese	Choose fat-free cottage or ricotta cheeses.
89	Fat-free cheeses	
90	Low-fat cheeses	
91	Regular full-fat cheeses	Choose low-fat cheeses such as mozzarella.
92	Fat-free yogurt	
93	All other yogurt	Choose fat-free yogurt.

Table G.4 –Food Messages (cont.)

Line #	Food Description for "Top 10 List"	Food Message
	SWEETS	
94	Frozen desserts	Choose fat-free frozen desserts.
95	Puddings or custards	Prepare with fat-free milk.
96	Pies or fried pastries	Choose fat-free cookies and cakes.
97	Cookies or cakes	Choose fat-free cookies and cakes.
98	Low-fat chocolate	Choose chocolate sorbet, fudgesicles and fat-free chocolate syrup.
99	Chocolate or candy bars	Choose low-fat chocolate candy such as York peppermint patties.
	MILK AS BEVERAGES	
100	Milk	Choose fat-free milk.
101	Milk-based drinks	Choose fat-free milk.
102	Milk or cream in tea or coffee	Choose fat-free milk.

G.7.3 PEFI-F Samples

This appendix provides three samples of PEFI-F generated from the PEFI-Q. The samples include:

- *Figure G.1 – Over Fat Gram Goal* provides a sample of what tailored feedback might look like for a participant whose fat grams reported on the PEFI-Q are over fat gram goal.
- *Figure G.2 - $\leq$ Fat Gram Goal, but $\geq$ 15 Grams of Fat* provides a sample of what tailored feedback might look like for a participant whose fat grams reported on the PEFI-Q are $\leq$ fat gram goal, but $\geq$ 15 grams of fat.
- *Figure G.3 - < 15 Grams of Fat* provides an example of what tailored feedback might look like for a participant whose fat grams reported on the PEFI-Q are < 15 grams of fat.

Refer to *Vol. 2, Section 6.15.2.2 - Tailored Feedback (PEFI-F)* for a complete description of the tailored materials generated from the PEFI-Q.

Figure G.1

Fat Grams Reported on PEFI: Over Fat Gram Goal

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

for

<Participant Name>
Questionnaire completed on: <Date>

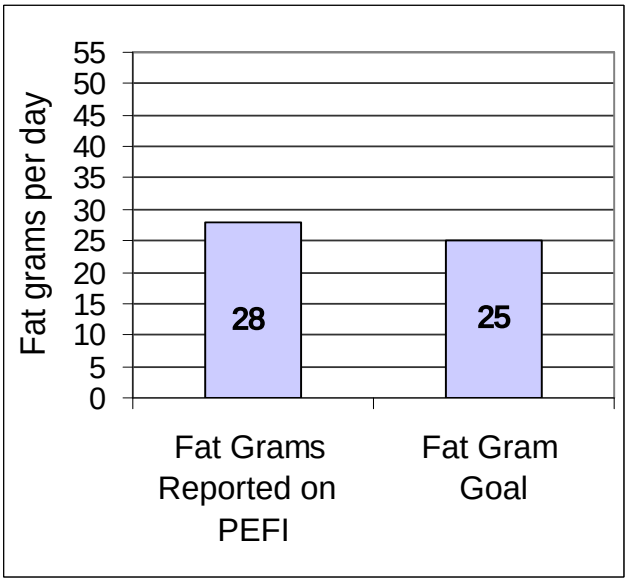
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create a fresh look at your sources of dietary fat. Your personalized packet contains detailed information about the fat in your eating pattern and a variety of ideas for food choices that support meeting and maintaining your fat gram goal.

We will be talking about this information during the Fall session. Feel free to call me if you have any questions.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

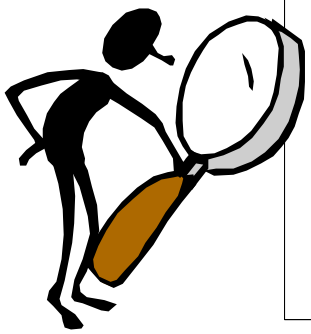
<Participant Name>
Group #

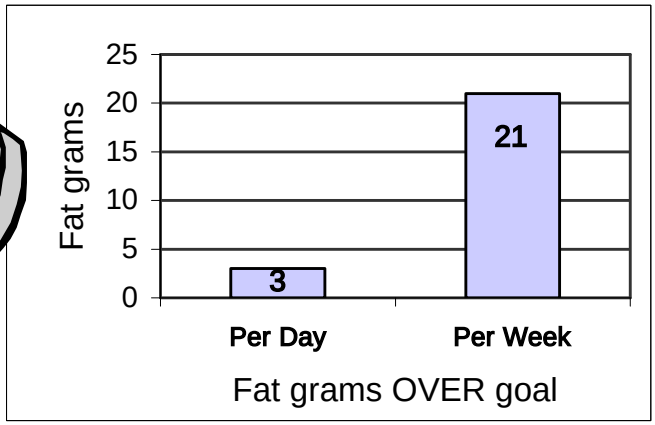
Where Are You in Relation to Your WHI Fat Gram Goal?



Is there a difference between your fat gram goal and the fat grams reported on the PEFI self-assessment questionnaire?

PEFI reported fat grams:		*28*
Fat gram goal:	-	*25*
Difference per day:	=	*3 grams*



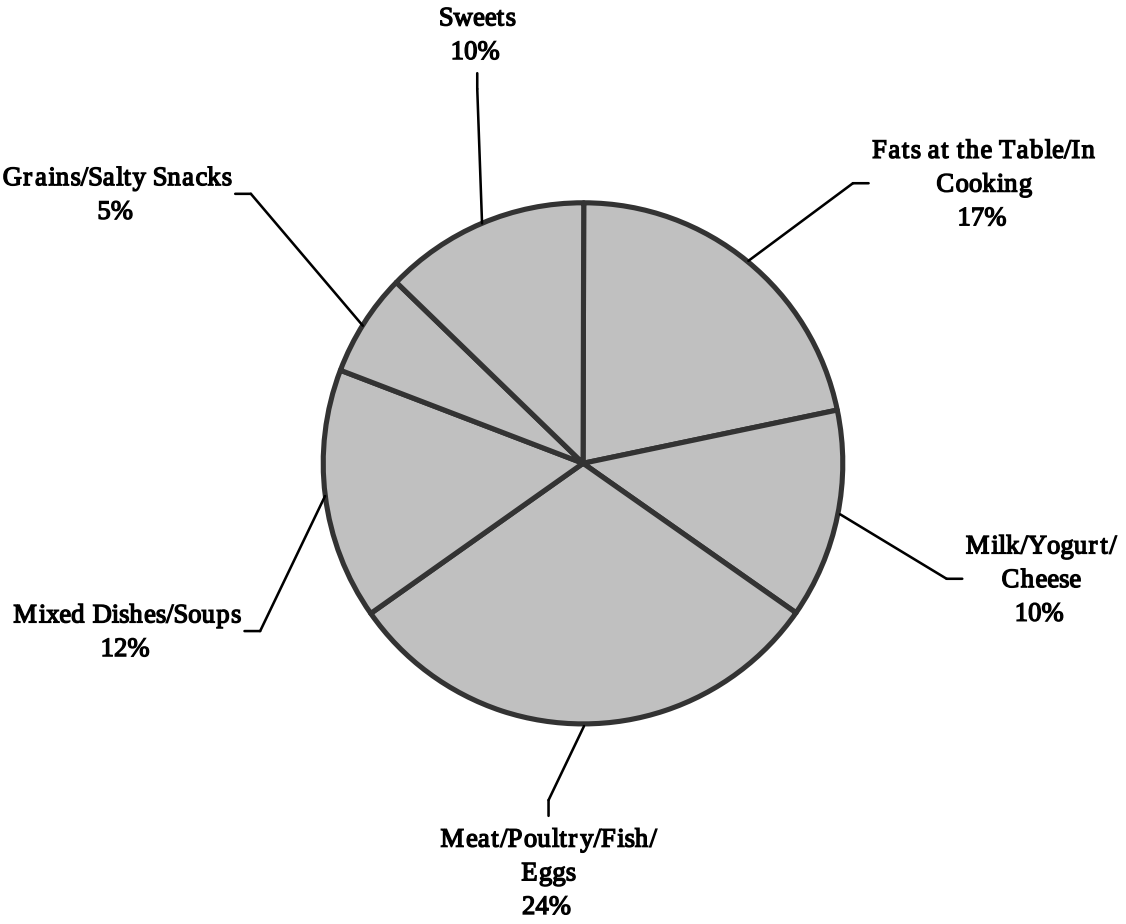


Based on the information you provided on the PEFI self-assessment questionnaire, you are about **3** grams over your fat gram goal **per day**. This adds up to about **21** additional fat grams **per week**. The following pages can help you:

- Identify the foods and food groups that provide fat in your eating pattern.
- Think about ways you could begin to reduce your weekly fat intake.
- Look at how even small changes can make a big difference.

Group #

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

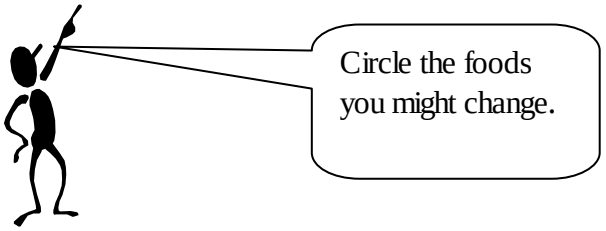
- Meat, Poultry, Fish and Eggs – 24%
- Fats Used at the Table or Added in Cooking – 17%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page….

Top Ten Foods That Provide Fat in Your Diet

There are many different ways that you can reduce your fat intake. Below are some ideas for lower-fat choices.

Food – Your usual serving size and how often you ate the food.	**FAT (grams per week)**	**If you made these lower-fat choices, you could reduce your fat intake by….** →	**…this many fat grams per week**
Stews or casseroles 1½ cups, 3-4 per week	109	• Prepare with less fat and low-fat ingredients. • Reduce to twice per week.	94 55
Peanut butter 2 Tb, 3-4 per week	66	• Decrease serving to 1 Tb. • Choose reduced-fat peanut butter.	33 18
Butter or margarine on breads 2 tsp, once per day	57	• Choose fat-free margarine or fruit spreads. • Decrease serving to 1 tsp.	57 29
Salad dressings 2 Tb, 3-4 per week	55	• Choose fat-free dressings. • Decrease serving to 1 Tb.	55 28
Eggs or egg substitutes with fat 1 egg, 5-6 per week	40	• Choose egg whites or fat-free egg substitutes. • Reduce to 3-4 times per week.	40 13
Beef, pork/ham or lamb 3 oz, twice per week	33	• Trim meat or choose lean cuts. • Reduce to once per week.	16 16
Chicken or turkey 4½ oz, twice per week	29	• Remove the skin. • Reduce to once per week.	15 14
French fries or fried potatoes 3/4 cup, twice per week	26	• Choose oven-baked fries or a baked potato. • Decrease serving to 1/3 cup.	26 15
Ground meat or ground poultry 3 oz, once per week	17	• Choose extra lean ground beef or ground turkey breast. • Reduce to 2-3 times per month.	12 5
Regular full-fat cheeses 1 oz, once per week	9	• Choose low-fat cheeses such as mozzarella. • Reduce to 2-3 times per month.	5 4



<Participant Name>

Group #

Next Steps: Where Do You Go From Here?

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!**

I <u>would consider</u> making the following changes:

- Reduce my portion size.
  - ❑ Food: _____ New portion size:_____
  - ❑ Food: _____ New portion size:_____

- Change how often I eat a food.
  - ❑ Food: _____ Times per week to eat:_____
  - ❑ Food: _____ Times per week to eat:_____

- Cut back on the fat I use to prepare and cook my food.
  (examples: trim fat off meat, use non-stick spray, oven baked fries)
  - ❑ Food: _____ New way to cook: _____
  - ❑ Food: _____ New way to cook: _____

- Choose a low-fat or fat-free food instead of the regular full-fat choice.
  (examples: fat-free mayonnaise, low-fat cheese, fat-free lunch meat)
  - ❑ New food to use: _____ Instead of: _____
  - ❑ New food to use: _____ Instead of: _____

- Other Idea:_____

☑ **Check the changes that you are <u>willing to try</u> over the next 3 months.**

Remember – if every woman made just a <u>small</u> change in her eating pattern, it could make a <u>big</u> difference to the Dietary Change program!! Thank you for helping to make WHI successful.

4 <Participant Name>
Group #

Figure G.2

Fat Grams Reported on PEFI:
≤ Fat Gram Goal, but ≥ 15 Grams of Fat

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

for

<Participant Name>

Questionnaire completed on: <Date>

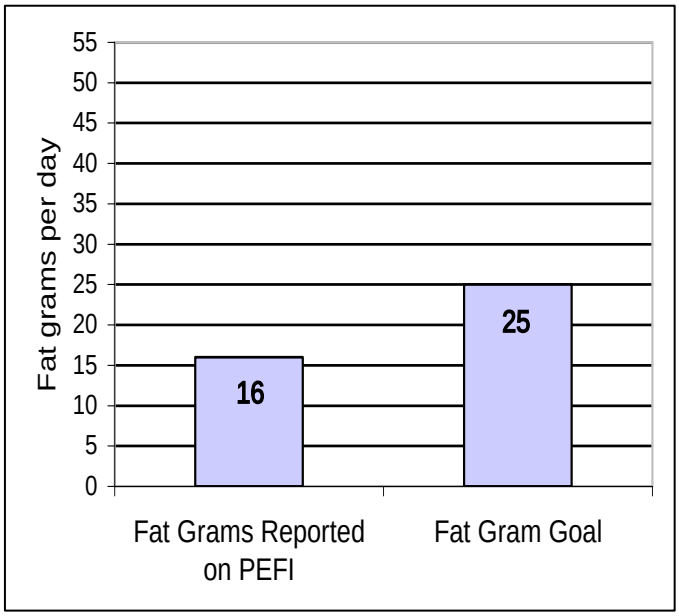
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create a fresh look at your sources of dietary fat. Your personalized packet contains detailed information about the fat in your eating pattern and a variety of ideas for food choices that support meeting and maintaining your fat gram goal.

We will be talking about this information during the Fall session. Feel free to call me if you have any questions.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

<Participant Name>
Group #

Where Are You in Relation to Your WHI Fat Gram Goal?



Based on the information you provided on the PEFI self-assessment questionnaire, you are at or below your fat gram goal!

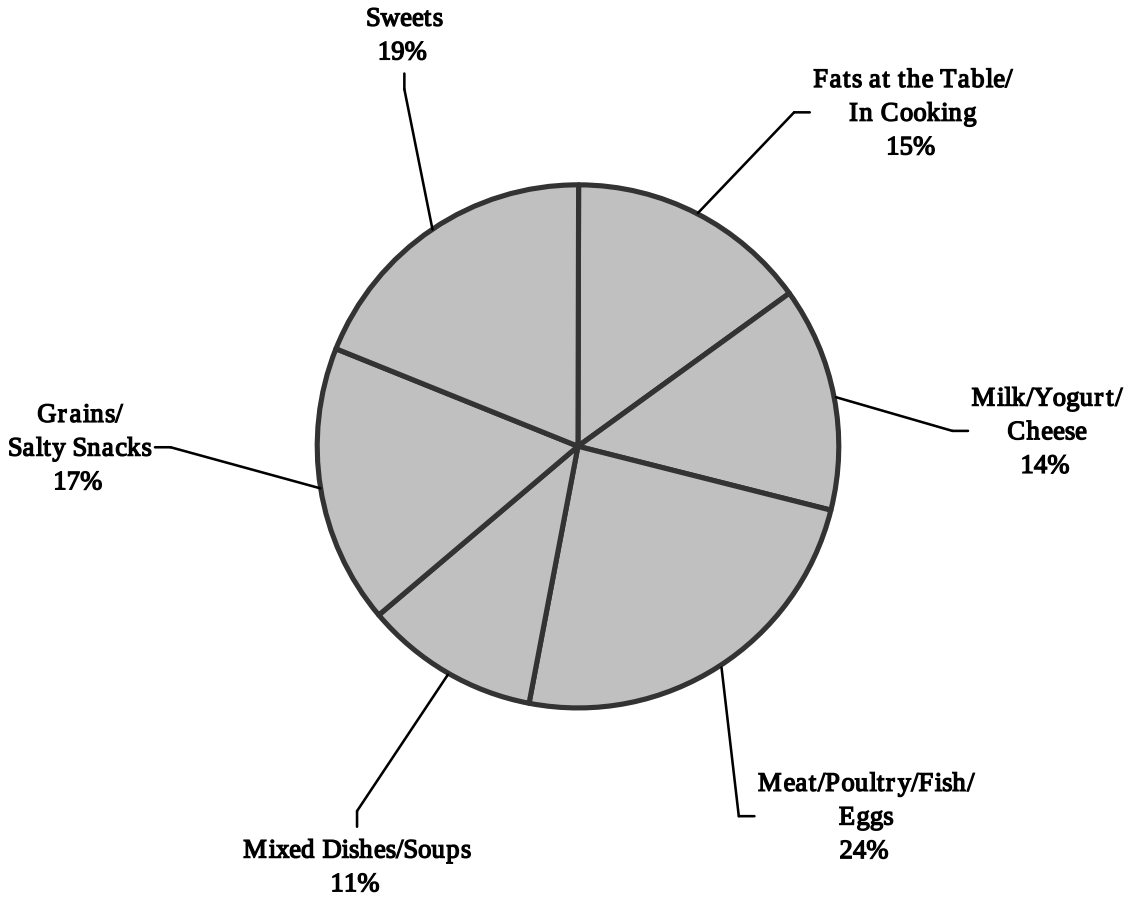
PEFI reported fat grams: 16
Fat gram goal: 25

The following pages provide some information that can help you:

- Take a look at the foods and food groups that provide fat in your eating pattern.
- Think about how closely this information matches what you eat.
- Consider how you could use this information to **maintain** your current fat intake, or make some changes if they seem right for you.

<Participant Name>
Group #

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

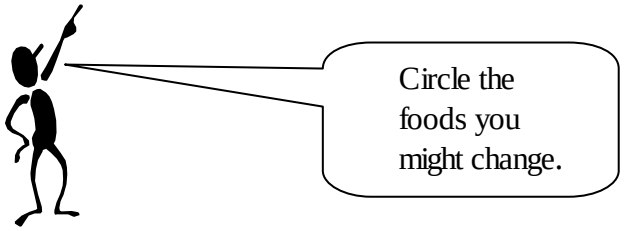
- Meat, Poultry, Fish and Eggs – 24%
- Sweets – 19%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page….

Top Ten Foods That Provide Fat in Your Diet

There are many different ways that you can reduce your fat intake. Below are some ideas for lower-fat choices.

Food – **Your usual serving size and how often you ate the food.**	**FAT (grams per week)**	**If you made these lower-fat choices, you could reduce your fat intake by….** ⟶	**…this many fat grams per week**
Breads 2 slices, 5-6 per week	10	Healthy choice.	--
Chicken or turkey 3 oz, twice per week	10	• Reduce to once per week.	5
Low-fat cheeses 1 slice, twice per week	9	• Reduce to once per week.	4
Frozen desserts ¾ cup, twice per week	9	• Reduce to once per week.	4
Beef, pork/ham or lamb 4 oz, once per week	8	• Reduce to 2-3 times per month.	4
Eggs or egg substitutes with fat 2 eggs or ½ cup, 2-3 per month	8	• Choose egg whites or fat-free egg substitutes. • Reduce to once per month.	8 5
Pies or fried pastries 1 sm. slice, 2-3 per month	7	• Choose fat-free cookies and cakes. • Reduce to once per month.	6 4
Pancakes or waffles 2 pancakes or 1 med. waffle, twice a week	6	• Reduce to once per week.	3
Reduced-fat peanut butter 1 Tb, once a week	6	• Choose fruit spreads. • Reduce to 2-3 times per month.	6 3
Salad dressings 2 Tb, once a week	6	• Choose fat-free salad dressings. • Decrease serving to 1 Tb.	6 3



Group #

Next Steps: Where Do You Go From Here?

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!

I <u>would consider</u> making the following changes:

- Reduce my portion size.
  - ❑ Food: _____ New portion size:_____
  - ❑ Food: _____ New portion size:_____

- Change how often I eat a food.
  - ❑ Food: _____ Times per week to eat:_____
  - ❑ Food: _____ Times per week to eat:_____

- Cut back on the fat I use to prepare and cook my food. (examples: trim fat off meat, use non-stick spray, oven baked fries)
  - ❑ Food: _____ New way to cook: _____
  - ❑ Food: _____ New way to cook: _____

- Choose a low-fat or fat-free food instead of the regular full-fat choice. (examples: fat-free mayonnaise, low-fat cheese, fat-free lunch meat)
  - ❑ New food to use: _____ Instead of: _____
  - ❑ New food to use: _____ Instead of: _____

- Other Idea: _____ _

☑ **Check the changes that you are willing to try over the next 3 months.**

Remember – if every woman made just a small change in her eating pattern, it could make a big difference to the Dietary Change program!! Thank you for helping to make WHI successful.

4 <Participant Name>
Group #

Figure G.3

Fat Grams Reported on PEFI: <15 Grams of Fat

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

for

<Participant Name>
Questionnaire completed on: <Date>

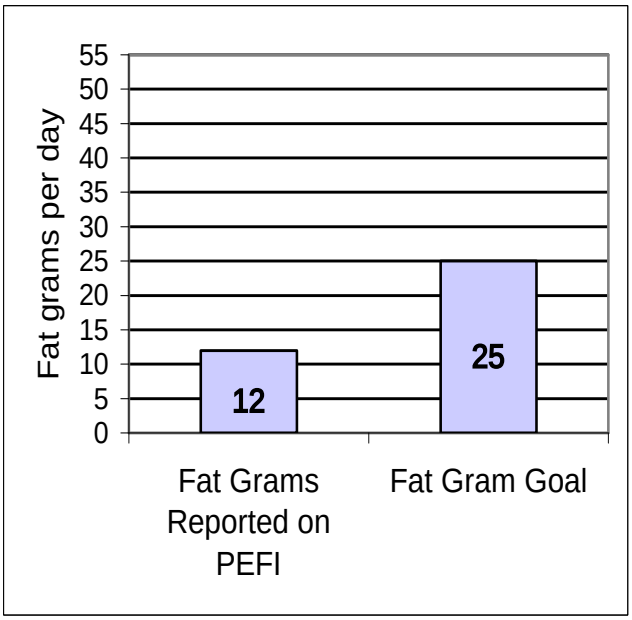
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create a fresh look at your sources of dietary fat. Your personalized packet contains detailed information about the fat in your eating pattern and a variety of ideas for food choices that support meeting and maintaining your fat gram goal.

We will be talking about this information during the Fall session. Feel free to call me if you have any questions.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

<Participant Name>
Group #

Where Are You in Relation to Your WHI Fat Gram Goal?



Based on the information you provided on the PEFI self-assessment questionnaire, your estimated fat intake is very low. We encourage you to talk with your nutritionist to explore your personalized information further.

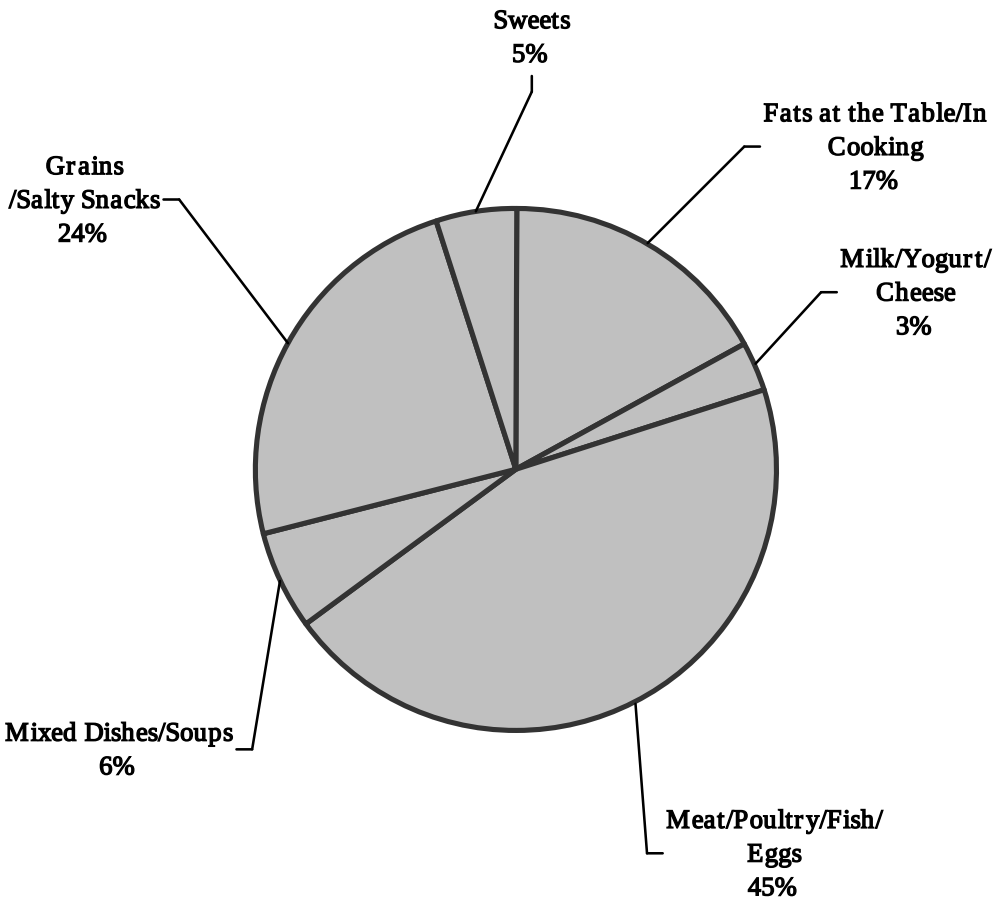
PEFI reported fat grams: 12
Fat gram goal: 25

The following pages provide some information that can help you:

- Take a look at the foods and food groups that provide fat in your eating pattern.
- Think about how closely this information matches what you eat.
- Consider how you could use this information to make some changes, if they seem right for you.

<Participant Name>
Group #

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

- Meat, Poultry, Fish and Eggs – 45%
- Grain Products and Salty Snacks – 24%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page….

<Participant Name>
Group #

Top Ten Foods That Provide Fat in Your Diet

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.

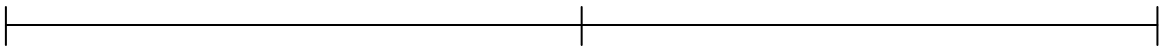
Food – **Your usual serving size and how often you ate the food.**	**FAT (grams per week)**	**If you made these lower-fat choices, you could reduce your fat intake by….** →	**…this many fat grams per week**
Reduced-fat peanut butter 1 Tb, twice per week	12	• Choose fruit spreads. • Reduce to once per week.	12 6
Breads 2 slices, 5-6 per week	10	Healthy choice.	--
Chicken or turkey 3 oz, twice per week	10	• Reduce to once per week.	5
Beef, pork/ham or lamb 4 oz, once per week	9	• Reduce to 2-3 times per month.	4
Low-fat lunchmeats 2 slices, once per week	6	• Choose fat-free lunchmeat. • Reduce to 2-3 times per month.	5 2
Biscuits or muffins 2 sm., once per week	5	• Reduce to 2-3 times per month.	2
Hot dogs or sausages 1½ oz, 2-3 per month	5	• Reduce to once per month. • Choose low-fat varieties.	3 2
Cookies or cakes 3 sm. cookies or 1 piece of cake, once per week	4	• Reduce to 2-3 times per month.	2
Ground meat or ground poultry 3 oz, 2-3 per month	3	• Reduce to once per month.	1
Eggs or egg substitutes with fat 2 eggs or ½ cup, once per month	3	• Choose egg whites or fat-free egg substitutes.	3

<Participant Name>
Group #

Next Steps: Where Do You Go From Here?

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.

1. How closely does this very low fat intake match what I eat? Mark the line below.



Not Close **Fairly Close** **Close**

2. Are there any high-fat foods that I missed recording on my PEFI self-assessment questionnaire? Yes ___ No ___

If yes, high-fat foods I missed? How often do I eat these foods?

_____ _____

_____ _____

_____ _____

3. Am I interested in making some changes in what I eat? Yes ___ No ___

If yes, what changes might I consider? For example:

- Change my portion?
- Change how often I eat a food?
- Change how I prepare a food?
- Choose a different food?
- Other?

_____

_____

_____

We encourage you to talk with your nutritionist to explore your personalized information further. Thank you for helping to make WHI successful.

Group #

G.8 Personalized Evaluation of Fat Intake 2003 (PEFI 2003)

This appendix provides: a) information on modifications to the tailored messages displayed for the top 10 foods listed on page 3 of PEFI-F and b) copies of the PEFI 2003 materials. Refer to *Vol. 2, Section 6.16 – Personalized Evaluation of Fat Intake 2003 (PEFI 2003) (including all subsections)* for a complete description of PEFI 2003.

G.8.1 PEFI 2003 Modifications to Tailored Messages for Top 10 Foods on PEFI-F

The tailored messages used for PEFI 2003 are the same as the original PEFI intervention (*see Vol. 2- Appendix G7.2. - Tailored Messages for Top 10 Foods on PEFI-F*) with the exception of the items described below.

For PEFI 2003, two changes were made in the programming of 'healthy choice' messages: a) changes in the message wording to reduce confusion with the *Healthy Choice* brand name and b) the addition of low-fat protein foods that will receive a 'healthy choice' message. Table G.5 - *Modifications in 'Healthy Choice' Messages for PEFI 2003* shows the PEFI-Q line items affected by these programming changes.

Changes in message wording:

To reduce confusion with the *Healthy Choice* brand name, the 'healthy choice' message for PEFI 2003 reads "This is already a low-fat choice". Exception: the 'healthy choice' message for breads (line item 28) reads "This is already a healthy choice, especially if whole grain".

Addition of low-fat protein foods:

To better acknowledge participant effort to make low-fat selections, low-fat protein foods have been added to the list of foods that will receive a 'healthy choice message. If a participant selects the lowest-fat option for the low-fat protein foods listed in Table G.5 - *Modifications in 'Healthy Choice' Messages for PEFI 2003*, she will receive the 'healthy choice' message designated for that specific food line item.
For example: If a participant indicates that she "Always" removes the skin from her chicken or poultry, and this food appears on her PEFI-F Top 10 List, the message will be: " Choosing white meat and removing the skin is already a low-fat choice."

> Note: When a 'healthy choice' message is used, no other message will be given for the food (i.e., there is no frequency or serving size message).

Table G. 5 – Modifications in 'Healthy Choice' Food Messages for PEFI 2003

Line #	Food Description for "Top 10 List "	Modified Wording for "Healthy Choice" Food Message
	Changes in Message Wording:	
28	Breads	This is already a healthy choice, especially if whole grain.
33	Air-popped popcorn	This is already a low-fat choice.
38	Egg whites or fat-free egg substitutes	This is already a low-fat choice.
42	Fat-free lunchmeats	This is already a low-fat choice.
51	Shellfish, not fried	This is already a low-fat choice.
52	White fish	This is already a low-fat choice.
86	Fat-free cottage cheese	This is already a low-fat choice.
89	Fat-free cheeses	This is already a low-fat choice.
92	Fat-free yogurt	This is already a low-fat choice.
	Low-Fat Protein Foods	
48	Chicken or turkey	Choosing white meat and removing the skin is already a low-fat choice.
57	Tofu or tempeh	This is already a low-fat choice.
73	Pasta or rice dishes with tomato sauce	This is already a low-fat choice when made with low-fat ingredients.
76	Asian-style noodle/rice dishes	This is already a low-fat choice when made with low-fat ingredients.
77	Asian-style stir-fried dishes	This is already a low-fat choice when made with low-fat ingredients.
80	Beans or bean/rice dishes	This is already a low-fat choice when made with low-fat ingredients.
84	Bean soups	This is already a low-fat choice when made with low-fat ingredients.
85	Milk or cream on cereal	Choosing skim milk products is already a low-fat choice.
100	Milk	Skim milk is already a low-fat choice.
101	Milk-based drinks	Choosing beverages made with skim milk is already a low-fat choice.

G.8.2 PEFI 2003 Materials

This section includes copies of the following PEFI 2003 materials:

- Figure G.4 – PEFI-Q Cover Letter/Instructions
- Figure G.5 – PEFI-Q Request for Additional Information Letter
- Figure G.6 - Sample PEFI-F (Over Fat Gram Goal)
- Figure G.7 - Sample PEFI-F ($\leq$ Fat Gram Goal, but $\geq$15 Grams of Fat)
- Figure G.8 - Sample PEFI-F (<15 Grams of Fat)
- Figure G.9 - Guide for Your PEFI Packet

A copy of Form *73* - PEFI-Q (ver. 2) can be found in *Vol. 3 – Forms.*

Figure G.4

PEFI 2003

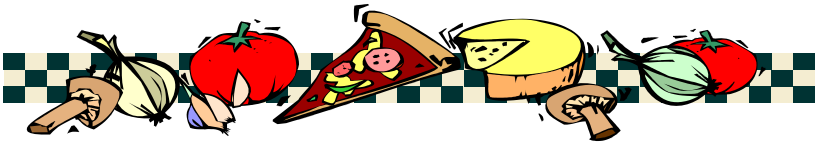
PEFI-Q Cover Letter/Instructions

Personalized **E**valuation of **F**at **I**ntake **Q**uestionnaire
(PEFI-Q)

Dear Dietary Change Participant,

We are pleased to offer you another opportunity to receive a personalized packet of information showing the sources of fat in your eating pattern. The enclosed questionnaire is a self-help version of the original PEFI questionnaire that many of you had an opportunity to complete during the Summer and Fall of 2002.

To receive your personalized packet, please complete this questionnaire and return it in the enclosed envelope to the **WHI Clinical Coordinating Center in Seattle** as soon as possible. Approximately four weeks later, you will receive your packet in the mail. This questionnaire is voluntary and the information is for your use only.



The questionnaire asks about all of the fat-containing foods you ate during the past MONTH.

Helpful Hints:

- Think about all the places you ate during the past month. Include all the fat-containing foods you ate. This includes foods you ate at home, at the office, as a guest in the homes of family and friends, as well as restaurants or fast-food places.
- The first part of the questionnaire asks about the FAT in the foods you ate.
- The second part of the questionnaire asks about HOW OFTEN you ate the foods and the AMOUNT you ate.

(Please turn this page over)

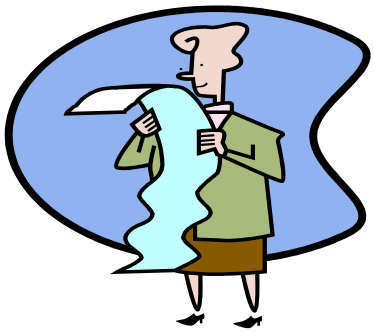
IMPORTANT

The two most common problems that occur when completing this questionnaire are:

- leaving an entire page blank, and
- leaving unanswered questions on pages 2-5.

Please answer every question –
<u>even if you did not eat the food</u>.

When you are finished with the questionnaire,
please take a few minutes to review the form.
Make sure there are no blank pages or unanswered questions.



If you have questions on how to complete this questionnaire, please call your WHI nutritionist at your Clinical Center.

Thank you for your time, enthusiasm, and continued commitment to WHI.

Figure G.5

PEFI 2003

PEFI-Q Request for Additional Information Letter

Personalized **E**valuation of **F**at **I**ntake **Q**uestionnaire -

Request for Additional Information

Dear (Participant's Name),

We were unable to create your personalized packet of information showing the sources of fat in your eating pattern because your questionnaire had some unanswered questions or circles that were too lightly marked for the computer to read.

If you would like to receive your personalized packet, please take another look at your questionnaire and answer all the questions and/or darken the circles on the following pages:

Page(s) __, ___, ___, ___.

Please return your completed questionnaire (in the enclosed envelope) to the **WHI Clinical Coordinating Center in Seattle** as soon as possible. Your personalized packet will be mailed in about four weeks. This questionnaire is voluntary and the information is for your use only.

Thank you for your time, enthusiasm, and continued commitment in WHI.

PEFI_Q Booklet ID#

Figure G.6

PEFI 2003

Sample PEFI-F:
Over Fat Gram Goal

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

<Participant Name>
<Address>
<Address>
<Address>

Dear <Participant Name>,

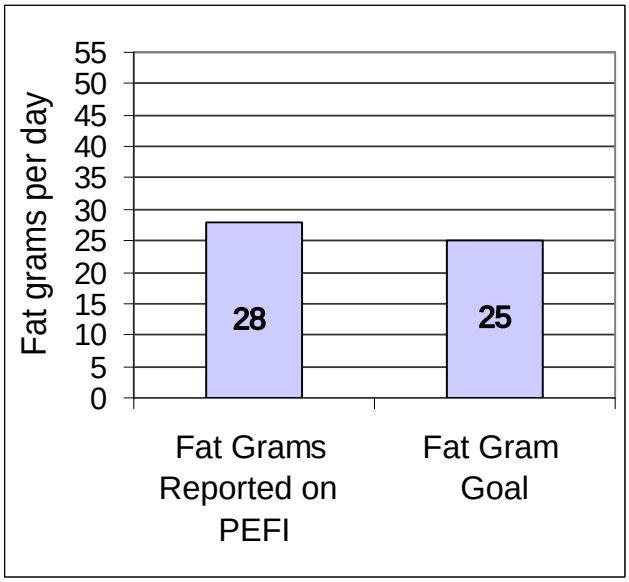
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create this packet to help you look at your sources of dietary fat. Your packet contains detailed information about the fat in your eating pattern and ideas for food choices that support meeting and maintaining your fat gram goal.

To help you review your personalized information, we've enclosed a **Guide for Your PEFI Packet.** If you have any questions about your PEFI information, please don't hesitate to give your WHI nutritionist a call.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

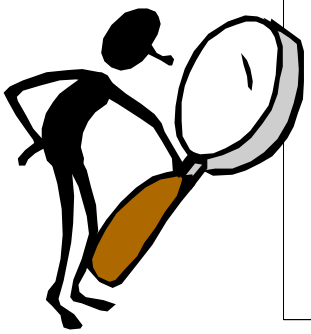
<Participant Name>
Group #, <Date Completed>

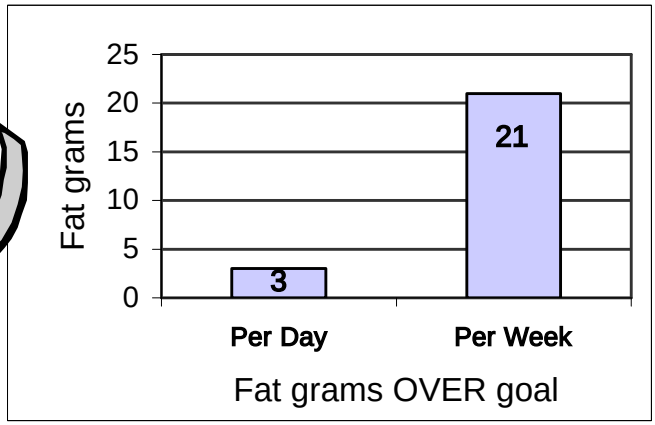
Where Are You in Relation to Your WHI Fat Gram Goal?



Is there a difference between your fat gram goal and the fat grams reported on the PEFI self-assessment questionnaire?

Fat grams reported on PEFI: 28
Fat gram goal: - 25
Difference per day: = 3 grams



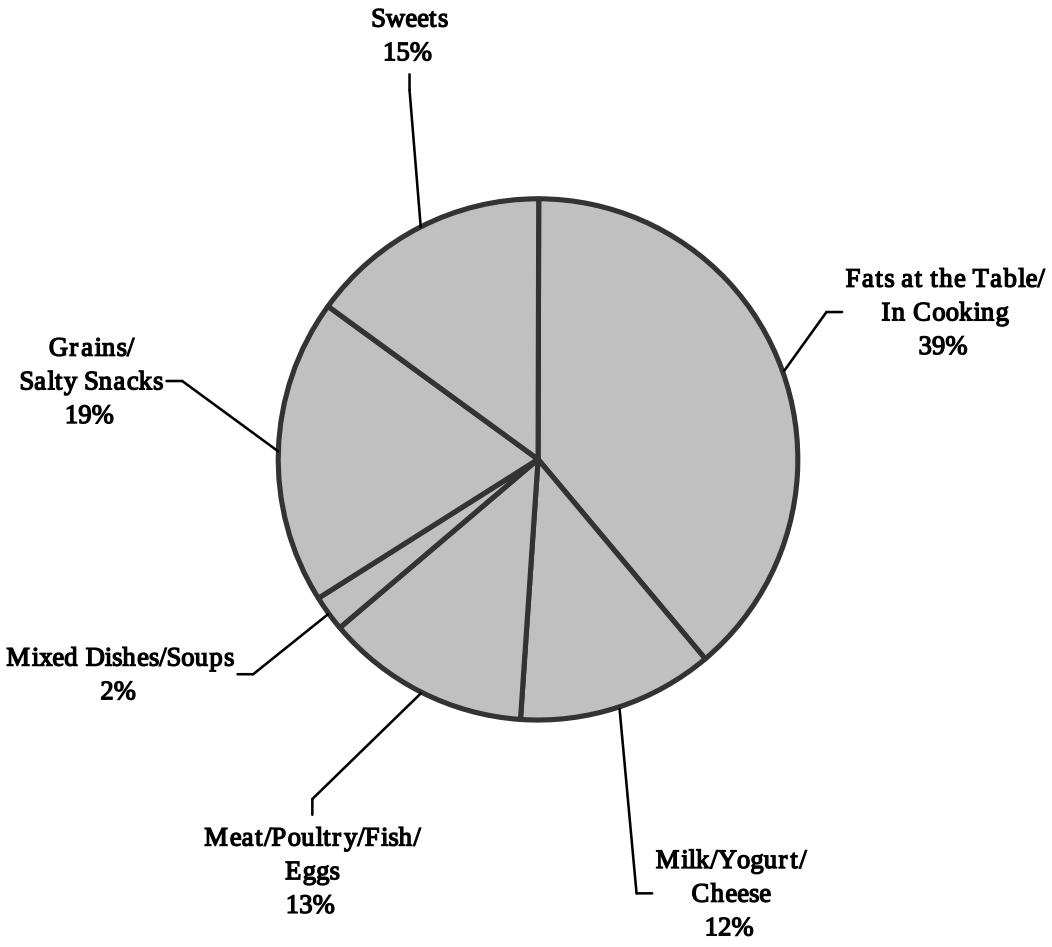


Based on the information you provided on the PEFI self-assessment questionnaire, you are about **3** grams over your fat gram goal **per day**. This adds up to **21** additional fat grams **per week**. The following pages can help you:

- Take a look at the foods and food groups that provide fat in your eating pattern.
- Think about how closely this information matches what you eat.
- Consider how you could use this information to help you **meet** your fat gram goal.

<Participant Name>
Group #, <Date Completed>

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. There is no perfect distribution of fat in the diet. The pie chart simply gives you an idea of where your fat comes from. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

- Fats Used at the Table or Added in Cooking – 39%
- Grain Products and Salty Snacks – 19%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page…

<Participant Name>

Group #, <Date Completed>

Top Ten Foods That Provide Fat in Your Diet

There are many different ways to eat low-fat. Below are some ideas for lower-fat choices. Circle any ideas that are new to you or that you think might help you meet your fat gram goal.

TOP TEN FOODS that provide fat in your diet	**FAT (grams per week)**	**IDEAS FOR LOWER-FAT CHOICES If you were to make these choices, the fat gram savings would be …→**	**FAT SAVINGS (grams per week)**
Mayonnaise or mayo-type spreads 1Tb, 5-6 per week	50	• Choose fat-free mayonnaise or spreads. • Reduce to 3-4 times per week.	50 18
Salad dressings 1 Tb, 3-4 per week	24	• Choose fat-free dressings. • Reduce to twice per week.	24 10
Cookies or cakes 3 sm. cookies or 1 piece cake, 3-4 per week	21	• Choose fat-free cookies and cakes. • Reduce to twice per week.	15 9
Peanuts and other nuts 2 Tb, 3-4 per week	19	• Choose soy nuts. • Reduce to 2-3 times per month.	8 8
Biscuits or muffins 1 sm., 3-4 per week	12	• Choose crumpets or bagels. • Reduce to twice per week.	5 5
Milk or cream on cereal ¼ cup, 5-6 per week	11	• Choose fat-free milk.	11
Chicken or turkey 3 oz, twice per week	10	• Choosing white meat and removing the skin is already a low-fat choice.	--
Ground meat or ground poultry 1½ oz, twice per week	9	• Reduce to once per week	5
Milk 1 cup, 2-3 per day	7	• Skim milk is already a low-fat choice.	--
Breads 1 slice or 1 tortilla, once per day	7	• This is already a healthy choice, especially if whole grain.	--

Look at the next page for ideas about where you might go from here….

<Participant Name>
Group #, <Date Completed>

Next Steps: Where Do You Go From Here?

Based on your responses on the PEFI self-assessment questionnaire, your estimated fat intake is over your fat gram goal. Consider asking yourself the questions below to help you think about your eating pattern.

1. How closely does my estimated fat intake match what I eat? Mark the line below.

Not Close — Fairly Close — Close

2. How interested am I in making any changes to help me meet my fat gram goal?

Not very interested — Somewhat interested — Very interested

Based on my interest level, I <u>might consider</u> the following:

- ❑ Reduce my portion.
  (examples: look at the foods you circled on page 3)

  Food: _____ New portion size:_____

- ❑ Change how often I eat a food.

  Food: _____ Times per week to eat:_____

- ❑ Cut back on the fat I use to prepare and cook my food.
  (examples: trim fat off meat, use non-stick spray, oven baked fries)

  Food: _____ New way to cook: _____

- ❑ Choose a lower-fat food instead of the regular full-fat choice.
  (examples: fat-free mayonnaise, low-fat cheese, fat-free lunch meat)

  New food to use: _____ Instead of: _____

- ❑ Other Idea:_____

☑ Consider which choices might be right for you and check any that you would be <u>willing to try</u> over the next 3 months. Remember…the choice is yours!

Thank you for helping to make WHI successful.

<Participant Name>
Group #, <Date Completed>

Figure G.7

PEFI 2003

Sample PEFI-F:
≤ Fat Gram Goal, but ≥ 15 Grams of Fat

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

<Participant Name>
<Address>
<Address>
<Address>

Dear <Participant Name>,

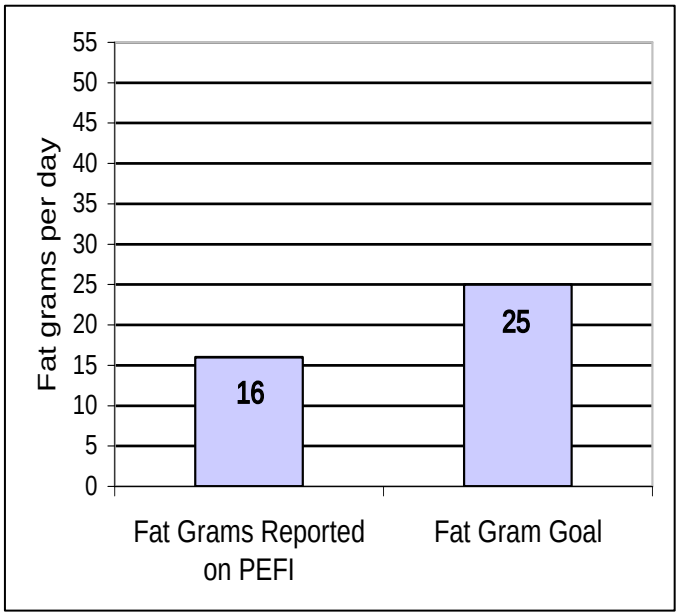
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create this packet to help you look at your sources of dietary fat. Your packet contains detailed information about the fat in your eating pattern and ideas for food choices that support meeting and maintaining your fat gram goal.

To help you review your personalized information, we've enclosed a **Guide for Your PEFI Packet**. If you have questions about your PEFI information, please don't hesitate to give your WHI nutritionist a call.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

<Participant Name>
Group #, <Date Completed>

Where Are You in Relation to Your WHI Fat Gram Goal?



Based on the information you provided on the PEFI self-assessment questionnaire, you are at or below your fat gram goal! Congratulations!

Fat grams reported on PEFI:	16
Fat gram goal:	25

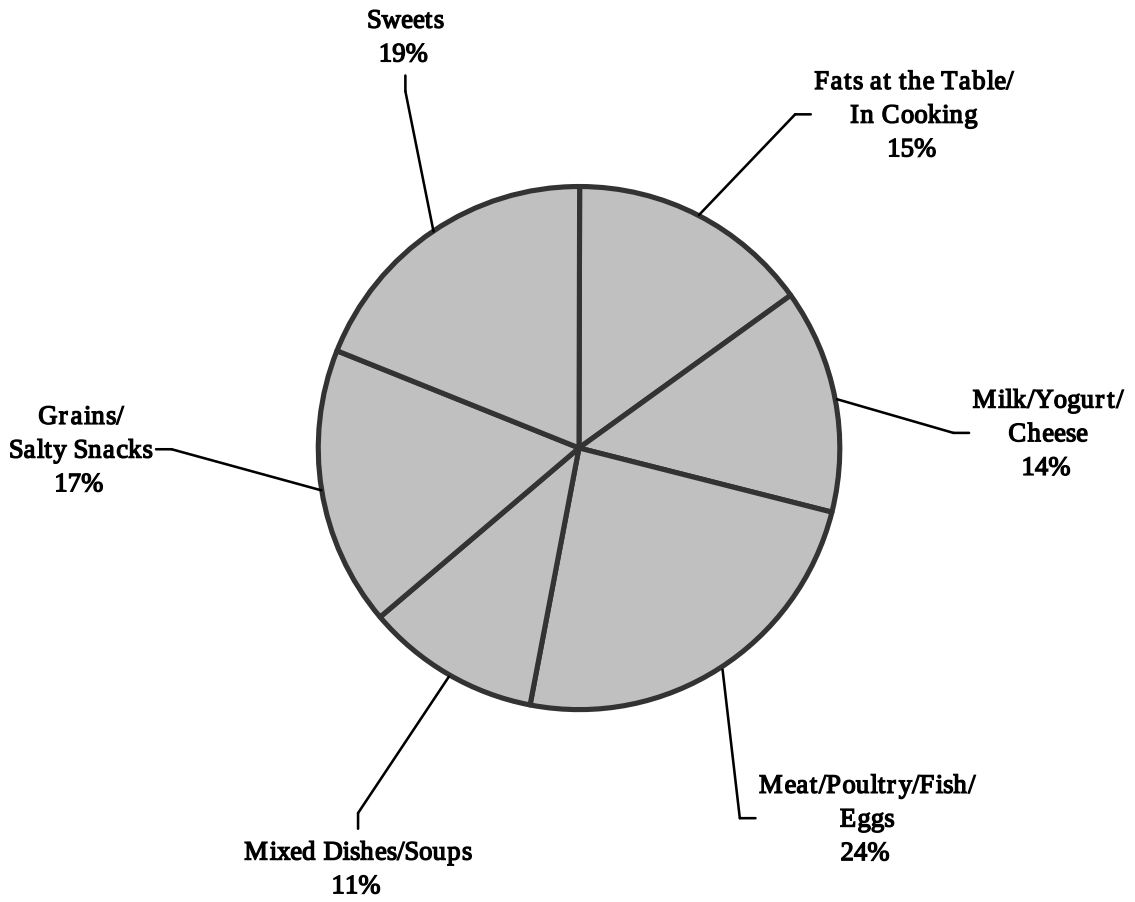
The following pages provide some information that can help you:

- Take a look at the foods and food groups that provide fat in your eating pattern.
- Think about how closely this information matches what you eat.
- Consider how you could use this information to help you **maintain** your fat gram goal.

<Participant Name>

Group #, <Date Completed>

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. There is no perfect distribution of fat in the diet. The pie chart simply gives you an idea of where your fat comes from. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

- Meat, Poultry, Fish and Eggs – 24%
- Sweets – 19%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page….

<Participant Name>

Group #, <Date Completed>

Top Ten Foods That Provide Fat in Your Diet

There are many different ways to eat low-fat. Below are some ideas for lower-fat choices. Circle any ideas that you think might add to the low-fat choices you are already making.

TOP TEN FOODS that provide fat in your diet	**FAT (grams per week)**	**IDEAS FOR LOWER-FAT CHOICES If you were to make these choices, the fat gram savings would be …** →	**FAT SAVINGS (grams per week)**
Breads 2 slices, 5-6 per week	10	• This is already a healthy choice, especially if whole grain.	--
Chicken or turkey 3 oz, twice per week	10	• Choosing white meat and removing the skin is already a low-fat choice.	--
Low-fat cheeses 1 slice, twice per week	9	• Reduce to once per week.	4
Frozen desserts ¾ cup, twice per week	9	• Reduce to once per week.	4
Beef, pork/ham or lamb 4 oz, once per week	8	• Reduce to 2-3 times per month.	4
Eggs or egg substitutes with fat 2 eggs or ½ cup, 2-3 per month	8	• Choose egg whites or fat-free egg substitutes. • Reduce to once per month.	8 5
Pies or fried pastries 1 sm. slice, 2-3 per month	7	• Choose fat-free cookies and cakes. • Reduce to once per month.	6 4
Pancakes or waffles 2 pancakes or 1 med. waffle, twice a week	6	• Reduce to once per week.	3
Reduced-fat peanut butter 1 Tb, once a week	6	• Choose fruit spreads. • Reduce to 2-3 times per month.	6 3
Salad dressings 2 Tb, once a week	6	• Choose fat-free salad dressings. • Decrease serving to 1 Tb.	6 3

Look at the next page for ideas about where you might go from here….

<Participant Name>
Group #, <Date Completed>

Next Steps: Where Do You Go From Here?

Based on your responses on the PEFI self-assessment questionnaire, your estimated fat intake is at or below your fat gram goal. Consider asking yourself the questions below to help you think about your eating pattern.

1. How closely does my estimated fat intake match what I eat? Mark the line below.

Not Close — Fairly Close — Close

2. How interested am I in making any changes to help me maintain my fat gram goal?

Not very interested — Somewhat interested — = Very interested

Based on my interest level, I <u>might consider</u> the following:

- ❑ Change my portion.
  (examples: look at the foods you circled on page 3)

  Food: _____ New portion size:_____

- ❑ Change how often I eat a food.

  Food: _____ Times per week to eat:_____

- ❑ Change how I prepare a food.
  (examples: trim fat off meat, use non-stick spray, oven baked fries)

  Food: _____ New way to cook: _____

- ❑ Choose a different food.
  (examples: fat-free mayonnaise, low-fat cheese, fat-free lunch meat)

  New food to use: _____ Instead of: _____

- ❑ Other Idea:_____

☑ **Consider which choices might be right for you and check any that you would be <u>willing to try</u> over the next 3 months. Remember…the choice is yours!**

Thank you for helping to make WHI successful.

<Participant Name>
Group #, <Date Completed>

Figure G.8

PEFI 2003

Sample PEFI-F:
<15 Grams of Fat

Your **P**ersonalized **E**valuation of **F**at **I**ntake (PEFI)

<Participant Name>
<Address>
<Address>
<Address>

Dear <Participant Name>,

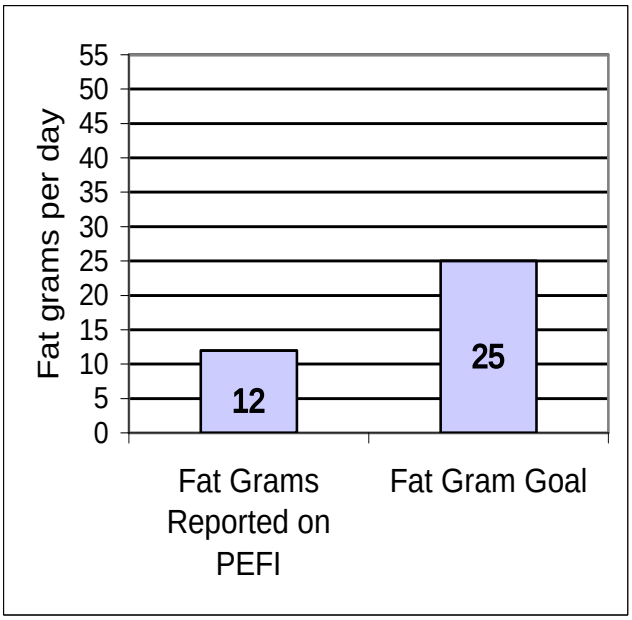
Thank you for completing the **P**ersonalized **E**valuation of **F**at **I**ntake self-assessment questionnaire! We used the information to create this packet to help you look at your sources of dietary fat. Your packet contains detailed information about the fat in your eating pattern and ideas for food choices that support meeting and maintaining your fat gram goal.

To help you review your personalized information, we've enclosed a **Guide for Your PEFI Packet**. If you have any questions about your PEFI information, please don't hesitate to give your WHI nutritionist a call.

Thank you for your energy, enthusiasm and continued commitment to WHI. Your determination and efforts are greatly appreciated.

<Participant Name>
Group #, <Date Completed>

Where Are You in Relation to Your WHI Fat Gram Goal?



Based on the information you provided on the PEFI self-assessment questionnaire, your estimated fat intake is very low. We encourage you to talk with your nutritionist to explore your personalized information further.

Fat grams reported on PEFI:	12
Fat gram goal:	25

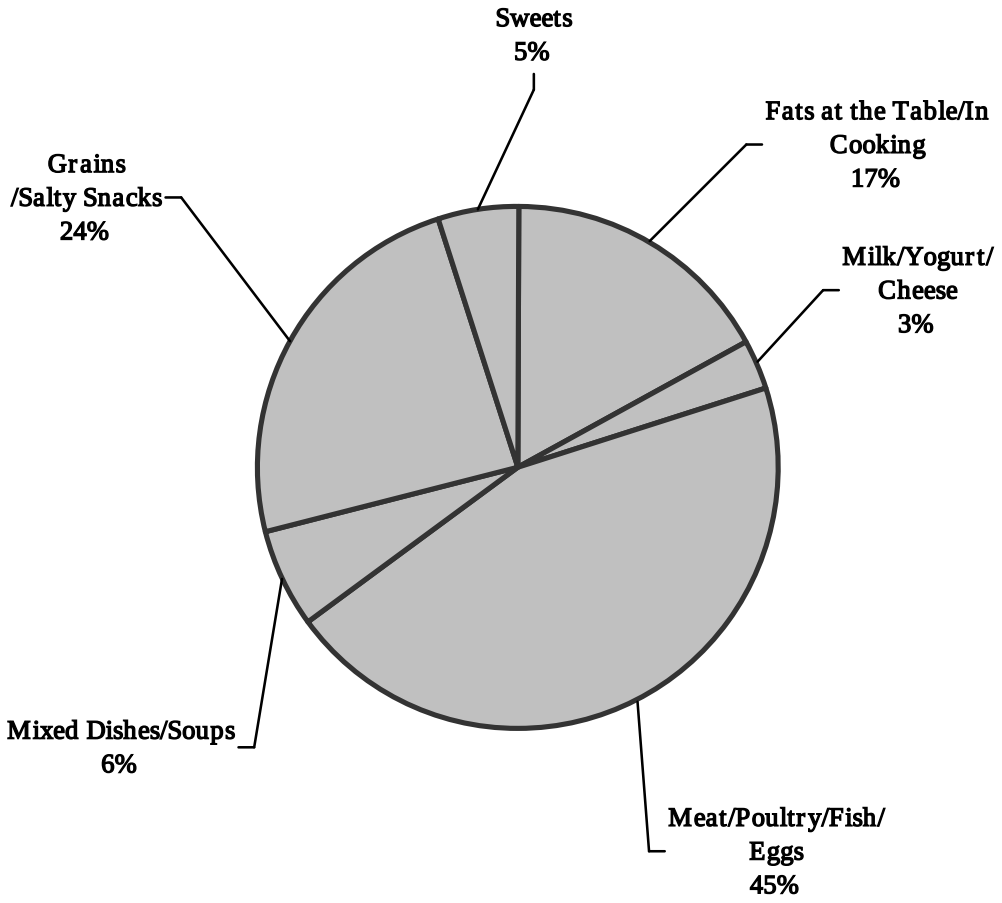
The following pages provide some information that can help you:

- Take a look at the foods and food groups that provide fat in your eating pattern.
- Think about how closely this information matches what you eat.
- Consider how you could use this information to make some changes, if they seem right for you.

<Participant Name>

Group #, <Date Completed>

Where Does Your Dietary Fat Come From?



The pie chart above gives you a 'big picture view' of the food groups that provide fat in your diet. There is no perfect distribution of fat in the diet. The pie chart simply gives you an idea of where your fat comes from, even though your reported fat intake is very low. According to your responses on the PEFI self-assessment questionnaire, the food groups that provide the most fat in your diet are:

- Meat, Poultry, Fish and Eggs – 45%
- Grain Products and Salty Snacks – 24%

What foods do you think might be contributing the most fat to your eating pattern? For ideas, look at the next page….

<Participant Name>

Group #, <Date Completed>

Top Ten Foods That Provide Fat in Your Diet

Based on your responses on the PEFI self-assessment questionnaire, your fat intake appears to be very low. These ten foods are the top sources of fat within your very low fat intake.

TOP TEN FOODS that provide fat in your diet	**FAT (grams per week)**
Reduced-fat peanut butter 1 Tb, twice per week	12
Breads 2 slices, 5-6 per week	10
Chicken or turkey 3 oz, twice per week	10
Beef, pork/ham or lamb 4 oz, once per week	9
Low-fat lunchmeats 2 slices, once per week	6
Biscuits or muffins 2 sm., once per week	5
Hot dogs or sausages 1½ oz, 2-3 per month	5
Cookies or cakes 3 sm. cookies or 1 piece of cake, once per week	4
Ground meat or ground poultry 3 oz, 2-3 per month	3
Eggs or egg substitutes with fat 2 eggs or ½ cup, once per month	3

Look at the next page for ideas about where you might go from here……

<Participant Name>
Group #, <Date Completed>

Next Steps: Where Do You Go From Here?

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.

1. How closely does this very low fat intake match what I eat? Mark the line below.

Not close | Fairly Close | Close

2. Are there any fat-containing foods that I may have missed recording on my PEFI self-assessment questionnaire? Yes ___ No ___

If yes, fat-containing foods I missed? How often do I eat these foods?

_____ _____

_____ _____

_____ _____

4. How interested am I in making any changes in what I eat?

Not very interested | Somewhat interested | Very interested

Based on my interest level, what changes might I consider? For example:

- Change my portion?
- Change how often I eat a food?
- Change how I prepare a food?
- Choose a different food?
- Other?

_____

_____

We encourage you to talk with your nutritionist to explore your personalized information further. Thank you for helping to make WHI successful.

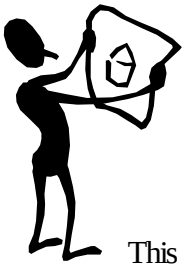
<Participant Name>

Group #, <Date Completed>

Figure G.9

PEFI 2003

Guide for Your PEFI Packet



Guide for Your PEFI Packet

This guide walks you through each page of your PEFI packet. It also provides some questions for thought. We encourage you to take your time when reading both the guide and your PEFI packet. Consider answering the questions from the guide as you go along. We hope you find this guide helpful as you review your PEFI information.

Page one of your PEFI packet helps you compare the fat grams you reported on the PEFI self-assessment questionnaire to your fat gram goal.

Question: Where is my fat intake compared to my fat gram goal?

Page two helps you see the 'big picture view' of where your dietary fat comes from by showing how your fat intake is distributed among different food groups. A pie chart shows the percent of your total fat contributed by each food group.

Question: Which food group provides the most fat in my diet?

Page three shows your top 10 sources of dietary fat reported on the PEFI self-assessment questionnaire. If you reported that you are eating 15 grams of total fat or more per day, you also receive some ideas for lower-fat choices.

Question: What does page 3 tell me about the top 10 foods providing the most fat in my diet?

Page four provides an opportunity for you to begin brainstorming ideas for change that you might consider. Use the questions on the back of this guide to help you think about your next steps.

-over-

NEXT STEPS

If you've brainstormed some ideas for change, the questions below can help you create a plan to make a change you are considering. If you're ready to make the change today, great! If you're considering the change but aren't quite ready to do it today, that's OK too.

1. Of the changes I'm considering, the change that I can see myself most likely making is:

   _____

   _____

   _____

2. Why did I choose this change over others?

   _____

   _____

   _____

3. What can I do to achieve this change?

   _____

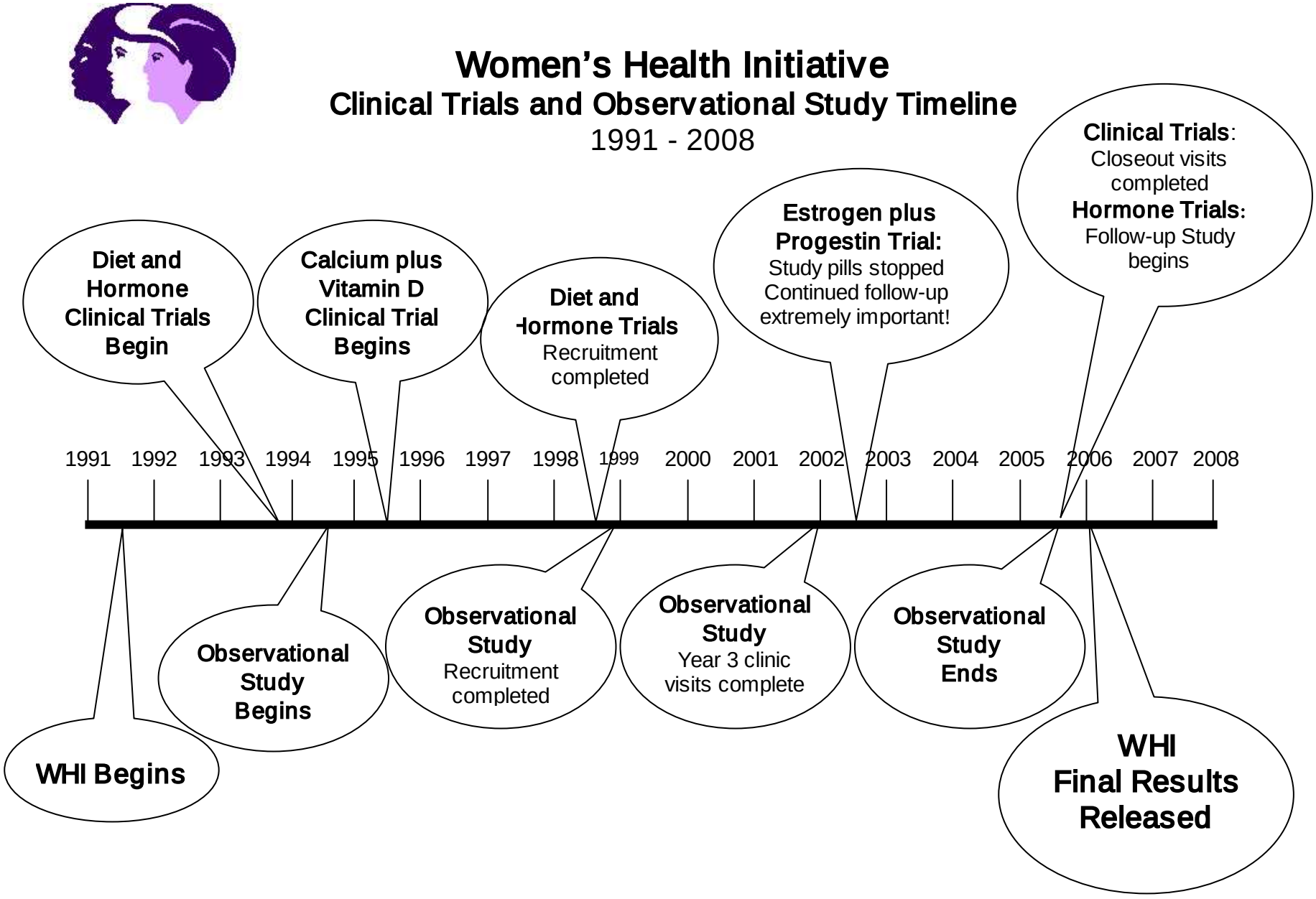
   _____

   _____

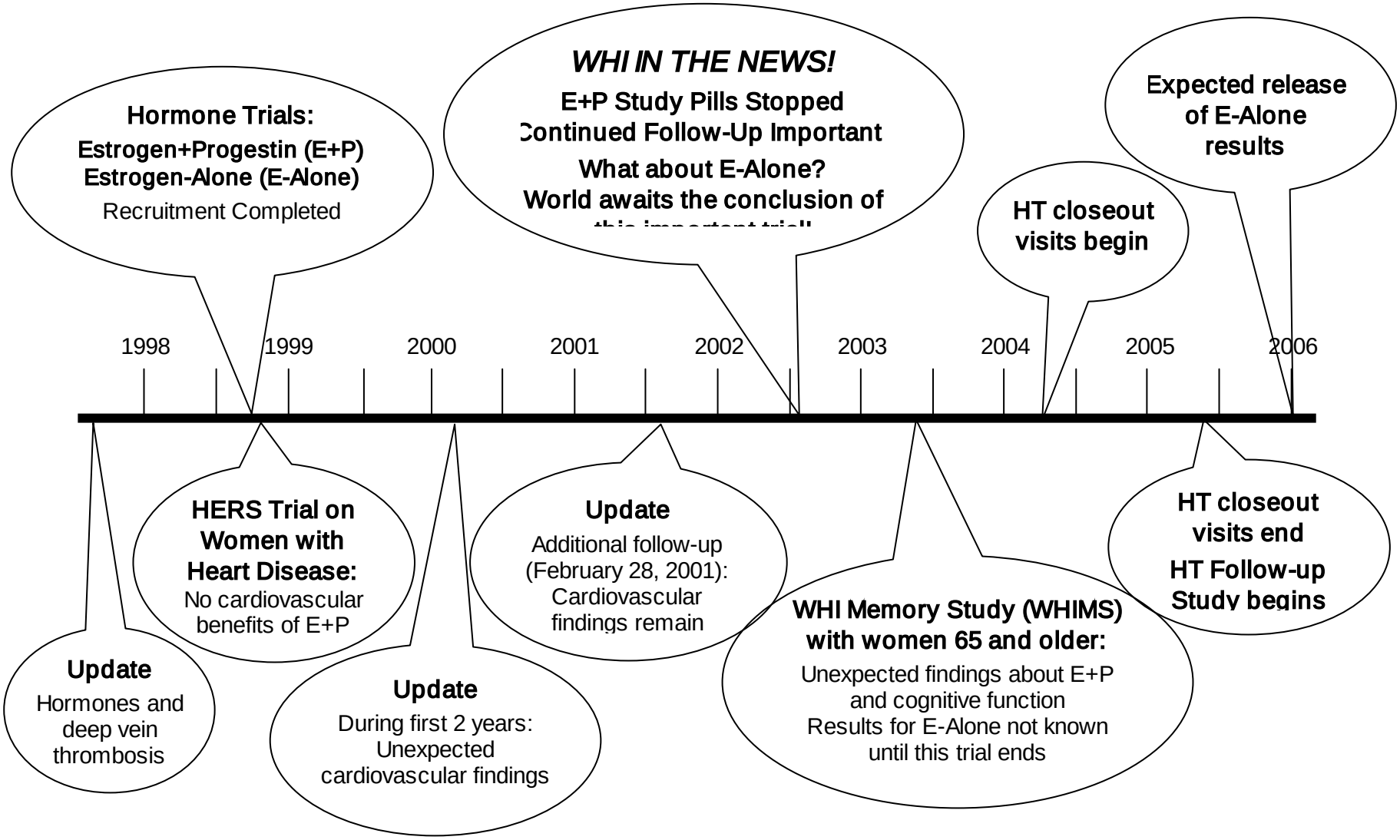
Thank you for participating in the WHI Dietary Study!

G.9 Optional Materials for a Required "Pre-Close-out Contact" with HT, CaD, and DM Participants

G.9.1 Timelines and Milestones



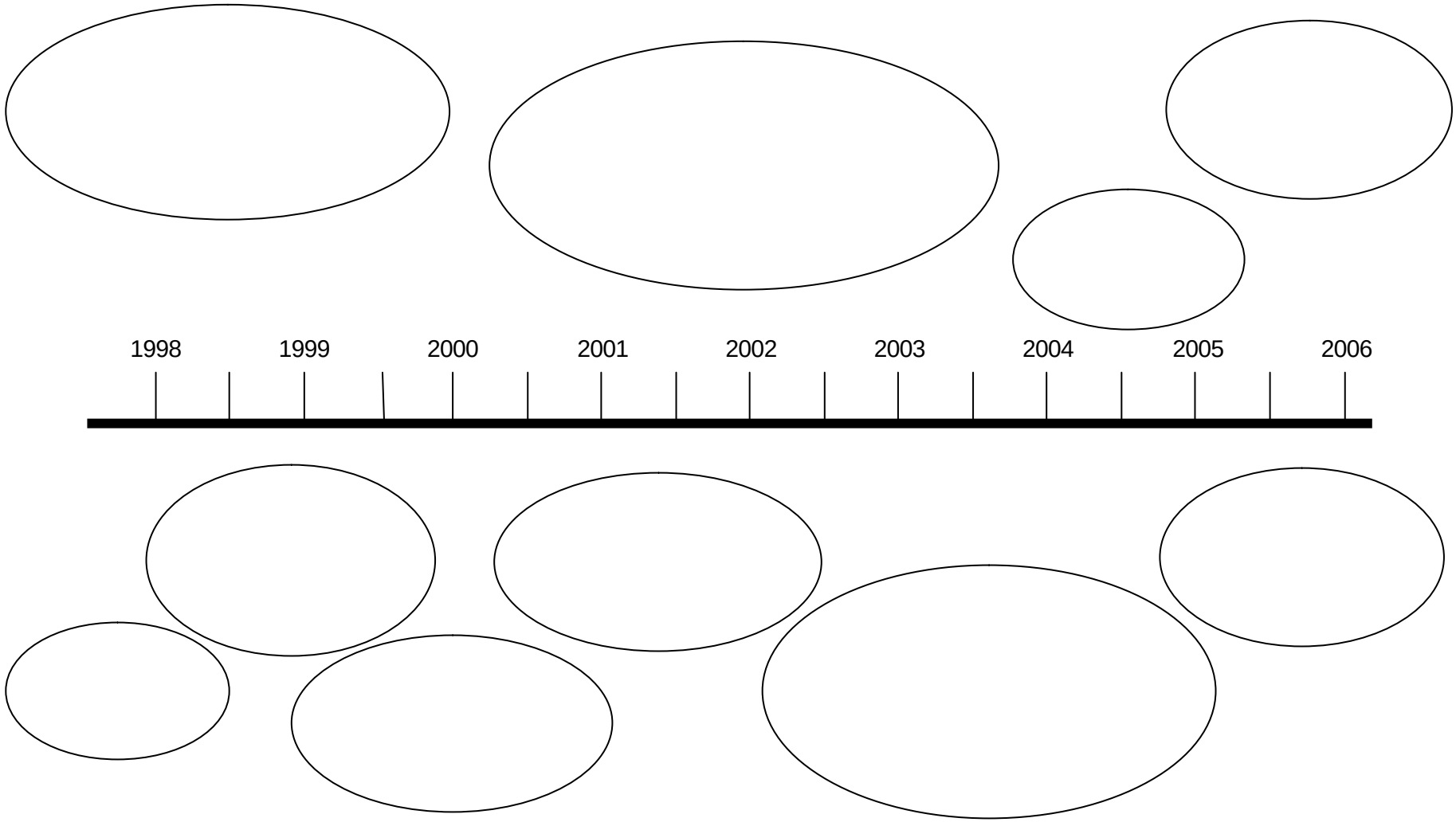
Women's Health Initiative
Hormone Trials (HT) Milestones
1998 - 2006



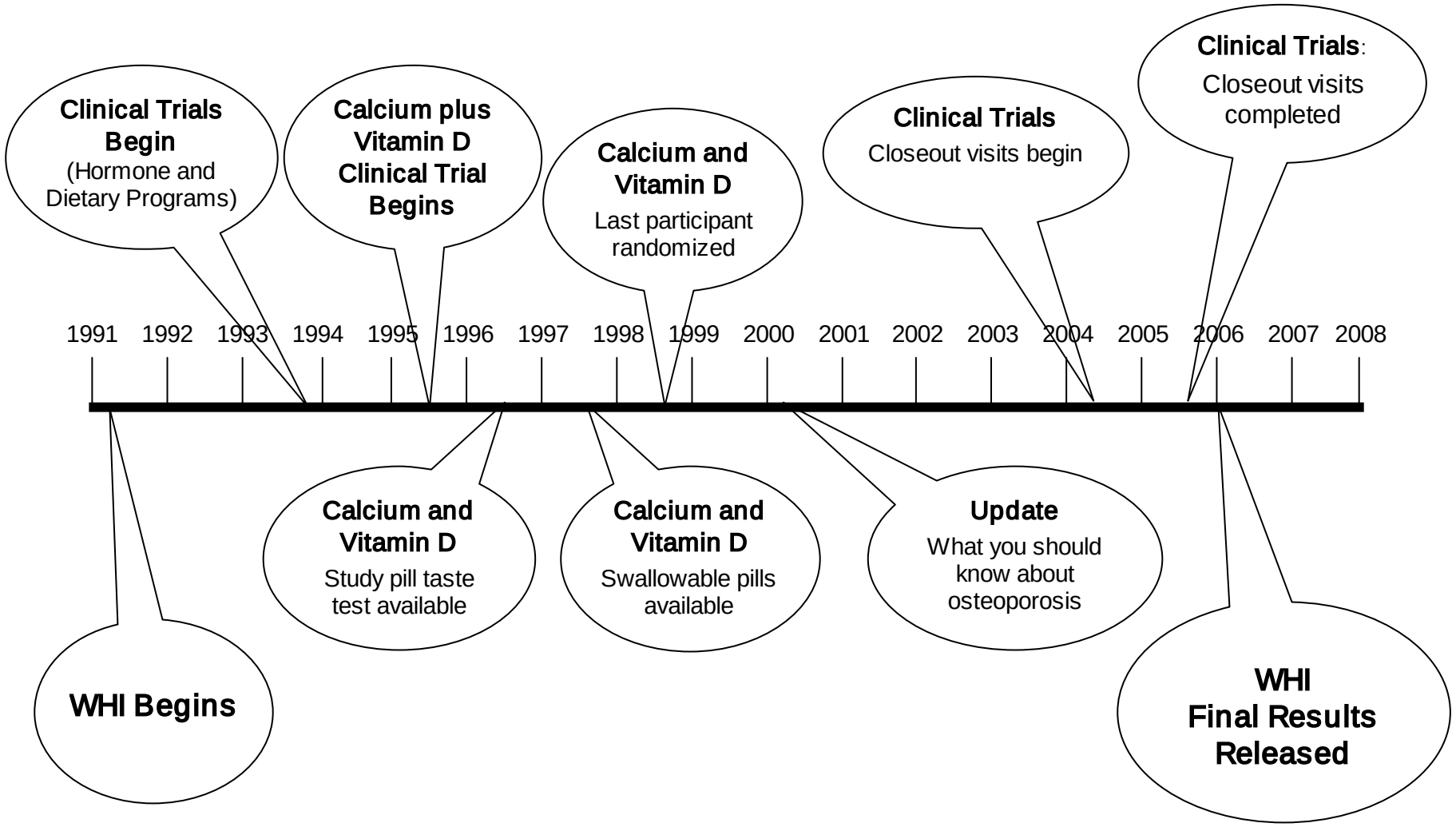
Women's Health Initiative

Personal Milestones for _____

1998 - 2006



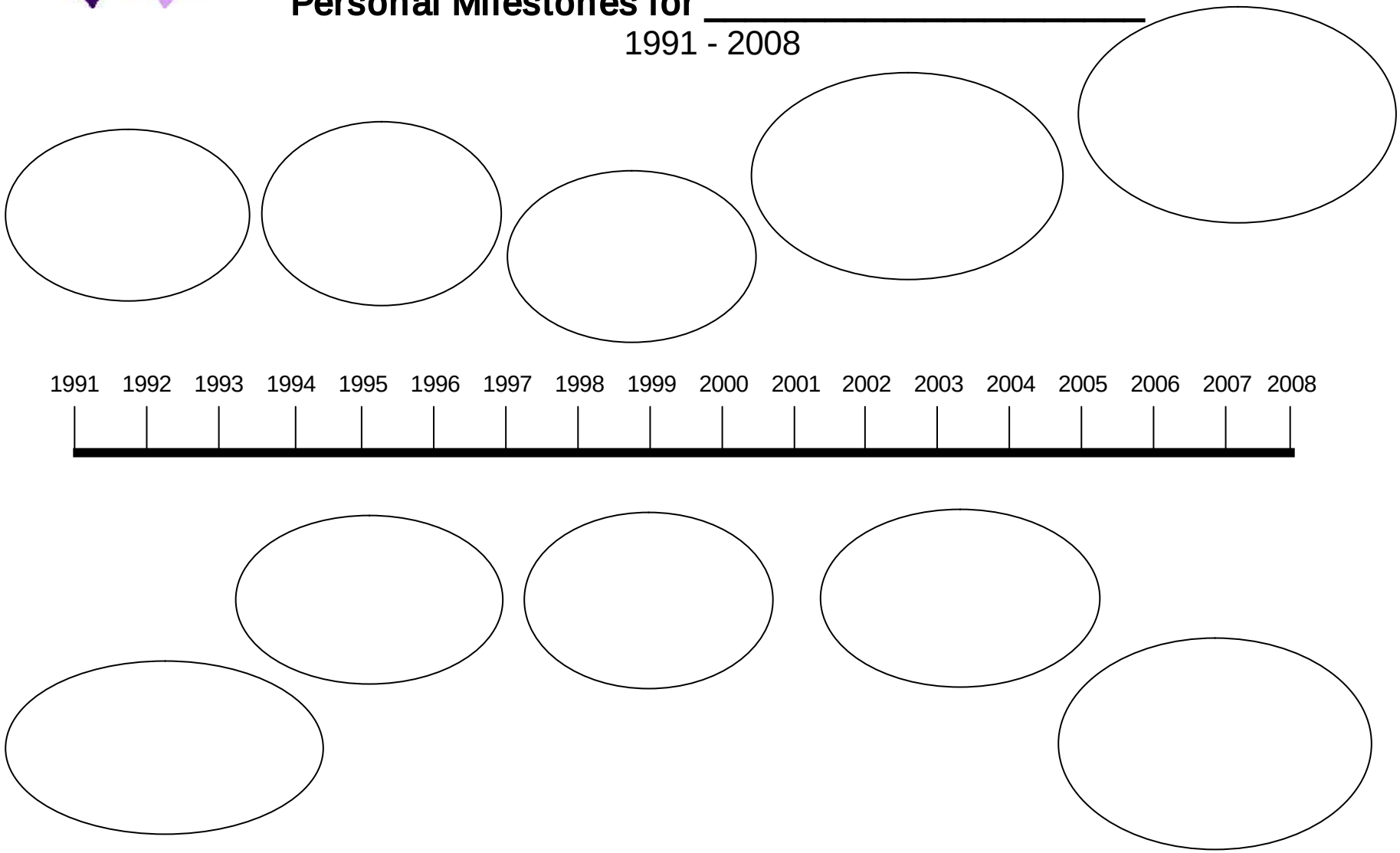
Women's Health Initiative
Calcium and Vitamin D Clinical Trial Timeline
1991 - 2008



Women's Health Initiative

Personal Milestones for _____

1991 - 2008



G.9.2 Dear Dr. Letter and Information Sheet

[Dear Dr. Letter and Information Sheet]

Date

Dear Health Care Provider,

As a health care provider of a Women's Health Initiative (WHI) participant, you may be interested in the accompanying material. It provides information about the progress and ongoing plans for participants in the WHI.

You have a vital perspective on women's health and play the key role in addressing your patient's health care needs. The WHI investigators have greatly appreciated your professional collaboration and support over the years. We hope that you will partner with us in congratulating the WHI participants on what they have accomplished so far. As we continue to follow participants' health and learn more about the risks and benefits of the interventions we're studying, your ongoing care protects them and the investment that they have made in the future health of all women.

Regards,

Principal Investigator
XXXX Clinical Center
Women's Health Initiative

The Women's Health Initiative: Progress and Future Plans

Since July 2002, there has been a watershed of new data from the WHI Estrogen plus Progestin trial that has forever changed our understanding of the balance of health risks and benefits associated with postmenopausal hormone therapy. Putting the WHI findings into perspective has been a challenging but rewarding experience. One lesson we have learned since July 2002 is the tremendous impact that a well designed clinical trial can have on our thinking about women's health. However, the full story of the WHI participants is only beginning to be told.

We all eagerly await the analysis and publication of the Estrogen-Alone trial results, as well as the important contributions that will be made by the Dietary Modification and the Calcium and Vitamin D trials. We invite you to regularly check the WHI and NHLBI web sites (respectively, www.whi.org and www.nhlbi.nih.gov/whi), where we will continue to post the growing WHI bibliography and fact sheets about our study findings as soon as they can be made public.

The Data and Safety Monitoring Board continues to monitor WHI outcomes data every six months and makes recommendations to the National Heart, Lung, and Blood Institute, which oversees the WHI. As before, we will continue to inform our participants of important study findings. We feel a serious obligation to be sure that our participants learn about new findings from us, not from news reports.

In March 2004 WHI will begin its final year. Between October 2004 and March of 2005, each of the WHI participants will have her last visit to a WHI Clinical Center. For the women in the Estrogen-Alone, Dietary, and Calcium and Vitamin D trials this last year of intervention is just as important as the years that came before, perhaps more so because it is our last opportunity to meet with our participants in-person and learn about their health.

After their last WHI visits, when the centers cease active CC operations, WHI participants will look to you for all of their future health examinations, even those they may have obtained as part of WHI. Participants in the Hormone Trials (Estrogen plus Progestin and Estrogen-Alone) received annual pelvic exams (women with a uterus), clinical breast exams, and review of mammograms, as well as Pap smears (women with a cervix) and ECGs every three years. Dietary Trial participants had biannual review of mammograms and ECGs every three years. These examinations were conducted to monitor the effects of our blinded interventions. Continued annual breast examinations and mammography will be particularly important for our Hormone Trial participants. In fact, we will be asking these participants to continue providing WHI with information about their health for another two years beyond the close-out of active CC operations.

WHI investigators are hopeful that we will be able to follow the health outcomes of all of our participants and analyze future data long after the conclusion of this phase of the study. However, in the years after the WHI is completed, any further knowledge that we gain about the health of our former participants will depend on you, their health care providers. We sincerely thank you for your past and present support and eagerly look forward to our future collaborations on behalf of women's health.

G.9.3 Potential Questions and Answers During Pre-Closeout Contacts

Potential Questions and Answers During Pre-Closeout Contacts

(For CC staff; not for participant distribution)

1. **When will the study end? [All Participants]**
   - *The closeout process will begin October 1, 2004 and end March 30, 2005. You will have one last visit at your Clinical Center during this period.*
   - *There are plans to continue to follow the health of women in the Hormone Program for another two years after the closeout of active Clinical Center operations. However, these contacts would only be by mail or phone. We will talk more about these plans at the Closeout Visit.*

2. **Should I continue my study pills during the final study year? [E-Alone and CAD participants]**
   - *ABSOLUTELY! Your participation in this final year is crucial to the study's success as many questions remain unanswered. The scientific acceptance of the WHI results will be strengthened if as many participants as possible continue taking their study pills during the final year.*
   - *After the WHI trial is completed, you and your health care provider will decide whether or not to continue to take (hormone/CaD) pills.* [Staff is encouraged to use their own personal style to convey appreciation and encouragement.]

3. **When will I know what I was taking? [E-Alone and CAD participants]**
   - *At the Closeout Visit you will learn whether the pills you were taking contained active ingredients or were a placebo.*

4. **What if I am not able to receive information about the pills I was taking? Will my contacts or proxy be informed? [E-Alone and CAD participants]**
   - *We will try to complete this visit with you either in the Clinical Center or by phone.*
   - *In the past you designated a health care proxy to provide us with information about your health in order to answer important health-related questions for the WHI. However, information we have about you and your health is strictly confidential. We can not share this information with your health care proxy or contacts without your permission.*
   - [If participants want to know how to give such permission, CC staff can advise them regarding local IRB and HIPAA regulations concerning release of personal information. You should be aware of what these local regulations are and have the resources available to allow participants to sign such a release of information, as developed at each individual institution.]

5. **What will happen at the last visit and how long will it be? [All Participants]**
   - *The Closeout Visit will be similar to a Clinical Center visit but will not include physical measurements or examinations. Participants and staff will be unblinded (told what study pills they were assigned to) at the Closeout Visit and study pills will be stopped and collected.*
   - [In 2001 the Closeout WG estimated time required for the Closeout Visit to be about an hour, depending on Clinical Trial component(s). This estimated time requirement was based on average times for completing established tasks across a sample of five CCs and estimated times for new tasks. There may be additional time required for HT participants to sign Follow-up Study consents, and for all participants to sign consents for analysis of genetic information.]
   - *The following is a list of what you can expect at your final visit:*
     a) Review of forms
     b) Completion of an updated medical release

c) *Personal information update*
d) *Pill collection and safety interview [E-Alone and CaD participants who are still taking study pills]*
e) *Exit interview. This interview includes:*
   - *A thank you for participation*
   - *Unblinding explanation (if you were on pills, the type of pill—either active or placebo)*
   - *A discussion of current guidelines for calcium and vitamin D supplementation, appropriate dietary patterns, and hormone therapy*
   - *Distribution of information regarding how participants will receive updates on results from WHI in the future*
   - *Information about future WHI activities*

6. Where do I go from here for my gynecological exams? [HT Participants]

- *You should contact your health care provider to continue your gynecological care. If you do not have a provider we will assist you in identifying one in your area. As there will not be a GYN exam at the last visit, it is important to make follow-up arrangements now for your care.*
- *We can provide you with information to give your healthcare provider or we can mail it directly, with your permission.* [Provide or mail a copy of the "Dear Dr. Letter", per participant request.]
- [CCs will prepare a resource list of possible providers/clinics in the participants' area and establish links with social services to help uninsured participants seek care.]

7. When will I find out the study results and how? [All Participants]

- *We are still working out the plans for how to keep you updated on WHI study results after the Clinical Centers close their active operations. We will let you know more about these plans at your Closeout Visit.*
- *The WHI is committed to keeping you informed! Therefore, it is MOST IMPORTANT that you keep us informed of any changes in your contact information, including the telephone numbers and addresses of you and your contacts.*
- *Remember, we need your support to enable us to get information about the WHI results to you. The WHI data comes from YOU, thanks to your dedication and commitment, and we are privileged to share the scientific analysis with you!*

8. How will my health care provider learn of the results? [All participants]

- *We encourage you to share the information you will receive at your Closeout Visit with your health care provider.*
- *Your provider will also be encouraged to visit our WHI web site as it is continuously updated with information when it becomes available.*

9. Who can I contact after the CC closes if I have a problem or question? [All Participants]

- *After WHI your personal health care providers will be solely responsible for you care.*
- WHI study related questions that arise after the study may be directed to (local WHI PI).

APPENDIX G

Resource Materials

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