SECTION 17

RETENTION

INTRODUCTION

Retention in the Clinical Trial (CT) and Observational Study (OS) components of the Women's Health Initiative (WHI) is crucial to the success of the WHI. Retention refers to the overall strategies and procedures used to assure a participant's adherence, performance, participation, and contact in the study. Retention of study participants as defined by the study protocol is the dominant focus after the participant is randomized (CT) or enrolled (OS).

This section describes study-wide and local retention activities designed to keep participants interested and active in the study. These activities include enhancing participant identity with WHI, providing incentives for ongoing participation, and having regular, ongoing contact with study participants. Follow-up contacts conducted in a personal and motivating way allow the Clinical Centers (CCs) to continue a professional, caring relationship with the participant throughout the entire study, which will help maintain the participant's retention.

Every effort should be made to encourage full participation until the end of the study. Before a participant decides to discontinue participation in the study, specific retention activities should be conducted to encourage her to continue. Suggestions for dealing with those who are reluctant to continue as full participants in the study ("retention challenges") and strategies to promote adherence to study requirements are included in this section. In addition, procedures for locating hard-to-find or "lost" participants and transfer procedures for participants who move during the study are included.

Occasionally a participant will become unable or unwilling to fully participate in the study, necessitating a change in her participation status. Participation expectations for each component of the study and procedures for changing participation status, if necessary, are described in this section.

Participation status includes both intervention and follow-up status. A participant changes intervention status if she is not willing to participate in the WHI intervention(s) to which she was randomized or she needs to stop intervention for safety or other reasons. If full participation is not possible, it is important to maintain some form of contact with the participant. For example, a woman who insists on "dropping out" of the intervention should be encouraged to still come in for CC visits. For a woman who refuses CC visits, it is important to at least get agreement to contact her by mail and/or phone to follow her medical history. A participant's follow-up status changes if she is not willing or able to participate in full follow-up, if she cannot be located, or if she has died.

17.1 General Activities to Promote Retention

Retention of study participants is the primary focus of activity following enrollment or randomization in the WHI. Retention has several components: adherence (taking study pills), performance (maintaining low-fat dietary consumption), and participation (attending or completing DM Intervention sessions, attending follow-up visits, and accepting phone calls). Strategies and procedures to assure a participant's retention, adherence, performance, participation, and identification with WHI must be used throughout the course of the study, from initial screening to the last follow-up contact. Below is a list of retention enhancement methods; some are implemented on a study-wide basis (e.g., the newsletter), and some are recommended strategies for CC use (e.g., appointment reminders). Each CC should implement its own local retention efforts to complement study-wide activities and designate staff members with specific retention responsibilities.

A table at the end of this section (*Table 17.1 - Summary of Retention Activities*) summarizes retention activities for the various components of WHI and provides a quick reference to other Volume 2 sections dealing with retention and adherence issues.

17.1.1 Clinical Center Facilities and Operations

17.1.1.1 CC Environment

The CC environment should be clean, pleasant, and oriented to the comfort of the participant. A quiet waiting room area, an efficient reception and appointment scheduling area, appropriate reading materials and posters, and a clean, organized interview area are important. Pleasant experiences with the CC staff, visit contents, appointment scheduling, and exiting can all encourage the participant to continue in the study. A feedback mechanism for the participants, for example a suggestion box in the waiting area, may be a good idea.

17.1.1.2 Convenience and Accessibility

Aspects of convenience and accessibility include:

- telephone access
- CC location
- availability of transportation
- convenient clinic hours

Depending on local circumstances, different approaches may be used. Appointments should be available at times and on days that do not interfere with the participant’s working schedule. All CCs should have at least some appointments available on evenings or weekends, outside of usual working hours. Pre-arranged parking should be available if at all possible. Maps, parking information, and public transportation information should be made available to participants.

Convenience and accessibility should be reviewed at each CC twice a year and obstacles eliminated to the greatest possible degree. Parking fee reimbursements or other travel expenses or arrangements may need to be considered by the CC if retention lags due to transportation problems. You may need to come up with creative solutions to help transportation problems. For example, local churches or other volunteer organizations may be able to help through the use of their van or other vehicles and/or by providing volunteers to drive participants to and from visits.

17.1.1.3 Time in Clinical Center

The length of a CC visit, as well as the time waiting for the visit, may be of vital importance in keeping participants returning for visits over a prolonged period of time. Try to keep total CC visit time on all visits to a minimum, but not be so brief at follow-ups that the travel time and effort seem excessive. It is especially important to keep waiting times to a minimum. If an extended waiting period becomes necessary, do what you can to avoid anxiety and hostility in the participant:

- encourage completing or review of study forms
- explain the situation and give the participant some alternatives from which to choose
- offer the option of seeing another staff member, if possible, or rescheduling if necessary
- have the daily newspaper, magazines, or other reading materials available.

17.1.2 Clinical Center Staff

17.1.2.1 Participant-Staff Relationships

A key element in successfully maintaining long-term participation is the development of a personal relationship between the individual participant and individual members of the staff. Good communication is essential to promoting and maintaining retention in the study. Consistency among staff and clarity of instructions are key to good communication. At all times, the participant should be helped to understand the beneficial nature of participation in the study. Encourage her to ask questions at visits, or to call between visits to clarify questions and problems that may arise. Assure participants that they should not hesitate to bring up any issues of concern.

17.1.2.2 Retention Specialist

It is recommended that each CC identify CC staff to serve as retention specialists. This staff member or members will participate in developing local retention strategies, will serve as contacts for Clinical Coordinating Center (CCC) retention activities, and will coordinate management of retention problems at the CC. Retention specialists should identify CC activities to promote retention that can be offered to women in each component of WHI.

17.1.3 Participant Identification with WHI (Required)

All CC staff should focus on promoting participant identity with WHI. Regular communication from the CC will encourage such identity. Building participant identity with WHI should begin during the recruitment process and continue through the end of the study. The following are suggestions for activities to promote identity with WHI.

17.1.3.1 Routine Contacts

<u>During Recruitment</u>

Early identification with WHI may enhance a woman's interest in joining the study. Inclusion of the WHI logo and catch-phrase "Be Part of the Answer" on brochures, posters, and other recruitment materials help promote identity with WHI. In addition, identify barriers to attending screening visits and develop procedures and materials to help overcome barriers. For example, send women maps showing the location of the CC clinic and transportation/parking information. Elevators and rooms should be clearly signposted with welcoming messages and the WHI logo. Distribute CC contact information: from the first contact, it is important to let women know that they are always welcome to call the clinic with questions or concerns.

Other activities or materials may be used to promote identity during recruitment, such as reports or letters from a significant person outside the study (e.g., community spokesperson, congressperson, governor) pointing out the importance of WHI and the valuable contribution being made by each participant. Thank you cards sent to potential enrollees following their initial screening visit may also encourage further participation in the screening process. These cards should stress the importance of the study and your appreciation to the participant for her interest.

<u>During Enrollment</u>

During enrollment/randomization into WHI, the participant receives a baseline welcome packet (see *Section 4.4.11 - Baseline Welcome Packet*) and other materials designed to promote identity with the study, including:

- WHI logo kit folder (required for CT and OS) - ordered through the CCC using *Form 172 - Supplies Order*
- WHI magnet with the CC name and telephone number (required for CT and OS) - provided annually by the CCC during the recruitment phase
- Membership Identification Card (required for CT and OS) - ordered through the CCC using *Form 172 - Supplies Order* (see *Section 17.1.3.3 - Membership Identification Cards*)
- "Welcome to the [study component]" handouts (required for CT and OS) - ordered through the CCC using *Form 172 - Supplies Order*
- WHI Calcium Handout (recommended for OS, required for CT, except for DM Intervention women who receive a modified low-fat version during their DM sessions) - ordered through the CCC using *Form 172 - Supplies Order*
- Component-specific Chart Stickers (recommended for CT and OS) - ordered through the CCC using *Form 172 - Supplies Order*
- Exercise Brochure (required for CT) - ordered through the CCC using *Form 172 - Supplies Order*
- Other NIH approved health brochures (recommended for CT and OS, CC discretion) - see *Section 2.3.2.6 - Other Equipment and Supplies* and *Section 17.1.3.6 - Health Information and Education*
- Contact schedule or appointment reminders (recommended for CT)
- Component-specific information, such as USDA Dietary Guidelines (DM Comparison group participants only) and Hormone Replacement Therapy (HRT) Handbook (required for HRT participants) (see *Section 4.4.13 - Participant Hand-Outs*)

<u>During Follow-up</u>

During follow-up, maintaining identification with the study is particularly important for retention. Identification is promoted by regular contact with the CC and by distributing materials that keep the participant connected to the study. The goal is to have some type of contact with every participant at least every six months, whether by mail, telephone, or in person. These contacts help promote retention in study activities. Identification after enrollment is achieved through several activities:

- Annual follow-up visits and contacts with the CC (See *Section 16 - Follow-up Contacts*)
- Incentives (see *Section 17.1.6 - Retention Incentives (Required)*)
- Participant Newsletter (CT and OS) - see *Section 17.1.5 - Participant Newsletter (Required)*
- DM Newsletter (DM dietary change participants only) - see *Section 6.12.2 - Newsletter*
- Birthday, thank you, anniversary, bereavement, and holiday cards - CCs are encouraged to maintain contact with participants by sending greeting cards to mark special occasions in the participant's life. Birthday (a new card is designed annually), thank you, and multi-purpose, generic cards can be ordered through the CCC using *Form 172 - Supplies Order*. (Run the *Happy Birthday Report (WHIP 0788)* for a list of participants with a birthday during any specified month.) Purchasing/designing and distributing other types of greeting cards (anniversary, bereavement, or holiday) is at CC discretion.

17.1.3.2 Involvement of Family Members

Encourage the support and involvement of participants' family members throughout WHI using the following strategies:

- Invite husbands, partners, or significant others to attend the CC visits, especially the initial visits, as well as special events held during the course of the study. Both retention and adherence are more likely if family members are involved in the process.
- Encourage family members to learn about the study's purpose and general design, and inform them of the ongoing safety monitoring of participants.
- Encourage family members to notify the CC if the participant becomes ill or happens to be out of town when contact is to be made or a visit scheduled.

17.1.3.3 Membership Identification Cards

Participant membership identification cards are distributed to participants at the time of enrollment (OS) or randomization (CT). The purpose of these cards is to provide a quick identification of the participant's name and study ID, give the participant easy access to her CC's telephone number, enhance identification and bonding with WHI, and provide the participant with a card to show her health care provider, if appropriate.

These wallet-sized cards are printed with the WHI logo and CC name and phone number on one side. A label including the participant's name, participant ID, and ID barcode is placed on the backside of the card at time of enrollment. At the same time, mark the participant's study component(s) with a permanent ink marker. The label may need to be replaced periodically throughout the study, depending on wear. Membership cards are ordered through the CCC using *Form 172 - Supplies Order*.

17.1.3.4 Participant Representative

Clinical Centers are encouraged to establish a participant representative to meet periodically with the CC staff. Representatives can provide CC staff with the participant's perspective on the WHI experience. She may be able to help address barriers to retention by making suggestions, for example, about enhancing the waiting room environment, helping to deliver educational and informational materials, organizing alternative or cooperative transportation, and providing feedback from other participants.

17.1.3.5 CC Group Events and Activities

Clinical Centers are encouraged to plan events and activities to promote retention. The frequency of retention events and activities is at the discretion of the Clinical Centers. Clinical Centers are encouraged to consider their own CC's retention data and resources when considering the frequency of events and activities.

Open house events where all WHI participants are invited to attend are permitted, if study component information is not made apparent. During studywide events, care should be taken to avoid contamination between DM Dietary Change and Comparison groups. Topics for discussion at events and social activities should focus on information not related specifically to one study component or another and should not include discussion of topics relating to WHI interventions (e.g., nutrition) or outcomes. For example, it is okay to present health information such as tips for quitting smoking, but is not okay to present information on ways to prevent heart disease. Discussion of study progress (e.g., number of randomizations to date) is appropriate. Non-health related activities, for example, fashion shows or WHI birthday parties are allowed. During events, express appreciation for participating in the WHI and reinforce the importance of every participant's continued involvement to the success of the study.

Foods served at CC-wide events should include moderate- or high-fat choices as well as low-fat choices, similar to the acceptable cultural foods of your region. Although low-fat choices should not be stressed, avoid serving "junk" food or foods that send an unhealthy message; given that this a study on women's health, we

don't want to promote the use of unhealthy foods. Fat content of foods should not be labeled and recipes should not be provided. If a separate meeting is held for Dietary Change participants, then it would be appropriate to serve only low-fat foods and to provide recipes. For DM participants, CCs should focus adherence and retention efforts on Dietary Change group participants rather than on DM Comparison group participants.

The following is an example of a studywide event: A "WHI birthday party" to celebrate the WHI is held. All participants (CT and OS) are invited, and they may bring a spouse or guest. Participants are asked in advance not to identify themselves by group assignment. A large hall is rented as the site for the reception, and a variety of low-fat and "regular-fat" foods are available. In addition, a large number of door prizes, donated by local merchants, are distributed. After a brief overview of WHI recruitment progress, an invited speaker presents a brief talk of interest to participants.

17.1.3.6 Health Information and Education

Both CCC and CC staff will address participant health information and concerns in standardized formats. Some suggestions for distribution of health information are the following:

- Create a distribution center or display for free health-related (not diet-related) materials in the waiting area or other convenient, accessible location. Free publications approved by the National Institute of Health (NIH) for WHI distribution (see *Section 2.3.2.6 - Other Equipment and Supplies*) can be ordered from the NIH by calling 1-800-4-CANCER. Publications not on this list need NIH approval before being distributed to participants. Health materials developed by the CC must be approved by the CCC, following the standard procedures for CC materials review, before distribution at the CC. The display might include copies of the informed consent forms for participants to read again, if interested, or health educational videos for viewing on site or at home.
- Compile a list of all local services and programs for health promotion (e.g., smoking cessation) and for special support groups (e.g., bereavement, cancer). Copy and display this list at the distribution center. Make these referral sheets available for participants at each local site.
- Invite participants to health promotion events that do not interfere with WHI interventions, such as sessions on smoking cessation or administering CPR.

17.1.4 Tracking (Required)

17.1.4.1 Tracking System for Study Visits

The Post-Randomization Visit Reminder (*WHIP 0787*) is a WHILMA report generated by CCs that lists, by target date, all women who are due for a given post-randomization follow-up visit during a specified time period. This report should be used with your CC's system to track and set up participant follow-up contacts.

17.1.4.2 CC Visit Appointment Reminders

During the screening and randomization phases, when the CC process is still relatively new to participants, CC staff may contact participants by telephone to remind them of upcoming CC appointments, check to see if they have questions or concerns, and make sure they are properly prepared (e.g., fasting, wearing light clothes).

During follow-up visits, use appointment reminders to prompt participants to come for CC visits and to bring their current medications, study pill bottles, forms, and food records with them. These reminders can be postcards, telephone calls, or letters. To save time, you may want to send a postcard or letter to the participant well before the visit time window, reminding her that she is due for a visit and asking her to call the clinic for an appointment.

During all contacts, use procedures to aid participants in overcoming any reluctance to attend follow-up visits, such as a discussion of transportation reimbursement or daycare facilities, if available. Remind participants at

each follow-up visit that they have ready access to study personnel. Specify the days and hours for your CC, as well as after-hour contacts. Encourage participants to call with questions, concerns, or symptoms.

17.1.4.3 Thank You Cards Following CC Visits

You may want to send a thank you card or postcard following attendance at clinic visits, either screening and/or follow-up visits. Stress the importance of these visits and your appreciation to the participant for taking the time to come into the clinic. Thank you cards can be ordered through the CCC using *Form 172 – Supplies Order*.

17.1.4.4 Maintaining Up-to-Date Personal Information on Participants

It is important to maintain contact with participants for the full duration of the study to ensure that study results are valid and, at the very least, to ensure that vital status (dead or alive) is known on each participant at the end of the study. The task of maintaining contact with participants will be facilitated by maintaining up-to-date personal information in each participant's file. Although participants are not required to answer every question on *Form 20 - Personal Information*, encourage them at a minimum to complete questions on full name including middle initial; address; phone number; the names, addresses and phone numbers of two personal contacts; Social Security Number; and name of health care provider. It is generally preferable to have personal contacts who are younger than the participant, in good general health, and who are not likely to move during the course of the study.

It is important to confirm during follow-up contacts that information on the participant's name, address, phone number, personal contact information, and health care provider is still current. This information should be reviewed at least once a year with the participant, even if she does not visit the clinic. If any of this information has changed, the participant should update *Form 20 - Personal Information*, and the participant's personal information should be updated on the member screen in WHILMA. This will minimize the possibility of participants becoming "lost" at any subsequent stage of the study. Participants should be asked to provide the name of a new personal contact if either of the personal contacts named at the start of the study is no longer suitable to act as a contact person.

17.1.4.5 Maintaining Complete and Deliverable Participant Addresses

When a participant's address is found to be no longer valid, the undeliverable address should be flagged on the participant's member screen and activities should be initiated to establish the participant's new address (see *Section 17.2 - Locating "Hard to Find" Participants*). Each month, CCs should run two reports to help maintain up-to-date and deliverable addresses in WHILMA (see *Vol. 5- Data System, Section 9.2 - Reports* and *Appendix D - WHILMA Reports* for information on running these reports):

- *WHIP 0611 - Members With an Incomplete Address or Long Name/Address*. This report provides a list of all (CT and OS) participants with a problem address (e.g., the address is incomplete or will not fit on a mailing label). Participants with address lines that are too long should be fixed immediately by using address line 2 for the second line of the address, or abbreviating words in the first line so that it stays within the 30 character width limit of the mailing labels. Those that are incomplete should be investigated as soon as possible. If the zip code is missing, try calling the post office or, if that fails, call the participant to obtain the correct address. If you cannot fix the address right away, set the undeliverable address flag on the "Contact Information Screen" in WHILMA. This will prevent mailings, such as OS follow-up mailings or the participant newsletter, from being sent to an undeliverable address. Try to fix incomplete addresses within two weeks of their appearance on the report. Participants will continue to appear on this report until either the address has been fixed or the "undeliverable address" flag has been set.

- *WHIP 1211 - Undeliverable Address Report*. This report provides a list of all (CT and OS) participants with undeliverable addresses (indicated by the undeliverable address flag) in the CC's database. The report does not include those with participation status of "no follow-up", "deceased", or "lost to follow-up". Items that may appear on the report are the participant's name and (undeliverable) address; participant ID; home

phone; work phone; a note indicating that the workplace should not be contacted, if applicable; best time to call; phone of other contact; follow-up status; and date the undeliverable address flag was turned on.

For participants appearing on this report, attempt to correct the address by contacting the participant at home and, if necessary, at work. If these attempts fail, telephone her personal contacts using information listed on the report. If preliminary attempts to contact the participant fail, initiate a formal search to locate the participant (see *Section 17.3.1 - Initiating a Search to Locate Participant (Form 23) (Required)*.

Undeliverable addresses should be updated as soon as possible, since a participant will not receive any mailings until the address is fixed. The sooner you try to get an address correction, the more likely you will be successful in tracking down the participant. Undeliverable addresses should be corrected within one month of appearing on the report. Participants will continue to appear on this report until the "undeliverable address" flag has been removed or follow-up status changes.

17.1.5 Participant Newsletter (Required)

All CT participants receive a trial-wide WHI newsletter (*WHI Matters*) twice a year during the fifth and tenth months after the anniversary of their enrollment month; OS participants receive the newsletter once a year during the fifth month after their enrollment anniversary month. The goal of the participant newsletter is to present news about WHI in an interesting and readable fashion, to encourage retention of study participants, and to promote participant identification with WHI as an important, national research effort. The newsletter is also useful in keeping up-to-date addresses for participants. All participants, unless otherwise requested, receive the newsletters at their home addresses. Clinical Centers are responsible for documenting on *Form 7 - Participation Status* those participants who request to be deleted from the newsletter mailing list.

A newsletter written specifically for DM dietary change participants is also distributed three to four times per year. For information about this newsletter, see *Section 6.12.2 - Newsletter*.

17.1.5.1 Production and Distribution

The CCC is responsible for the production and distribution of the annual newsletters, including content, design, layout, graphics, production costs, and coordination of printing through the Government Printing Office. Staff members at the CCC or any of the CCs are welcome to contribute ideas or articles for consideration. The CCC is responsible for keeping CCs informed of deadlines relating to submission of these articles.

The CCC is responsible for the mailing of the annual newsletters to CT and OS participants. Clinical Center-specific return addresses are printed on the newsletters mailed to that CC's participants.

17.1.5.2 Content

Newsletters include both project-specific and general, health-related information. Each newsletter includes the following general content areas:

- A column from the WHI Director at the NIH describing the progress and importance of the WHI.
- A section with articles on relevant health topics (not diet related).
- A section describing overall progress on study activities.
- A section with features and interviews of WHI participants.
- A section featuring segments submitted by and about the CCs (optional).

The following guidelines are to be followed for all newsletter submissions:

- Articles should be written at a 6th grade reading level; a slightly higher level may be acceptable for more complex articles, such as science or health articles.

- Original sources for articles, such as articles reporting the results of scientific research, will be carefully consulted for technical accuracy and kept on file at the CCC.
- When quoting an individual, the interviewer must ask the individual for permission to quote him or her. Quotes must be used verbatim, with quotation marks. Quotation marks are not used unless a direct quote is cited.
- If quotations are used from sources such as magazines, journal articles, or books, permission must be obtained from the publisher. This information is cited at the end of the article (for example: used with permission, name of source, date). When contacting a source to obtain permission, be sure to identify yourself as a non-profit research organization; permission will usually be granted without a fee. When reprinting cartoons, permission must be obtained from the syndicate that represents the cartoonist.

The newsletter staff and Project Directors at the CCC make initial discretionary decisions regarding newsletter content, appropriateness of articles, readability level, layout, and emphasis in coverage. Before final approval by the Project Office and Steering Committee, a draft of the newsletter is sent to the following committees for input and approval: Behavioral, CC Staff Group, Observational Study, and Special Populations.

17.1.5.3 Updating Addresses for Undeliverable Newsletters

One purpose of the participant newsletter is to help CCs make sure that they have up-to-date address information for each participant. A mailing label for each participant's newsletter is generated at the CCC based on the address listed on the Personal Information Screen in WHILMA. When the address on the mailing label is incorrect and the newsletter is not deliverable, the local Post Office will notify the CC. This notification is in the form of a photocopy of the mailing portion of the newsletter, along with address correction information (because newsletters are mailed bulk rate, undeliverable newsletters are neither returned nor forwarded to the new address). The CC is charged for each notification of an undeliverable address ($.50 per address as of 10/95). Update the contact information screen in WHILMA immediately when an address correction notification is received to ensure that future mailings are sent to the correct address and to avoid additional postal charges.

When a CC is notified of an updated address, the CC should try to contact the participant by telephone to make sure that her telephone number is still current. If this contact is made as soon as the CC is notified of the change of address, there may still be a recorded message with the new number, if it has changed. If a new telephone number is obtained, update the Personal Information Screen in WHILMA.

If a participant has a changed address, the Post Office does not forward the newsletter. The CCC will send an extra supply of newsletters annually to each CC. When you are notified of a new address, you may want to put one of the extra newsletters in an envelope and mail it to the participant at her new address; otherwise, she will not get a newsletter that year. Another option is to notify the CCC of the change, and a new newsletter will be sent to the participant from there. Note: you may not mail the newsletters using the "Bulk Rate" permit printed on the newsletters. This is for CCC use only and misuse by CCs can result in the cancellation of the CCC's mailing permit.

If address correction information is not available (i.e., "forwarding address unknown"), set the undeliverable address flag on the "Contact Information Screen" in WHILMA and initiate procedures to locate the participant. Try to contact the participant and, if necessary, telephone her personal contacts using information listed on *Form 20 - Personal Information* to get an updated address. If preliminary attempts to contact her fail, initiate a formal search to locate the participant [see *Section 17.3.1 - Initiating a Search to Locate Participant (Form 23) (Required)]*. Participants with an undeliverable address will appear on the *Undeliverable Address Report (WHIP 1200)* the next time it is produced (see *Section 17.1.4.5 - Maintaining Complete and Deliverable Participant Addresses*).

If the Post Office indicates that the participant is deceased, initiate contact with persons listed on *Form 20 - Personal Information*. If a death is confirmed, update *Form 7 - Participation Status*, complete *Form 120 - Initial Notification of Death*, and process according to procedures outlined in *Volume 8 - Outcomes*.

17.1.6 Retention Incentives (Required)

All participants coming in for annual visits receive a retention incentive provided by the CCC. In addition, Clinical Centers may provide their own incentives, within budgetary constraints, in the form of small gifts (e.g., pencil, lapel pin, t-shirt) or health information (non diet-related). Incentives will generally include the WHI logo to promote identification with the project.

17.1.6.1 Annual Incentives Provided by CCC

The CCC produces and delivers to the CCs one retention incentive (e.g., magnet, mug, bookmark, pocket planner) per year for each CT participant and guidelines for distribution at the annual visit. The CCC also provides a retention incentive for OS participant attending their Year 3 annual visit. Selection of annual incentives is subject to approval by the Behavioral, CC Staff Group, and Special Populations Committees.

17.1.6.2 CC Incentives

Each CC may use its own incentives for increasing participant retention. Examples of incentives are small gifts (e.g., t-shirts, bags, certificates of appreciation), educational materials (e.g., non diet-related health brochures), coupons (e.g., free coffee or soft drink from local cafe), or raffle tickets for small prizes (e.g., every participant who comes in for a follow-up visit is entered in a monthly drawing for a small prize). Clinical Centers may purchase incentives, if their budget allows, or obtain donated incentives from outside sources. If incentives are donated from outside sources, it is important that the WHI not appear to endorse a particular company or product. Therefore, a donated incentive cannot include both the WHI logo and the sponsors name or logo, unless a disclaimer of endorsement of the sponsor appears on the incentive.

17.1.6.3 Distributing Incentives

All participants should receive an annual retention incentive when they come in for their annual visit. It is probably easiest to hand out the incentive at the same time during each visit; use whatever timing works best for you. If a participant does not attend her annual visit, try to mail that year's incentive to her.

Research shows that incentives can help improve retention when their distribution is accompanied by a positive message. Please take the idea of an incentive seriously. When the incentive is distributed, be sure to stress that this is a token of our appreciation for her time and effort. For example, you may want to say something like:

"Thank you so much for your ongoing participation in WHI. As a token of our appreciation for your efforts, would you please accept this [incentive]? We know it is a small measure of the time and effort that you have put into the study so far, but we want you to know how important you are to us. Because of your contribution and the contributions of other women like you, we will be able to answer important questions about women's health. Remember, you are part of the answer! Thanks again, and we hope you enjoy the [incentive]!"

17.1.7 Media Relations and Handling Adverse Publicity

All sites would be well advised to pre-plan, as much as possible, their organizational response to media inquiries should a controversial announcement or event occur. Identifying spokespersons, establishing response protocols in advance, and communicating this information to all staff can help to minimize disruption. It may prove helpful to set up protocols and divide responsibilities for handling inquiries from the press, participants, and other key audiences should the need arise. In some cases, especially when a national or study-wide response is needed, the NIH Project Office is likely to supply talking points and a referral list of national WHI spokespersons to the CCs.

In all situations, crisis or otherwise, credibility is the key to successful media relations. With reporters, always be honest, brief, direct, and calm. Never say "no comment" and never "go off the record". Do not avoid or ignore a reporter's call. Honor deadlines. Be factual, accurate, and timely in your responses. Do not be

argumentative or defensive. Cultivate positive and professional relationships with reporters and follow through appropriately. If facts or remarks end up not being accurately represented, contact the reporter immediately and politely request that the correct information be supplied to their audience. This may not always result in a retraction or a correction, but it will put the reporter on notice that you are vigilant, focused on accuracy, and willing to work with them to produce better quality stories for their audiences.

Whenever you are representing WHI on a national level, make sure that your comments apply to the study as a whole, and not to just your own CC. Information that is not accurate for the study nation-wide can generate a lot of work for other centers who may then have to spend time responding to participant inquiries and clearing up misconceptions resulting from the interview or story.

17.2 Clinical Center Activities for Retention Challenges (Required)

Clinical Centers are required to initiate special retention activities for those participants identified as "retention challenges". A participant is considered to be a "retention challenge" if she wants to change her participation status in the study, i.e., if she is no longer willing to fully participate in the intervention to which she was randomized or she is not willing to fully participate in follow-up activities.

There are two types of participation status:

1) Intervention status, the degree to which a CT participant is willing to participate in the WHI intervention(s) to which she was randomized. CT participants having problems with adherence to the intervention (e.g., an HRT participant who is unwilling to take her study pills) are considered intervention retention challenges and require special retention activities.

2) Follow-up status, the degree to which a CT or OS participant is willing to participate in follow-up activities. CT and OS participants who refuse follow-up visits and/or contacts are considered to be retention challenges, as are those who consistently miss visits without actually refusing to participate. Both types of follow-up retention challenges require special retention activities.

Before removing a participant from full intervention and/or full follow-up activities, CC staff should conduct special retention activities to try to reverse the participant's decision to reduce participation and maintain retention in all relevant aspects of the study (unless safety is an issue).

Those participants who decide to reduce their participation level can usually change one aspect of their participation and continue to maintain activity in the other aspects of WHI, i.e., even when a participant has dropped out of the intervention, the CC should still maintain her follow-up participation, unless otherwise requested.

Refer to *Table 17.2 – Summary of Clinical Center Activities for Retention Challenges* for an overview of procedures for retention challenges by study component.

Refer to *Section 17.4 - Changes in Participant Status* and *Form 7 – Participation Status*) for information about changing participation status.

17.2.1 Identifying Retention Challenges and Tracking Special Activities

Most participants will perform their WHI activities as planned with no retention difficulties. Some participants, however, will want to reduce or eliminate their intervention or follow-up participation status due to a variety of reasons. These retention challenges need more attention and motivation from CC staff.

Use the general model described below to try to identify participants who are retention challenges before they are lost to follow-up or decide to drop out of the study. Detailed information on conducting special activities specific to study component is located in the following sections: for HRT/CaD intervention challenges, refer to *Section 17.2.2.2 – Initiating Special Activities for HRT and CaD Retention Challenges*; for DM intervention challenges, refer to *Section 17.2.3.2 – Initiating Special Activities for DM Retention Challenges*; for CT and OS follow-up challenges, refer to *Section 17.2.4.2 – Initiating Special Activities for Follow-up Retention Challenges.*

- **Conduct Standard Procedures.** Ensure that all standard procedures as listed in *Sections 5 (HRT), 6 (DM), 7 (CaD), 8 (OS), 15 (Medications), 16 (Follow-up Contacts)*, as well as this section, have been attempted to maintain the participant's full participation in WHI.
- **Identify Retention Challenges.** Develop a system for identifying retention challenges (e.g., regularly review WHILMA reports on adherence, note women who miss annual appointments) and initiate special activities as soon as possible. Specific ways to identify intervention retention challenges for each part of the CT are listed in *Section 17.2.2.1 – Identifying HRT and CaD Intervention Retention Challenges* and

Section 17.2.3.1 – Identifying DM Intervention Retention Challenges. Identify follow-up retention challenges is described in *Section 17.2.4.1 – Identifying Follow-up Retention Challenges.*

- **Conduct Special Retention Activities.** Attempt special retention activities as appropriate to promote retention. The CC should develop its own list of possible special retention activities that fit within the CC budget, preferences, and judgments. Try different activities for each participant, depending on previous experience with the participant and with her particular problems. Involve the appropriate intervention staff in making decisions about choice of activities. In addition to the special activities described below, refer to *Table 17.3 – Reasons for Poor Retention and/or Adherence* to help better understand some of the reasons participants may have with adhering and staying in the study, and *Tables 17.4 - Strategies to Retain Full Participation in CT and OS, 17.5 - Strategies for Adherence to CT Intervention,* and *17.6 – Examples of Retention Strategies.*

  It is at the CC's discretion to decide whether or not to complete retention activities in specific situations or for certain women. For example, when a participant reports that her doctor has told her to go off WHI HRT study pills so that she may go on (active) HRT, some CCs may conduct retention activities (attempt to discuss the importance of the WHI trial and alternative treatments with the woman and/or her physician), while other CCs may decide to not interfere in the doctor-patient relationship. Similarly, when a woman says she is too ill to continue on intervention, CCs should decide whether or not to conduct retention activities, depending on the type and severity of her illness and other factors.

  Participants who say they want to become inactive often change their minds after a "cooling off" period, so waiting for a few weeks or more may be appropriate. If a participant indicates that she wants no further contact with WHI, retention activities should be put on hold for a few months. After this period, CC staff may attempt to dissuade her from inactivation. Each CC should develop a system for tracking participants during this period.

- **Conduct Retention Meetings Regularly.** Staff with retention responsibilities should hold regular meetings to discuss general and participant-specific retention issues. These staff include but are not limited to the Clinic Manager, Lead or Group Nutritionist, Clinic Practitioners, the Principal Investigator or designee, Behavioral Scientist, and any other staff identified as retention specialists. Each CC should identify the key retention staff and schedule regular meetings to meet the needs of the clinic flow. Use these meetings to discuss general ideas for improving CC-wide retention, adherence, participation, and other interactions with participants. Discuss specific participants who pose retention challenges at these meetings and decide upon a course of action with the appropriate staff present. Before changing the status of any participant (see *Section 17.4 - Changes in Participant Status*), obtain agreement at a meeting that all strategies have been exhausted and that changing status is the only option open at this point.

- **Document and Track Special Activities.** When a contact has been made to conduct special retention activities with a participant who has a retention (or adherence) problem, complete and data enter a *Form 24 – Adherence and Retention Worksheet* to help document and track activities (refer to *Vol. 3 – Forms, Instructions for Form 24 – Adherence and Retention Worksheet* and *Vol. 5, Appendix B.3.4 – Adherence and Retention Worksheet)*. This optional worksheet can be helpful by keeping track of which participants have received contacts, recording the result of the contacts, and identifying participants needing further retention assistance. If additional retention contacts are needed following the initial contact, complete the "date for next contact" portion of *Form 24*. The names of participants needing additional contact, as indicated on *Form 24*, will then appear on the *Member Adherence and Retention Activity Tracking Report (WHIP 1238)* to help CCs keep track of the need for and timing of additional contacts.

  A new *Form 24* should be completed for each special retention activity. Note that *Form 24* is for special activities that occur between participants with retention problems and the CC primary contact for that activity (e.g., Lead or Group Nutritionist for DM Intervention, Clinic Practitioner for HRT and CaD, Interviewer for missed follow-up visits, etc.); *Form 24* does **not** need to be completed for routine retention activities (e.g., newsletters, appointment reminders).

  Although use of *Form 24* is optional, its use is strongly encouraged as a way to help track activities, especially by CCs who do not have other retention activity procedures and tracking systems in

place. Note that there is not a "right" or "wrong" way to use *Form 24*. CCs should use the form in whatever way it is most useful in helping them track retention activities.

- **End Special Activities.** If special retention/adherence activities have not been successful and the participant insists on "no" or "less than full" participation in follow-up or "no" participation in intervention, refer to *Section 17.4 - Changes in Participation Status.*
- **Re-Contact Non-Participants Occasionally.** Contact participants with less than full participation status at least once a year throughout the study to see if they are willing to resume some or all aspects of their participation (see *Section 17.4.5 - Reactivation of Participants with Changes in Participation Status*).

17.2.2 Special Activities for HRT/CaD Intervention Retention Challenges

This section describes special activities designed for retention challenges enrolled in the HRT or CaD intervention study component. It includes information on identifying HRT and CaD Intervention retention challenges, initiating special activities for retention challenges, tracking and documenting special activities, and ending special activities.

17.2.2.1 Identifying HRT and CaD Intervention Retention Challenges

Intervention retention challenges in HRT and CaD are defined as having either low adherence (less than 80% of study pills) or non-adherence to the intervention's pill taking regimen. Participants identified as retention challenges require special retention activities to improve adherence (refer to *Section 17.2.2.2.1 – Intensive Adherence Program (IAP)* for specific procedures).

Clinical Center staff may identify HRT or CaD intervention retention challenges at a clinic visit, telephone contact, mail contact, or through discussion with other CC staff. Retention challenges in HRT and CaD can be identified in at least four ways:

- Participants with a calculated adherence rate of less than 80% at a clinic visit, based on pill weights or pill count estimates. However, if a participant has poor adherence but a concrete, reasonable reason for such poor adherence rate (e.g., loss of the pill bottle, inability to return to the CC to obtain more pills in time, illness), she may not require special retention activities.
- Participants with responses to the adherence questions on *Form 10 - HRT Management and Safety* or *Form 17 - CaD Management and Safety* that indicate adherence problems. Both *Form 10* and *Form 17* contain an item to check if the participant should be referred to the IAP based on the interview.
- Participants who CC staff determine need more assistance with adherence regardless of the adherence rate calculated. Examples of participants who may need special retention activities even though they meet the guidelines for good (>80%) adherence are:
  - Participants who the CC interviewer feels could benefit from a more systematic approach to adherence discussion. This could occur if the interviewer has limited discussion skills or minimal experience with adherence problems, or sees a situation with multiple or diverse adherence problems.
  - Participants who express concern about study pill symptoms or impact on health problems.
  - Participants who anticipate or are going through major changes in their routines, such as illness or death of a family member, extended trip away, etc.

While a participant is not removed from active HRT or CaD intervention status for low adherence, achieving an adherence of rate of at least 80% is desired if the goals of the study are to be met.

Refer to the *HRT/CaD Medication Adherence (WHIP 1260)* report to identify which HRT/CaD women need special retention activities to improve their adherence. Also refer to *17.2.2.1.3 - Documenting and Tracking Special Activities for HRT/CaD Retention Challenges* for a list of other reports and forms that may be useful in identifying which HRT/CaD participants need special activities.

17.2.2.2 Initiating Special Activities for HRT and CaD Retention Challenges (IAP)

When a participant has been identified as an HRT or CaD retention challenge, initiate the special retention activities outlined in *Section 17.2.2.2.1 – Intervention Adherence Program (IAP)*. To help keep track of special activities, complete *Form 24 – Adherence and Retention Worksheet*.

Section 7.2.2.2 - Dealing with Non-Adherence, and *Tables 17.3 – Reasons for Poor Retention and/or Adherence, 17.4 - Strategies to Retain Full Participation in CT and OS, 17.5 - Strategies for Adherence to CT Intervention,* and *17.6 - Examples of Retention Strategies* provide interviewers and CPs with additional items for discussion and ideas for improving adherence and retention of HRT/CaD participants. These are methods of identifying participants who have poor adherence before they become non-adheres.

17.2.2.2.1 Intensive Adherence Program (IAP)

Adherence to study pills is an important part of the WHI study design and critical for testing the study hypothesis. The Intensive Adherence Program (IAP) is a series of special non-data-collected participant contacts aimed at improving poor adherence and dealing with pill adherence problems. IAP contacts are made with participants who report low adherence or because of CC staff referral for adherence problems. The number, frequency, and content of the contacts vary according to participant need and CC staff discretion.

IAP Staff

The CC staff person(s) initiating and coordinating the IAP (IAP Coordinator) must have experience and skills in communication, adherence monitoring, and study pill dispensation. Some C.c.s will have more than one IAP Coordinator and will assign a specific coordinator to a specific participant based on CC developed criteria. This coordinator may be a CP or directly monitored by the CP. This person should also be one of the primary contacts for the participant at the CC to increase rapport and promote consistency and continuity in participant contacts.

Initiating the IAP

Initiation of the IAP comes from the CC staff person(s) coordinating the program at your CC. The method of initiation is the same, regardless of how the participant was identified. Use the *IAP Checklist* to assure good communication and documentation of strategies used (see *Figure 17.2 - Intensive Adherence Program Checklist*). Complete the top portion of the *IAP Checklist* with the participant information and the reason for enrollment into the IAP. If the IAP Coordinator is available, the participant can be enrolled in the IAP immediately at the time of identification. If the IAP Coordinator is not available, the CC staff can let the participant know that someone will follow up with her on a future phone call. Use *17.3 - IAP Participant Call Record* to help track call attempts and contacts

Number of IAP Contacts

There should be at least two contacts made with the participant for the IAP: one to initiate the IAP and one to follow-up. The IAP Coordinator decides how many contacts are needed, balancing participant need with CC workload. The participant should also be encouraged to request more calls as needed.

Content of IAP Contacts

The content of the IAP contacts will vary, but include defining the specific nature of the adherence problem, self-monitoring of the problem, identifying solutions for the problem, and follow-up to see if the solutions worked in either eliminating the problem or making it better. The focus should be on the behavioral, symptom-related, cognitive, and affective reasons for poor adherence and what to do about them (see also *Table 17.3 - Reasons for Poor Retention and/or Adherence*).

IAP contacts should follow the simple steps described below. Suggested materials produced for use in the program to help guide the staff person through the steps of the program are included in this section.

1. Define the specific nature of the adherence problem.

   Discuss with the participant her adherence patterns during her time with WHI. Many adherence problems will have shown up before in similar ways. Discuss her adherence during the most recent period and the specific problems recently identified. Identify the point at which the participant started having difficulties, the time course (whether episodic or constantly occurring), and the participant's best guess as to the cause of the adherence problem. If the participant does not think she has an adherence problem per se, review her adherence in the very recent past. Ask for times that the participant has forgotten to take the pills and what those times were like.

   End this initial discussion with an "assignment" for the participant to self-monitor for a limited period of time to obtain more information about pill-taking behavior. Ask the participant to record in a diary her own monitoring of adherence (*Figure 17.4 - Daily Adherence Diary*). Negotiate the length of time and approximate dates of this self-monitoring. The minimum time for self-monitoring should be at least one week; longer would be better. Complete the information in the upper left hand corner of each diary page. Complete each cell of the Day/Date column on each diary page for each week. Send these pages to the participant and record the date and your action on the *IAP Checklist*.

2. Review the participant's self-monitoring activity.

   The purpose of reviewing the self-monitoring activity is to identify the cues and reinforcers for the adherence problem. Record pertinent information on the *IAP Checklist* as you discuss the following topics with the participant. Ask the participant to refer to her Diary during this discussion. Below are categories of cues and reinforcers that influence adherence. Point out specially any experiences or Diary notations that fall in these categories and discuss them in more detail with the participant.

   - Symptoms. The most common cue for nonadherence is the experience of a symptom. See *Section 5.4 - Managing Symptoms* for a list of HRT-related symptoms and *Section 7.3 - Adverse Effects* for CaD-related symptoms. Sometimes the participant will avoid taking study pills altogether when she feels that they are causing symptoms. Sometimes the participant will take pills sporadically when the symptoms change or worsen. Questions to ask about symptoms and resulting adherence problems are:

     - Frequency of symptoms.
     - Severity of symptoms.
     - Number of problems due to the symptoms.
     - Self-medication for the symptoms.

     Some participants attribute unrelated symptoms to the study pills, particularly in blinded studies. For example, a participant may claim that the pills are making her ear pain worse, when there is no known link between the ear pain and the active agent or placebo. Ask the participant direct questions about what she thinks causes the symptoms.

- Emotions and cognitions. Many cues and reinforcers for adherence behavior are emotional in nature. Common emotions that may drive adherence are fear, worry, anxiety, concern, relief, and strong conviction. Participants use these emotions as reasons to not take their pills (e.g., I was worried that the pills might make my recent illness worse) or as reinforcers (e.g., I felt much better after I stopped taking the pills). Stress and the resulting emotional reactions often interfere with adherence. Helping to organize a special event, such as a daughter's wedding, can be very stressful, and the many associated emotions and strains can result in poor adherence. Thoughts or cognitions (perceptions) can influence a participant's adherence and are often related to emotions. For example, if a woman believes that HRT causes breast cancer, she will also have fears about her own risk of breast cancer, and a belief that HRT is harmful. Ask about the participant's beliefs and thoughts regarding her study pills.
- Behaviors. Participants often use behavioral cues to remind themselves to take pills. When these behavioral cues fail, poor adherence can result. For example, if a participant takes her daily pill with her morning coffee, then she is likely to forget her pill on days when she does not have coffee. Ask the participant to identify the cues on both the days that she took the pills and on the days that she did not. Also ask her if something prevented her from responding to her normal cues on the days that she did not take the pills (e.g., distraction, disruption).
- Difficult situations. Often participants do not adhere to their pill-taking patterns when they experience a disruption in the flow of daily activities. Ask about several kinds of disruptions, including vacations, work disruptions, weekends and holidays, social events, shopping and day trips, illnesses, and problems of self and others. Discuss with the participant which of these are planned disruptions (e.g., weekends) and which are unplanned (e.g., health problems).

3. Identify solutions

Discuss the adherence problems and potential solutions with the participant. Match the solution to the nature of the problem. For example, if the problem is emotional, then discuss the emotions that get in the way of taking the pill. Use the categories of solutions below to discuss strategies for better adherence. Record your solutions and specific strategies on the *IAP Checklist*.

- Symptoms. Encourage the participant to deal with symptoms using methods that have worked for her in the past. Offer her new options if the ones she has used are not working. Reassure her that most symptoms are not signaling harm. Talk about the difficulty in a double-blind trial of not knowing what she is taking and assuming that the pills are causing all of the problems. Discuss with her the idea that aging produces changes in a woman's body and that potentially many of the symptoms she is experiencing might be due in part to these changes. Indicate that some of the symptoms may not go away, but they can occur "in the background" (be more tolerable) and not interfere with her daily life if you and she work together. Ask her if she thinks of these symptoms often or just once in a while. Ask her to identify methods of putting the symptoms "in the background" so that she can keep taking the pills and get the potential benefits from the trial.
- Emotions and cognitions. Deal with each specific fear, emotional reaction, or belief separately. Validate each reaction as normal and understandable and discuss each belief rationally. Be open about unknown findings, and correct misperceptions that she may have about the pills and associated health problems. Ask her if other things in her life have been difficult or problematic. Help her to understand that many different factors may be causing the emotional reactions that she attributes to the pill regimen. Ask her if she has a source of social support that can help her with difficulties. Ask her if she gets out of the house and sees friends and family. Discuss the fact that sometimes friends and family can be nonsupportive, and that the best sources of social support for her are ones that help but do not nag. Discuss strategies for obtaining support if needed.
- Behaviors. Discuss optional cues that can help the participants remember to take pills. These options include existing strategies (e.g., pill organizer) and new ones (e.g., asking a family member or friend to remind the participant on busy or non-routine days). Identify whether the participant has a consistent problem with forgetting, or whether the memory problem is specific to certain problem

areas. For consistent memory problem, discuss her usual daily activities and how to fit the pills into these activities. For sporadic problems, identify the specific activities, days, and/or times that remembering seems to be a problem.

- Difficult situations. Classify the situations in which the participant has difficulty taking her study pills into planned and unplanned disruptions. Discuss and strategize about each specific type of disruption. For planned disruptions, help the participant identify a set of steps to use in the anticipated situations. For example, some participants take frequent day trips. These can upset her daily routine and can cause difficulty taking the study pills. However, these types of activities are mostly scheduled in advance and require just a few additional steps to make sure that pills are available and taken. Participants can choose a time to review their calendar weekly or monthly to make concrete plans for remembering to take pills. Unplanned disruptions are more difficult. These types of disruptions in daily routine are often not noted on the participant's calendar, and so planning ahead for each one is not an option. For some participants, however, these unplanned disruptions occur frequently and disrupt pill-taking behavior. Therefore, it is important that participants with frequent unplanned disruptions develop a general contingency plan for dealing with them. For example, the participant can keep 1-3 pills in her wallet, purse or glove compartment for emergencies, while leaving the bottle and pill organizer at home. Discuss strategies for always being prepared for the unexpected. Ask her for a step-by-step plan for being prepared for unusual or disruptive situations that she cannot control or anticipate.

4. Reinforce appropriate attributions

People sometimes set aside or forget motivators and commitments when they are faced with an immediate frustrating problem like symptoms or stress. Remind participants of the bigger picture as you progress through the IAP. Weave these comments into all of the above steps as appropriate. These categories of attributions or viewpoints will help increase adherence.

- Motivations. Remind the participant of her reasons for joining the trial and the skills that she currently possesses that can get her through the difficult parts. Examples include:
  - "I know that you are the kind of person that contributes her time to the WHI because you want to help others, and you certainly are by continuing to take your study pills."
  - "You have been really successful in the past (or in other situations) taking these pills. Let's figure out what you can apply from other situations to this one."
- Persistence. Tell the participant that you know she is committed to taking the pills and seeing WHI succeed. Examples include:
  - "It's wonderful that you can manage your study pills despite the annoyance of minor symptoms or hassles."
  - "Your persistence with this problem shows that you are highly motivated to do well in this trial."
  - "Your perseverance shows that you can really keep on track with the study pills."
- Coping. Indicate that the participant has the determination and skills to get through this difficult period. Examples include:
  - "Your ability to come this far is the direct result of your ability to solve tough problems."
  - "I can see by your diary [or our discussion] that you can really figure out this kind of problem."

5. Check for success

Discuss with the participant her progress and difficulties in trying out some of the strategies you both have identified. Note her progress on the *IAP Checklist*. See how the solutions worked in improving or ending the problem. Have the participant self-monitor again, if necessary, to see where problems have been resolved and where they still need attention. Keep in contact with the participant and repeat the steps above if the problem is not resolved.

Ending IAP Contacts

The IAP Coordinator decides when to end the contacts. The program might end because it is successful or because it will never be successful, in the judgment of the IAP Coordinator. Document the conclusion of the IAP on the *IAP Checklist*. If adherence activities have not been successful and the participant has changed her participation status, complete *Form 7 – Participation Status* (see *Section 17.2.2.1.4 - Ending Special Activities for HRT/CaD Retention Challenges*).

Reactivating IAP Contacts

Participants might develop different problems over time and therefore become candidates for the IAP more than once. Follow the procedures outlined above, even if the person has been in the IAP before. The IAP Coordinator should refer to previous IAP documentation for information about earlier adherence problems and strategies for managing those problems.

17.2.2.3 Documenting and Tracking Special Activities for HRT/CaD Retention Challenges

The following forms and reports may be useful in identifying which participants need special retention activities and documenting and tracking activities that have been initiated or completed:

- *HRT/CaD Medication Adherence (WHIP 1260)* – Use this report to identify which participants require special retention activities due to low adherence levels (i.e., less than 80%).

- *Form 10 – HRT Management and Safety* – This form is completed at each semi-annual visit to evaluate safety issues related to HRT use. Refusal to complete this form results in a participant's removal from the intervention. Item 13 on this form indicates that a participant needs to be enrolled in the IAP.

- *HRT Management Recontact (WHIP 0616)* – This form lists participants who need to be recontacted as indicated on *Form 10*. The report output indicates whether the needed contact is a one-month safety contact or an IAP contact.

- *Form 17 – CaD Management and Safety* – This form is completed at each annual visit to evaluate safety issues related to CaD use. Refusal to complete this form results in a participant's removal from the intervention. Item 11 on this form indicates that a participant needs to be enrolled in the IAP.

- *CaD Management Recontact (WHIP 1048)* - Use this report to identify which participants should be receiving IAP contacts, as indicated on Form 17.

- *IAP Checklist* and *IAP Participant Call Record* - Use these to document IAP activities.

- *Form 24 – Adherence and Retention Worksheet* - This form can be used to track retention activity, to identify which participants need further adherence/retention assistance, and to indicate when (i.e., date) future contacts should be made.

- *Member Adherence and Retention Activity Tracking (WHIP 1238)* – This report is used to track which participants have received retention/adherence contacts (based on *Form 24* data) and the date to conduct

future contacts, as needed. The report can be sorted by member ID or name, retention problem (i.e., in which study component), or date for next contact.

17.2.2.4 Ending Special Activities for HRT/CaD Retention Challenges

When special adherence and retention strategies have been exhausted and the participant indicates that she is no longer willing to take her study pills and/or complete follow-up safety procedures (HRT and CaD) complete a *Form 7 - Participation Status* to reflect the change in status. If the participant decides to resume with intervention and/or follow-up activities that had been previously stopped, update *Form 7 - Participation Status* as appropriate to

indicate the current level of participation status (i.e., make sure that the participation status [intervention and/or follow-up status] indicated on Form 7 accurately reflects the level of participation she is currently willing to do).

Try to maintain the highest level of participation that the woman is willing to achieve. Even if she refuses to take her study pills, it is very important to try to keep her on a high level of follow-up status. Contact participants with less than full intervention status at least once a year throughout the study to see if they are willing to resume some or all aspects of their participation (see *Section 17.4.5 - Reactivation of Participants with Changes in Participation Status)*.

17.2.3 Special Activities for DM Intervention Retention Challenges

This section includes information on identifying DM Intervention retention challenges, initiating special activities for retention challenges, tracking and documenting special activities, and ending special activities.

17.2.3.1 Identifying DM Intervention Retention Challenges

Retention challenges for DM Intervention are characterized by difficulty meeting Dietary Change goals and/or difficulty completing Dietary Change sessions. Refer to *Section 6.10 (including all subsections) – DM Intervention Participation* and *Section 6.11 (including all subsections) – Intensive Intervention Protocol (IIP)*.

17.2.3.2 Initiating Special Activities for DM Intervention Retention Challenges

The Group Nutritionist uses the Triage System for DM Intervention to set priorities for managing participants having retention challenges. The system categorizes participants into one of four adherence categories where Level 1 reflects high adherence and Level 4 reflects low adherence. Refer to *Section 6.10.7 – Triage System for DM Intervention*.

Difficulty Meeting Dietary Change Goals
The Group Nutritionist uses high intensity Intensive Intervention Protocol (IIP) procedures with Level 2 and Level 3 participants having difficulty meeting Dietary Change goals. Refer to *Section 6.11 – Intensive Intervention Protocol (IIP)*.

Difficulty Completing Dietary Change Sessions
The Group Nutritionist most often uses low intensity Interrupted DM Intervention Participation procedures with Level 4 participants having difficulty completing Dietary Change sessions. However, the Group Nutritionist may use high intensity IIP procedures with Level 4 participants if CC resources support this level of effort. Refer to *Section 6.10.8 – Interrupted DM Intervention Participation Procedures*.

17.2.3.3 Documenting and Tracking Special Activities for DM Intervention Retention Challenges

The Group Nutritionist documents Intensive Intervention Protocol (IIP) contacts using *Form 64 – Individual Data Sheet* and progress notes. The Group Nutritionist tracks IIP contacts using the *IIP Triage & Tracking (WHIP 0444*) report. Refer to the following manual sections*: Vol. 2, Section 6.11 (including all subsections) – Intensive Intervention Protocol (IIP), Vol. 3 – Forms, Instructions for Form 64 – Individual Data Sheet, Vol. 5, Section 8.2 – DM Intervention Group Reports* and *Vol. 5, Appendix D – WHILMA Reports*.

The Group Nutritionist documents Interrupted DM Intervention Participation contacts using *Form 24 – Adherence and Retention Worksheet* and progress notes. The Group Nutritionist tracks Interrupted DM Intervention Participation contacts using the *IIP Triage & Tracking (WHIP 0444)* and *Member Adherence and Retention Activity (WHIP1238)* reports. Refer to the following manual sections: *Vol. 2, Section 6.10.8 (including all subsections) – Interrupted DM Intervention Participation Procedures, Vol. 3 – Forms, Instructions for Form 24 – Adherence and Retention Worksheet* and *Vol. 5, Appendix B.3.4 – Adherence and Retention Worksheet*.

17.2.3.4 Ending Special Activities for DM Intervention Retention Challenges

The Group Nutritionist stops special retention activities if the participant refuses all contact with the Group Nutritionist and other CC nutrition staff. Ideally, a non-nutrition CC staff member with retention responsibilities (e.g., retention specialist or designee) attempts to continue special retention activities when the participant refuses all contact with CC nutrition staff.

If the participant refuses all contact with CC nutrition staff and all special retention activities have failed, refer to *Sections 6.10.6.2.1 – Non-Participation* and *17.4 – Changes in Participation Status* for information about stopping intervention.

17.2.4 Special Activities for Follow-up Retention Challenges (CT and OS)

A participant becomes a follow-up retention challenge and requires special activities when she is unwilling to participate in follow-up activities, including visits (i.e., annual visits), phone calls, or mailings.

17.2.4.1 Identifying Follow-up Retention Challenges

Follow-up retention challenges are defined as follows:

- HRT/CaD Follow-up Problems: Follow-up retention challenges in HRT and CaD occur when a participant refuses phone and mail contacts during the follow-up period and/or refuses to come in for follow-up visits to complete the ongoing minimum safety requirements following randomization. Failure to meet minimum safety requirements will result in the participant's removal from active HRT or CaD intervention (see *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*).

- DM Follow-up Problems: Follow-up retention challenges in DM occur when a participant (intervention or control) refuses phone and mail contacts during the follow-up period and/or refuses to come in for follow-up visits (see *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*).

- OS Follow-up Problems: An OS participant who refuses phone and mail contacts during the follow-up period and/or who refuses to come in for the 3-year annual visit is a retention challenge and requires special retention activities.

17.2.4.2 Initiating Special Activities for Follow-up Retention Challenges

When a participant has been identified as a follow-up retention challenge, initiate any special retention activities available to help keep her on full follow-up. See *Section 16.4 - Follow Contact Problems for Annual (CT) and Third-Year (OS) Visits* for strategies on managing follow-up contact problems for annual (CT) and third-year visits. Refer to *Section 16.5.3 - CC Date Collection for Non-Respondents to OS Mailings* for procedures on initiating contact with OS participants who have not responded to data collection attempts by mail.

See also *Tables 17.3 - Reasons for Poor Retention and/or Adherence, 17.4 - Strategies to Retain Full Participation in CT and OS,* and *17.6 - Examples of Retention Strategies* for ideas on ways to keep participants on full follow-up.

17.2.4.3 Documenting and Tracking Special Activities for Follow-up Retention Challenges

The following forms and reports may be useful in identifying which participants need special retention activities and documenting and tracking activities that have been initiated or completed:

- *Missed Scheduled Visit (WHIP 0799)* – This report lists all participants who do not have any encounters for their most previously scheduled visit (as per the *Member Visit Schedule Tracking* screen).

- *OS Enrolled Members Needing Clinic Follow-up (WHIP 1206)* – Lists OS participants who have not completed a *Form 33 – Medical History Update* following the mailed data collection contacts (during Year 1, 5, 7, or 9). These women require CC mail or phone follow-up to obtain a completed *Form 33*.

- *Form 24 – Adherence and Retention Worksheet* - This form can be used to track retention activity, to identify which participants need further adherence/retention assistance, and to indicate when (i.e., date) future contacts should be made.

- *Member Adherence and Retention Activity Tracking (WHIP 1238)* – This report is used to track which participants have received retention/adherence contacts (based on *Form 24* data) and the date to conduct future contacts, as needed. The report can be sorted by member ID or name, retention problem (i.e., in which study component), or date for next contact.

17.2.4.4 Ending Special Activities for Follow-up Retention Challenges

Special activities may be discontinued when one of the following occurs:

- The participant agrees to some level of follow-up participation.

- The participant requests no further contact from the CC.

Try to maintain the highest level of participation that the woman is willing to achieve. Even if she refuses to take her study pills, it is very important to try to keep her on a high level of follow-up status. Contact participants with less than full intervention status at least once a year throughout the study to see if they are willing to resume some or all aspects of their participation (see *Section 17.4.5 - Reactivation of Participants*).

If at the end of special activities, the participant's follow-up status has changed (e.g., activities have failed and she requests "no-follow-up"), complete *Form 7 - Participation Status* to indicate the change. See *Section 17.4.2 - Changing Follow-up Status* for guidelines and procedures on changing follow up status.

If a participant cannot be located, initiate a search to determine her current location (see *Section 17.3.1 - Initiating a Search to Locate Participants (Form 23)*).

17.3 Locating "Hard to Find" Participants

The term "hard to find" is used to designate a participant the CC has lost contact with and is searching for. WHILMA automatically updates the participant's follow-up status to "lost-to-follow-up" as long as the participant is not "no follow-up" or "absolutely no contact," and if:

- For CT – either no *Form 33* within 18 months or no *Form 23* with "found" box marked within 6 months
- For OS – either no *Form 33* within 24 months or no *Form 23* with "found" box marked within 12 months

17.3.1 Initiating a Search to Locate Participant (Form 23) (Required for Vital Status Searches)

If at any stage in the study a WHI participant misses a scheduled contact for an unknown reason, it is important for the CC to re-establish contact with the participant as soon as possible to ensure that the participant does not become lost to follow-up.

A search to locate the participant should be initiated in any of the following circumstances:

- A participant misses a clinic visit for an unknown reason and CC staff cannot make contact with the participant either by phone or by mail.
- A participant fails to return a mailed questionnaire and CC staff cannot make contact with the participant either by phone or by mail.
- CC staff have unsuccessfully tried to contact the participant by phone for a phone interview, and have been unable to make contact with the participant by mail.
- Mail sent to the participant has been returned to the CC because the participant is no longer at the address (and an updated address is not available) and the participant cannot be contacted by phone.
- A participant is listed on *WHIP 1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up*.

A search need not be initiated if the participant is known to be away (on vacation, for example) and will be reachable at the address and phone number listed in her file at a later date. The CC staff should exercise discretion in deciding how soon after a missed contact to begin efforts to locate the participant. In general, a search should be initiated on all participants whose whereabouts have not been established once the time window for the scheduled contact has ended.

To initiate a contact search to locate the participant, complete and data enter the top part of *Form 23 - Search to Locate Participant*.

17.3.2 Strategies to Locate "Hard to Find" Participants (Recommended)

CCs should develop their own forms and procedures for tracking attempts to locate participants once a *Form 23 - Search to Locate Participant* has been initiated. A record of attempts to locate the participant should be kept in her file (refer to *17.1 - Sample Form to Track Contact Attempts* for a sample form to keep track of contact attempts). Refer to *Form 23* for procedures on locating the participant and use it to record which steps have been taken to locate her.

Each CC should designate one staff member to be in charge of efforts to locate "hard to find" participants although this person may use other staff members to assist in locating participants with whom contact has been lost. The range of strategies used to trace participants, the sequence and frequency in which tracing attempts are carried out, and the amount of effort expended in locating hard to find participants should be decided by each CC, depending on local circumstances and accessibility of useful sources of information. However, all CCs are required to meet the overall retention goals.

In the process of tracing a participant, try to avoid inconveniencing persons from whom information is requested. Be particularly sensitive when making contact with personal contacts of the participant if it is suspected that she may be "hard to find" because she has died.

The following strategies may be used to trace missing participants:

- Attempt to contact the participant by phone. Repeat attempts on several occasions on different days and at different times of day, including evenings and weekends. If the participant is employed, try her work number as well as her home number. If the participant is not in, leave a message for her to call the clinic with the person who answers the phone or on the answering machine. If there is no answer after several attempts, the participant may be away on vacation; try again a few weeks later.
- If the participant's phone number has changed, try to obtain her new number from the phone book, directory assistance, or by using a reverse directory (e.g., Polk, Coles). If the participant has changed to an unlisted phone number, you may request that a supervisor from directory assistance contact the participant and ask her to call the CC.
- Attempt to contact the participant by mail. Send her a letter with "Address Correction Requested" printed on the envelope, requesting that she contact the CC.
- If the above is unsuccessful, send a certified letter to the participant's last known address requesting that she contact the CC.
- Contact personal contacts named in *Form 20 - Personal Information* by phone or by mail in order to obtain updated address and phone number information on the participant, and to confirm that she is not deceased.
- If attempts at contacting personal contacts and the physician are unsuccessful, try contacting neighbors or the current resident at the participant's last known address (using reverse directories).
- Check with state and local public agencies, and other sources listed on *Form 23 - Search to Locate Participant* as appropriate, including: state death records, local cancer registries (e.g., SEER), State Department of Motor Vehicles, local Social Security Office, and local voter registration records.

17.3.3 Ending the Search to Locate Participant (Required)

The search to locate the participant should continue until one of the following has occurred:

- you have contacted the participant;
- you have obtained updated phone number and/or address information;
- you have discovered that she is deceased;
- repeated attempts to contact the participant and her personal contacts using all strategies have been exhausted and you have failed to reach the participant, receive updated phone/address information, or determine that she is deceased.

This last criterion for ending a search will only apply once attempts to contact the participant have been repeated at intervals over a 6 month time period. When you have exhausted reasonably accessible avenues of inquiry for locating lost participants, close out *Form 23 - Search to Locate Participant* by indicating the search result status. Enter the date that the search is ended and the result of the search on *Form 23*, and data enter the form in WHILMA to close out the search.

If search attempts yield updated address or phone information, update the member screen in WHILMA.

Once contact is made with the "hard to find" participant and/or you have updated phone/mail information, contacts that she has missed should be rescheduled, if appropriate (See *Section 16.4 - CC Follow-up of Missed Contacts*). If upon re-establishing contact with the participant, she states that she is no longer willing to maintain full participation status in the study, begin retention activities (see *Section 16.4 - Follow-up of Missed Contacts)*.

If the participant is found to have moved to an address far from the CC and is no longer able to attend clinic visits, her status should be changed to "no clinic visits" but follow-up by mail and phone should continue (See *Section 17.4 - Changes in Participant Status*). Participants who have moved and who no longer attend clinic visits may stay on intervention as long as the minimum safety procedures for their study component are carried out.

If the participant has moved to an address sufficiently close to one of the other CCs to be able to make clinic visits, arrangements should be made to transfer her to the nearest CC if she agrees (see *Section 17.5 - Transfer of Participants Between Clinical Centers*).

If search attempts yield information that the participant has died since the last contact, complete *Form 120 - Initial Notification of Death*, and process according to procedures outlined in *Volume 8 - Outcomes*.

The CCC will routinely request searches of the National Death Index for all participants with follow-up status "lost to follow-up" (see *Section 17.3.5 - Searches of the National Death Index*).

17.3.4 Procedures for Study Wide Vital Status Ascertainment (Required)

A. Definition of Vital Status

A participant's vital status is considered to be one of the three following categories: known to be alive, deceased, or lost-to-follow-up.

Deceased is defined as follows:
- *Form 120 - Initial Report of Death* or *Form 124 - Final Report of Death* completed.

Known to be Alive is defined as follows:
- Does not meet deceased criteria, and
- For CT participants: at least one of the following has happened:
  - a *Form 33* in the last 18 months, or
  - a *Form 23* in the last 6 months, with Item 4-Search Result, code 1 – "participant has been located" marked.
- For OS participants: at least one of the following has happened:
  - a *Form 33* in the last 24 months, or
  - a *Form 23* in the last 12 months, with Item 4-Search Result, code 1 – "participant has been located" marked.

WHILMA automatically updates the participant's follow-up status to "lost-to-follow-up" as long as the participant is not "no follow-up" or "absolutely no contact." Names appear on *WHIP 1591* under the following circumstances:
- CT – either no *Form 33* within 18 months or no *Form 23* with "found" box marked within 6 months.
- OS – either no *Form 33* within 24 months or no *Form 23* with "found" box marked within 12 months..
- "No follow-up" participants, when they meet the CT/OS criteria for "lost" (bullets 1 and 2 above). However, to ensure that participants do not fall off of reports, follow-up status remains "no follow-up."

Note: Participants with "no follow-up" status are only contacted/searched for annually.

Participants' names will not appear on *WHIP 1591* under these circumstances:
- *Form 120 – Initial Report of Death* and/or *Form 124 – Final Report of Death* has been data entered.
- Participants with "absolutely no contact" status.

Note: The lack of *Form 33* drives the definition of lost-to-follow-up. It is possible a participant has come into the clinic in the last 18 months and completed required clinic forms, excluding *Form 33*. By definition, this participant will be included on *WHIP 1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up* because outcomes data are missing. For this reason, CCs should make every effort to collect the medical information on *Form 33* each time they have a routine contact with a participant.

B. Procedures

1. *Vital Status Investigation (WHIP 1591)*

The CCC began distributing a new clinic-specific report, *WHIP 1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up*, for main and satellite sites, in January 2000. This report lists all CT and OS participants defined as Lost-to-Follow-Up (as defined in "Definition of Vital Status" above). The report includes the participant's ID, name, current vital status, last *Form 33* received date, last *Form 7- Participation Status* and *23 – Search to Locate Participant* information, and prior follow-up status. For each participant listed on the report, CCs are required to conduct a search to locate the participant.

WHIP 1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up also includes participants in the CT and OS who have a current follow-up status of "no follow-up," since Vital Status ascertainment needs to periodically occur for these women as well.

2. Conducting a search using *WHIP 1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up*

For each participant listed on the *WHIP 1591*, complete a search to locate the participant. The search to locate participant should include:

- Review of the participant's chart, including verification of phone number and retention documentation before making a contact.
- Review of *Vol. 2, Section 17 - Retention*, for a comprehensive review of retention strategies.

In general, use a six-month time period as a guideline for the search duration. For future searches, make every effort to conclude in time for the DSMB database freezes. (Notification of freeze dates are sent by the CCC.) However, do not compromise the search--if the search is on-going, do not close the search out. Continue to search until all sources are exhausted before you complete *Form 23* and close out the search.

3. Document search results on *Form 23 - Search to Locate Participant*.

Complete the forms based on the search results, as follows:

a. If participant has been in contact with the clinic in the last 18 months:
   - Document the contact information on *Form 23*:
     - Record the date you spoke or had contact with participant in Item 1-Initiation date;
     - Enter the current date in Item 4 - Date Search Ended.
     - Complete the rest of the form as appropriate.

b. If CC is in the process of searching for a participant:
   - Document the contact information on *Form 23*;
   - Attach documentation of the search to the *Form 23*;
   - Indicate the date you began the search in Item 2 - Initiation date on *Form 23* and continue searching for participant;
   - When the search is complete, record the search results and complete Items 4-6 - Date Search Ended, Search Ended By, and Search Result.

c. If participant is located (includes a participant who is deceased):
   - Document search on *Form 23 - Search to Locate Participant*;

- Complete rest of *Form 23*. Mark code 1 - "Participant has been located." in Item 6 - Search Result. If participant is deceased, also complete *Form 120 - Initial Report of Death* and ask a proxy to complete *Form 33*, if possible;

- Update *Form 7* to change a participant's follow-up status by using the "prior status" listed on *WHIP 1591* unless a new follow-up status is negotiated directly with the participant.

Note: If a participant listed on the report completes a *Form 33*:
- and you have not initiated a *Form 23*, you are not required to complete *Form 23*.
- if you have initiated a *Form 23*, you must complete the *Form 23* and data enter it to close out the search, regardless of whether or not the participant completed a *Form 33*.

d. Participant is not located:
- Document search on *Form 23*;
- Complete rest of *Form 23*. Mark code 4 - "The participant could not be located" in Item 6-Search Result.

4. Document changes in participant follow-up status on *Form 7 - Participation Status*, if appropriate.

For any participant listed on *WHIP 1591*, you need to update the participant's follow-up status on *Form 7*, if:

- participant completes a *Form 33*, or
- you complete a *Form 23*, marking code 1 – "participant has been located" in Item 6-Search Results."

Note: If the participant was previously on "no follow-up," it is not necessary to change the follow-up status unless she indicates that she wants to change (i.e., resume or increase her study participation).

For participants who appear on *WHIP 1591* who have a follow-up status set to "lost-to-follow-up," based on the criteria described in *B.1 - Vital Status Investigation* above:
- When you find the participant alive (i.e., collect a *Form 33* or indicate "participant has been located" on *Form 23*), you need to change the follow-up status from "lost-to-follow-up" to her prior status listed on *WHIP 1591* unless a new follow-up status is negotiated directly with the participant. To do this, complete *Form 7*, indicating if the participant is on full, partial, custom, or no follow-up.
- When you find the participant is deceased, do not update her follow-up status on *Form 7*. Instead complete *Form 120 - Initial Notification of Death*.

5. Data enter the *Form 23*, *Form 7* and *Form 33* before the DSMB database freeze dates, when possible.

17.3.5 Searches of the National Death Index (NDI)

For participants with follow-up status "lost-to-follow-up", the CCC will periodically send in requests to search the National Death Index (NDI) to the National Center for Health Statistics, in order to determine whether "lost" participants have died since the date of last contact with the CC.

The information required for requesting searches of the NDI is abstracted from the WHILMA database by the CCC. In order to maximize the chance of a valid match and to minimize the chance of a false match being made, it is important to have as complete and accurate information as possible in the WHILMA database on items used in searches of the NDI. The following information is used when requesting NDI searches:

- Full name of the participant including first name, middle initial, and last name
- Maiden name (or father's surname)
- Social Security Number
- Date of birth
- Sex
- Race
- Marital Status

- Last known state of residence
- Age at death (estimate) or age when the participant was last known to be alive, based on CC records. The CCC will inform CCs of the results of NDI searches once they are available. If a search yields information that a participant has died, the CC will then be responsible for completing *Form 120 - Initial Notification of Death* and processing according to procedures outlined in *Volume 8 - Outcomes*.

The CCC may also make use of other national sources such as the Social Security Administration, Health Care Financing Administration (Medicare), US Post Office National Change of Address Tape, and credit bureaus to ascertain the vital status and/or updated address information of participants lost-to-follow-up, if resources permit.

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17.4 Changes in Participation Status

Participants are assumed to be on full participation in WHI, unless a change is indicated using *Form 7 - Participation Status.* Participation status is divided into intervention status and follow-up status (see *Form 7 - Participation Status)*. A participant's intervention status indicates the degree to which she is willing or safely able to participate in the WHI intervention(s) to which she was randomized. A participant changes intervention status if she becomes unwilling to participate in intervention activities or needs to stop the intervention for safety or other reasons, or if she decides to resume intervention activities that she had previously stopped. A participant's follow-up status indicates the degree to which she is willing or able to participate in the follow-up activities for her study component. A participant changes follow-up status if she becomes unwilling or unable to participate in full follow-up (e.g., if she refuses any of: CC visits, phone calls or mailing), if she cannot be located ("lost to follow-up"), if she has died, or if she decides to resume full follow-up after being on less than full follow-up (e.g., partial follow-up).

Participation status is used primarily to indicate what procedures the participant is willing and/or able to participate in. Temporary changes, such as the inability of a participant to come to a CC visit due to an illness or family problem, do not change her participation status. Similarly, ambiguous situations such as a participant failing to show up for a scheduled CC visit multiple times in general does not change her status unless she actually states that she is no longer willing to make CC visits.

Every effort should be made to encourage full participation throughout the study (see *Section 17.1 - General Activities*). Before a woman voluntarily changes status, specific retention activities should be conducted (see *Section 17.2 - Clinical Center Activities for Retention Challenges*) to alleviate the problem(s). If full participation is not possible, it is important to maintain some form of contact. A woman who insists on "dropping out" of the intervention should be encouraged to still come in for CC visits. For a woman who refuses CC visits, it is important to at least get agreement to contact her by mail and/or phone to follow her medical history.

Participants with less than full participation status are contacted periodically to determine whether or not they are willing to resume participation. Procedures for contacting and reactivating participants are in *Section 17.5. 4 - Reactivation of Participants with Changes in Follow-up Status. Form 7 - Participation Status* is also used to resume those aspects of participation that were formerly limited on *Form 7 - Participation Status.*

When a participant's follow-up status changes, complete a new *Form 7 - Participation Status.* When completing the form, there is no need to complete sections on the form other than the relevant parts that indicate how and why the status has changed.

17.4.1 Changing Intervention Status (Required)

Below are the definitions and procedures relating to changing a woman's intervention status for each study component. Intervention status only applies to CT participants.

17.4.1.1 DM Participants

Stop DM Intervention

This status only applies to those participants who are randomized to DM Intervention groups (i.e., does not apply to women in the DM comparison group).

Two circumstances warrant the "Stop DM intervention" designation:

1. The participant refuses all contact with the Group Nutritionist and other CC nutrition staff, and all special retention activities have failed. Retention activities must first be completed for these women (see *Section 17.2.3 – Special Activities for DM Intervention Retention Challenges)*.

2. The participant was removed from active DM Intervention participation by CC staff due to unresolved symptoms. Retention activities are not required.

A participant classified as "Stop DM Intervention," must also be removed from her current DM Intervention group assignment (see *Vol. 5 - Data System, Section 8.1.3 - Assigning and Removing Participants from a DM Intervention Group)*.

Exceeding a fat gram goal is not a reason to change DM Intervention status. Refusal to come to CC follow-up visits or to fill out any or all forms is not a reason to "Stop DM Intervention." Because there are no required safety procedures for DM participants, women who refuse assessment procedures may continue intervention activities.

Resume DM Intervention

Use this classification if the participant agrees to actively participate in DM Intervention (see *Section 6.10.6.2.2 – Active Participation*), after having been previously classified as "Stop DM Intervention." Assign the participant to her previous or a new Dietary Change group (see *Vol. 5 - Data Systems, Section 8.1.3 - Assigning and Removing Participants from a DM Intervention Group)*.

17.4.1.2 HRT Participants

Stop HRT Intervention

This does not include going off or on HRT pills while you are trying to resolve symptoms (use *Form 54 - Change of Medications* if there are changes in HRT study pills schedules or dosages). Low adherence (not consuming the appropriate number of HRT pills in the time between follow-up contacts) is not a reason for changing HRT intervention status (instead, initiate the Intensive Adherence Program for these participants - refer to *Section 17.2.2.2.1 – Intensive Adherence Program*).

The circumstances warranting the "Stop HRT Intervention" status are:

1. The participant is no longer willing to take her HRT study pills and retention activities have failed. Retention activities must first be completed for these women (see *Section 17.2.2 – Special Activities for HRT and CaD Intervention Retention Challenges*).

2. The participant refuses any of the safety procedures, and retention activities to maintain these safety procedures have failed. The safety procedures required to remain on HRT Intervention are described in *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*. If the participant, or her proxy (if she is on proxy follow-up), refuses both CC visits and phone calls, then she must be changed to "Stop HRT Intervention" because she cannot meet the safety procedures.

   Note: retention activities must be completed before a participant's status is changed due to reasons 1 or 2 above.

3. The participant was removed from HRT pills by CC staff due to unresolved symptoms or an adverse event that necessitates removing her from the intervention permanently. Refer to *Section 5.5.4 - Health Problems Requiring HRT Termination* for a list of adverse events. These women should not have retention activities initiated.

Be sure to retrieve study medications from women classified as "Stop HRT Intervention" (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*). Indicate the date the participant stopped taking her pills (if known) on *Form 7*. If the date is not known, record the contact date.

Resume HRT intervention

Use this classification if the participant indicates she is willing to resume taking study pills after having previously been classified as "Stop HRT Intervention."

17.4.1.3 CaD Participants

Stop CaD Intervention

Low adherence (not taking the appropriate number of CaD pills in the time between follow-up contacts) is not a reason to classify a participant as "Stop CaD." (Instead, initiate the Intensive Adherence Plan described in *Section 17.2.2.2.1 - Intensive Adherence Program* for these participants.)

The circumstances warranting a "Stop CaD Intervention" status are:

1. The participant is no longer willing to take the CaD study pills and retention activities have failed (see *Section 17.2.2 – Special Activities for HRT and CaD Intervention Retention Challenges*).
2. The woman refuses to complete *Form 17 - CaD Management and Safety Interview* (at a CC visit or by phone or by proxy respondent) annually and retention activities have failed. The safety procedures required to remain on CaD Intervention are described in *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*. If she refuses *Form 17 - CaD Management and Safety Interview*, she is not given any more CaD study pills.

   Note: Retention activities must be completed before intervention status is changed due to the above reasons.
3. The participant was removed from CaD study pills by CC staff due to unresolved symptoms or a adverse event that necessitates removing her from the intervention permanently (refer to *Section 7.3.3.1 - Management of Major Adverse Effects*). These women should not have retention activities initiated.

Retrieve study medications from women classified as "Stop CaD" (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*). Indicate the date the participant stopped taking her pills (if known) on *Form 7*. If the date is not known, record the contact date.

Resume CaD Intervention

Use this classification if the participant indicates she is willing to resume taking CaD study pills after having previously been classified as "Stop CaD Intervention."

17.4.2 Changing Follow-up Status (Required)

Follow-up status refers to the participant's ability or willingness to participate in CC visits, phone calls and/or mailings for the WHI assessment forms and procedures. Follow-up status applies to all participants (CT and OS). Below are the definitions and procedures relating to change in follow-up status.

17.4.2.1 No follow-up

"No follow-up" status is used when a CT or OS participant wants no follow-up (no CC visits, no phone and no mail contact), and retention activities have failed. Retention activities must be conducted before changing status to no follow-up. For HRT and CaD participants, WHILMA will automatically set the intervention(s) to which the woman was randomized to "stop." If she insists on no follow-up, she must stop HRT and CaD study pills (for safety reasons), and study pills should be retrieved (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*). "No follow-up" status does not impact DM intervention status and DM dietary change participants may continue to attend DM sessions.

Only participants who verbally refuse follow-up should be classified as no follow-up. Failure to participate (i.e., consistent failure to show up for CC visits) should not be used to classify a participant as no follow-up.

Contact the no follow-up participants periodically to see if they are willing to resume contact. When a participant specifically states that she will not tolerate further contacts, change her status to "absolutely no follow-up" and do not attempt further contacts.

17.4.2.2 Partial follow-up

Partial follow-up means that the woman is not able or willing to continue one or two of: CC visits, phone and mail contact. If she is unwilling to continue CC visits, she must have retention activities. If she is unable to attend CC visits because she has moved or is seriously ill, retention activities are decided on by the CC. For a woman who has moved near another WHI CC, see *Section 17.4.5 - Transfer of Participants Between Clinical Centers*. If she has stopped both CC visits and phone contact and she is in the HRT and/or CaD intervention, she must stop HRT and/or CaD study pills (for safety reasons) (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*). For these women, WHILMA will set "HRT intervention" and/or "CaD intervention" to stop. Otherwise, "partial follow-up" women should be encouraged to stay on intervention. OS women who refuse the year 3 CC visit do not need to be classified as "No CC visits". Stopping DM intervention sessions only is not included as "No CC visits."

17.4.2.3 Proxy follow-up

If a woman can no longer communicate, for example, due to stroke or dementia, she may, if willing, continue in the WHI through a proxy respondent, usually one of her personal contacts. The order of priority for selecting a proxy respondent is: 1) spouse or partner; 2) nearest relative; 3) friend; 4) physician. On *Form 7 - Participation Status*, indicate "proxy follow-up" and identify the proxy who will be contacted. Participants on proxy follow-up may continue on intervention if the minimum procedures are followed. (See *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention.)* Specifically, a participant on HRT or CaD study pills on proxy follow-up must have her proxy approved (see *Section 16.7 - Follow-Up by Proxy)*. If the participant will not remain on intervention, check the appropriate "stop intervention" box(es). Also check any appropriate boxes: no CC visits, no phone calls, and/or no mailings.

17.4.2.4 Custom follow-up

Use for special circumstances, such as refusal of specific forms or procedures (e.g., blood draws). Also check any appropriate boxes: no CC visits, no phone calls, and/or no mailings.

17.4.2.5 Lost to follow-up

This status is used when a participant's location (i.e., address and/or phone number) cannot be determined and attempts to locate her over at least a six month period have failed (see *Section 17.1 - Locating "Hard to Find" Participants* and *Form 23 - Search to Locate Participant*) and she has had no contact with the CC for at least one year. *Form 23* must be completed before a participant can be classified as lost to follow-up. When a participant has been classified as lost to follow-up, WHILMA will automatically change the appropriate intervention status to "stop."

17.4.2.6 Deceased

When a woman has died, complete *Form 7 - Participation Status* and *Form 120 - Initial Notification of Death*. WHILMA will automatically change the appropriate intervention status to "stop." See *Volume 8, Section 2 - Outcome Identification, Ascertainment, and Documentation* for the remaining procedures.

17.4.2.7 Absolutely no follow-up

All WHI women, even those currently classified as "no follow-up," should be periodically contacted so that they may reconsider participation in follow-up activities. "Absolutely no follow-up" means a woman should never again be contacted about participating in follow-up activities. This classification should be reserved for women who are hostile to WHI and unlikely to change. This classification requires PI approval.

17.4.2.8 Full follow-up

Use to indicate/resume full follow-up (mail, phone, and CC visits).

17.4.3 General Steps in Changing Participant Status

The initial indications that a participant wants to or should change intervention status can come from a number of sources: the participant, a family member, or CC staff. The general steps are:

- Identify the problem — What aspects of the participant's WHI participation does the participant or CC staff want to change? What are the reasons?
- Determine if retention activities need to begin, based on guidelines in *Sections 17.4.1 - Changing Follow-up Status (Required)* and *17.4.2 - Changing Follow-up Status*. If so, set up a time for CC staff to begin retention activities. If, following the retention efforts, the participant still requires a change in participation status, complete *Form 7 - Participation Status*.
- Determine if a search for a lost participant needs to begin. If so, complete and data enter the top part of *Form 23*. Complete *Form 23 - Search to Locate Participant* within 6 months. If the woman still has not been located, complete *Form 7 - Participation Status* to indicate "lost to follow-up."
- Directly complete *Form 7 - Participation Status* when neither retention activities nor a search for lost participants is needed.
- Ask the participant to return all study medications, if appropriate (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*).
- Complete the remaining procedures (see *Sections 17.4.1 - Changing Intervention Status (Required)* and *17.4.2 - Changing Follow-up Status (Required)*).
- Thank the participant for her WHI activity to date.

As noted above, when a problem with participant status has been identified, one of three forms is entered: *Form 23 - Search to Locate Participant* (upper part), *Form 24 – Adherence and Retention Worksheet* or *Form 7 - Participation Status*. In this way, those women with less than full participant status can be tracked.

17.4.4 Retrieving Study Pills [HRT and CaD]

Old study pills should be retrieved and new pills not given when:

1. A participant no longer is willing to take study pills and retention activities have been completed.
2. A participant refuses a required safety procedure (see *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention* for safety procedures). In such a case, old pills should be retrieved before retention activities have begun.
3. A CC staff member removes a participant from intervention due to a termination event or due to unresolved symptoms.

Make concerted attempts to retrieve all old study medications from the participants when they are classified "Stop HRT or CaD intervention." If possible, send a postage-paid envelope to the participant to return pills. If the participant does not return the medications, ask the participant to estimate the number of pills remaining and then to discard them. Enter pill count via WHILMA. If a participant who has stopped HRT or CaD intervention later requests reactivation, make clear to the participant that she should not take medications from previously dispensed bottles.

17.4.5 Reactivation of Participants with Changes in Participation Status

Reactivation is the procedure by which participants who have changed their intervention or follow-up status are re-contacted to increase their follow-up activity or to obtain follow-up information.

17.4.5.1 Purpose

The purpose of reactivation is to:

- Resume CC visits for participants who have previously asked to have no CC visits
- Return participants to their routine follow-up schedules

- Resume some form of follow-up contact for participants who have previously elected to have no follow-up or who have been lost to follow-up
- Resume intervention for eligible participants who previously had stopped intervention (either voluntarily, because of a refusal to complete safety monitoring procedures, or because of an illness event that necessitated stopping intervention)

All randomized participants will be included in the final clinical trial data analysis ("once randomized, always analyzed"). Thus, ensuring that WHI participants stay on their intervention and continue appropriate follow-up contacts is important to maintain and detect potential effects of the intervention. Retention problems may also dilute any true difference between treatment groups. Thus, participants who change their follow-up or intervention status will be allowed, and even encouraged, to return to active participation in the study whenever feasible.

17.4.5.2 Eligibility for Reactivation

All participants who have stopped their intervention are eligible for reactivation of intervention, except those who were removed from intervention because of specific health conditions or events that necessitate stopping intervention (see *Sections 5 - HRT* and *7- CaD*) or for whom a specific request was made by their personal physician to stop intervention (unless their physician has since allowed their return to the study).

All participants who have less than full follow-up status are eligible for reactivation of activities. Do not contact participants for reactivation if they have elected "no follow-up" until at least one year has passed since their last contact of any kind. You may reactivate these participants, however, if they initiate the process and are otherwise eligible.

When a participant changes her follow-up or intervention status, the CC staff records the reason on *Form 7 - Participation Status*. Use this information and any other information available from the participant's file to determine whether it is appropriate to encourage reactivation. For future reference, mark the charts of no-contact participants indicating whether they are eligible for reactivation.

CT participants who want to reactivate and who have elected no follow-up or no intervention for one year or more must come to the CC for a visit (see *Section 17.4.5.3.1 - Reactivation from No Follow-Up or Stop Intervention Status)*. If their change in follow-up or intervention status has been for less than one year, they may be reactivated by phone.

17.4.5.3 Reactivation Approaches (Recommended)

17.4.5.3.1 Reactivation from No Follow-Up or Stop Intervention Status

Each time an eligible "no follow-up" or "stop intervention" status participant is contacted by mail or phone, she should be offered the opportunity to resume CC visits. Her response to this solicitation should be noted in the contact notes in her participant file. If she indicates that she might be interested, discuss the possibility with her by phone or in person and explain what would be needed (annual visits, routine phone contacts, becoming active in intervention) without offending or harassing her. Ask if concerns have changed since the last contact. Tell her that her contribution to the study so far is appreciated.

If prompted or requested by the participant, offer that some aspects of the visits may be modified if it would make continuing participation easier. Examples of these modifications may be:

- Convenient appointment days and times
- Annual visits instead of semi-annual
- Help with filling out forms during the visit
- No blood draw

- No bone densitometry
- Group follow-up, if available
- Help with transportation, if available
- Free, safe, or more convenient parking, if available
- Security assistance, if available

When a participant, who has previously requested no phone or visit follow-up, shows interest in returning to the study, schedule reactivation as soon as possible; do not wait for the next usual contact window. Proceed with reactivation following the guidelines in *Section 17.4.5.4 - Reactivation Visit*.

- For a participant who has had no phone or in-person contact for less than one year, schedule a telephone appointment, if possible.
- For a participant who has had no phone or in-person contact for one year or more, schedule a reactivation visit, if possible. Offer directions and a map to the CC, if needed.
- Ask the participant, *"Do you have any questions that I can answer now?"* Encourage her to call if she has any questions before the telephone appointment or CC visit. Give the CC phone number to the participant.
- Thank the participant for her time, tell her that you enjoyed talking with her and that you hope to talk to her or see her on the scheduled date.

If the participant indicates she is not interested in returning to full follow-up or intervention status, tell her that it is important that WHI maintain contact with her to meet study goals, regardless of whether she takes her study pills or follows the dietary change program.

17.4.5.3.2 Reactivation From No Follow-Up Phone Contacts

At each mail contact with a participant who has elected no phone contacts, include a solicitation to resume follow-up activities and note her response on the contact notes in the participant's file. If she indicates that she might be interested, discuss the possibility with her by phone or in person and explain what would be needed (annual visits, routine phone contacts, becoming active in intervention) without offending or harassing her. Ask if concerns have changed since the last contact. Tell her that her contribution to the study so far is appreciated.

If prompted or requested by the participant, offer that some aspects of the visits may be modified if it would make continuing participation easier (see examples above).

17.4.5.3.3 Reactivation From No-Contact Mailing (Recommended)

Telephone the participant if she responds to a mailed solicitation to rejoin the study or phones the CC to indicate she is interested in rejoining the study.

Use the following guidelines:

- Keep the tone of the phone call conversational: warm, friendly, informative, and not rushed.
- During the phone call, determine what information is applicable to the participant.
- Have the participant's chart in front of you while you are making the call. Review the chart for the participant's name, date of last contact, and reason(s) for becoming no-contact.

An example of what you might say is:

"May I speak with Mrs./Ms./Miss (participant)? Hello (participant), this is (your name) from the Women's Health Initiative at (institution name). Do you have a few minutes to talk with me?" If no, schedule a time for the call.

"Thank you for returning the postcard we sent you. I received it recently and am happy you are interested in rejoining the study. You are a valuable part of the national effort to answer important questions about women's health.

"Based on our information, you were last in the clinic in (last contact month and year)."

Follow the steps described in *Section 17.4.5.3.2 - Reactivation from No Follow-Up Phone Contacts.*

17.4.5.4 Reactivation Visit (Recommended)

The reactivation visit is designed to follow the flow of regular follow-up visits, if acceptable to the participant. Complete the same forms and procedures as you would for the routine follow-up contact, if possible.

Conduct the contact that is closest to the visit target date. If the reactivation visit date is closest to the semi-annual contact target date, do a semi-annual visit (but use your judgment about whether a semi-annual mail and/or phone contact would be more acceptable to the participant). If the reactivation visit date is closest to the annual visit target date, do an annual visit.

17.4.5.4.1 Preparation (Recommended)

The preparation for a reactivation visit is similar to that for a routine follow-up visit. Determine whether the participant has signed the current version of the appropriate consent form(s) (i.e., have participants been reconsented since this participant changed her status). If not, put two copies of the appropriate consent form(s) in the participant's file.

17.4.5.4.2 Conducting the Reactivation Visit (Recommended)

Follow the general procedure for conducting the appropriate type of visit (see *Section 16.2. - Semi-annual Contact* or *Section 16.3 - Annual (CT) and Third-Year (OS) Visits*), including the modifications below. Use judgment as to how much to include in the initial reactivation visit, because some women may need more reassurance before fully participating (some participants may need a series of visits before agreeing to fully participate).

- Informed consent interview: Begin the interview by re-introducing yourself and the study to the participant. Remind the participant of the requirements of the study as stated on the consent form. Consider whether reconsent procedures are needed and/or if they should wait until the second reactivation visit. Have the participant sign a new consent form, if appropriate. Give a copy to the participant and file the signed consent form in the participant's file.

- Medical history and personal information updates: Obtain updated medical, health, and personal information covering the period between the participant's last contact with the CC and the current visit. This information should be documented on *Form 33 - Medical History Update* and *Form 20 - Personal Information*.

- Procedures: A reactivated participant may generally be less compliant than the average participant. Be sensitive to her concerns in order to maximize further WHI involvement. Discuss with her the importance of following the WHI protocol, even though she may refuse. It is better to allow the participant to decline one particular activity (e.g., blood draws), rather than lose her entirely.

- Dispensing study pills: Do not give study pills to any reactivating participant who is unwilling to agree to appropriate safety procedures. Other procedures are also important to study goals and should be

performed unless the participant strongly opposes them. After you determine the next visit appointment date, calculate how many bottles of study pills to give to the participant. If the scheduled visit is less than six months away, give the participant one bottle of HRT and two bottles of CaD, as appropriate. If the visit is more than six months away, dispense two bottles of HRT and four bottles of CaD. Follow the usual study pill dispensing documentation procedure as outlined in *Section 15.4. - Medication Dispensing*.

- Scheduling future visits: Discuss with the participant the contact schedule in her file. If the current window for annual and semi-annual visits is inconvenient, you might modify the schedule slightly to accommodate the reactivated participant. Schedule the appropriate semi-annual or annual visit in the next visit window.

17.5 Participant Transfers Between Clinical Centers

During the course of the study, it may become more convenient for a participant to attend a CC other than the one that recruited her into the WHI study, and a participant may request a transfer to a more convenient CC. These transfers occur at the discretion of CC staff and are dependent on the feasibility of the transfer. For the purpose of participant transfers between clinics, satellite CCs are considered to be separate from their main CC, and the same policies and procedures apply to transfers between main and satellite CCs as apply to transfers between other CCs.

The primary concern when considering and carrying out participant transfers should be what is best for the participant and the study. The transfer process should be a positive experience for the participant and staff, yet still address study adherence and retention concerns. The responsibility for facilitating a smooth transfer is shared between the **originating** and **receiving** CCs. Both CCs must approve the transfers. If either CC is having difficulty with completing the process in a timely manner, referral to the Principal Investigator or designee may be appropriate.

Both the originating and receiving CCs must sign *Form 22-Participant Transfer* and submit it to the CCC before the CCC will initiate a transfer of data. When the CCC implements the data transfer, all of the participant's WHILMA records are moved from the originating CC's database to the receiving CC's database. That is, the originating CC will have no record of the participant ID, name, or other personal identifiers in its WHILMA database. The receiving CC will be responsible for any data changes, outcomes, or other tasks in WHILMA.

The following procedures are guidelines for CCs to use in communicating with each other during the transfer process.

Originating CC (see *Section 17.5.1 – Transfer Team Procedures [Originating CC]*):

- Participant makes an initial contact with the originating CC to tell staff that she has moved or will be moving. For information on appropriate considerations when a participant makes the initial contact about a transfer with the receiving CC, see *Section 17.5.2 – Transfer Team Procedures* (Receiving CC) under the heading "Participant Contacts Before Transfer Procedures Initiated."
- Based on information obtained from the participant, the originating CM and/or transfer team decides on the feasibility of transferring this participant to another CC and identifies the receiving CC.
- The Clinic Manager (CM) "transfer point person" and/or "transfer team" (see below under "Communications") identifies a CC staff person to make the next contact with the participant. This staff person contacts the participant to get further details about her move to facilitate completing the *Form 22 – Participant Transfer*. This step may occur at the same time that the participant initially contacts the originating CC about her move.
- The CM contacts (by email, fax or phone) the receiving CM to provide information about the impending transfer and to inform the receiving CC that basic documentation about the participant is being sent. Basic documentation to send to the receiving CC includes a copy of *Form 22 – Participant Transfer* (with originating CC information filled out) and reports. The originating CM may forward the *Form 22 – Participant Transfer* to the receiving CM for information, but should not sign Part I and initiate the formal transfer procedure until the participant has moved.

Receiving CC (see *Section 17.5.2 – Transfer Team Procedures [Receiving CC]*):

- Receiving CM is notified by the originating CM and receives basic documentation (see above) about the participant. Receiving CM acknowledges receipt of the information to the originating CM and identifies what steps have been or will be initially taken.
- CM and/or transfer team reviews the information, identifies an appropriate CC staff person to contact the participant, and identifies the next steps in the process.
- The appropriate CC staff contact person contacts the participant to establish if the participant is able and willing to come to the CC for visits.

- The receiving point person completes the *Form 22 – Participant Transfer*, stating that the CC agrees to accept the transfer, and sends it to the originating point person. The *Form 22 – Participant Transfer* sent to the originating CC also includes a request to send a:
  - copy or original of the participant's entire chart, including any archived sections
  - signed medical release from the participant giving the receiving CC permission to receive full CC documentation
  - sheet of participant labels
  - completed *Form 22 – Participant Transfer* signed by the originating CM.

Concluding the Transfer Process (see *Section 17.5.3. – Procedures to Finalize Transfer [Originating/Receiving CC]*):

- The originating CM sends the receiving CM the documents identified above.
- When the documents are received, the receiving CM faxes the last page of *Form 22 – Participant Transfer* to the CCC Data Coordinator.

The CCC Data Coordinator then enacts the WHILMA database transfer and informs both the originating and receiving CCs that the transfer has been completed.

Although there is no limit to the number of times a participant is allowed to transfer between CCs during the course of the study, transfers are intended to be used only for permanent (or long term) relocations of participants. Participants who will be moving closer to another CC for a limited period (less than one year), or seasonally (e.g., "snowbirds") should not be transferred.

Communications: Because communications between the originating and receiving CC is crucial to the transfer process, the originating and receiving CCs should each establish:

- a "transfer team" (e.g., CM, LN, CP, DC, OCS, retention or other staff)
- appropriate local guidelines for handling a participant transfer

The originating CM should then contact the receiving CM, provide all pertinent information about the participant and her need to transfer, and continue to follow-up with the other CM until the transfer is complete.

The CM at both CCs may also designate specific staff for contacting the participant about an impending transfer. The following are some component-specific considerations for identifying this participant contact person, as appropriate, at both the originating and receiving CCs:

- Clinic Manager or appropriate retention staff person for Observational Study or DM Comparison participants.
- Lead Nutritionist (LN) (or appropriate Group Nutritionist) for DM Intervention participants.
- Clinic Practitioner for HRT or CaD participants. Note that some CCs may designate CC staff other than the CP for CaD+DM participants.
- Staff person based on individual bonding (or anticipated bonding) with the participant may be most appropriate for participants in two or more of the Clinical Trials.

Timelines: Establish appropriate time frames for completing each step of the transfer process. Complete the steps of the transfer process quickly (e.g., the receiving CC should formally acknowledge the initial contact from the originating CC within one week of that contact). Once the receiving CM is notified by the originating CM of a transfer request and receives basic information, an acceptance or denial of the transfer should be communicated to the originating CM in a timely manner (less than 1 month). The length of time for completing the transfer process may vary because of the circumstances of each transfer (but should occur within a three month period). Send all information and documents to the receiving CC before the transfer participant's first clinic visit at the receiving CC.

Transfer Forms: The originating CC formally initiates the transfer process by completing all available information and signing Part I of *Form 22 – Participant Transfer*. The receiving CC completes and signs Part II of the *Form 22 – Participant Transfer* and faxes to the originating CC to complete Part III. The originating CC completes Part III and sends the completed *Form 22 – Participant Transfer* with the original or copied participant file to the receiving CC. The receiving CC faxes the completed *Form 22 – Participant Transfer* to the CCC Data Coordinator to complete the transfer.

17.5.1 Transfer Team Procedures (Originating CC)

The originating CC CM and/or transfer team establishes that a participant desires to be transferred to another CC (and a transfer seems appropriate) before an initial contact with the receiving CM. During this initial contact, the two CMs should discuss if it is appropriate for the CC to receive the transfer or if another CC is in a better location for the participant. The originating CC transfer team should be familiar with the participant's status to appropriately discuss and answer any questions for the receiving CC (e.g., contact information, previous transportation or attendance concerns, date of the proposed transfer).

Nutrition: If the participant is in the DM Intervention, the LNs (or appropriate Group Nutritionists) from both CCs should discuss the logistics of the transfer, schedule of classes available, and how to quickly involve the participant with the receiving CC. Discuss any logistical problems, such as transportation.

Have the appropriate originating CC nutrition staff person (e.g., LN for a DM intervention participant) conduct an exit interview with the participant. Run the final Individual Progress Report (*WHIP 0428*) and enter an end date for the participant in her originating DM intervention group in WHILMA.

It is highly recommended that an appropriate retention staff person at the receiving CC make the initial contact with DM Comparison transfer participants to enhance retention.

HRT/CaD: The originating CP (HRT, CaD) or other appropriate staff person (CaD) should be the initial person to contact the participant to initiate the transfer. Provide the participant with an adequate supply of study pills (not exceeding the usual limit) to last through the transfer process after the originating CC confirms that appropriate safety procedures, such as mammograms, are current. Have the appropriate originating CP contact and discuss the transfer with the receiving CP by email or phone. Review the participant's case, including information such as bleeding history, other symptoms or complaints, endometrial aspiration results, outstanding referrals or follow-up evaluations, adherence issues, step-down regimens, and alternative open label regimens with MPA or CEE.

The originating CC should review the participant's chart, noting the following:

- Date of next target contact and visit type (HRT, CaD)
- History and outcome of any Intensive Adherence Programs (HRT, CaD)
- Any safety issues or problems identified on any previous *Form 10 – HRT Management and Safety Interview/Form 17 – CaD Management and Safety Review* and dates of last follow-up (HRT, CaD)
- Date of randomization (HRT, CaD)
- Participation status as identified on *Form 7 – Participation Status* (HRT, CaD)
- Last two adherence rates (HRT, CaD)
- Any clinical problems or alerts identified on reports (HRT, CaD)
- Any outstanding follow-up tasks or when next are due (HRT, CaD)
- Any other information which you feel would be helpful to the receiving CC (HRT, CaD)
- Hysterectomy status (HRT)
- Date of screening EA and results (HRT)

- Any symptom (e.g., breast tenderness, bleeding, constipation, etc) that the participant may have experienced (HRT)
- Any altered dosages as identified on *Form 54 – Change of Medications* (HRT)
- Whether or not unblinding has occurred. (If so, a copy of the consulting gynecologist's records should be sent to the new CC's consulting gynecologist.) (HRT)
- Results and date of last mammogram (HRT)
- Results and date of last breast and pelvic exam and Pap smear (if applicable) (HRT)

The originating CP should conduct a "close out" interview with the participant, including:

- Date of departure
- New address and phone number of participant, if possible
- Assessment of pill supply and whether the participant needs another bottle dispensed to last her until her contact with the receiving CC
- Information on relevant receiving CC's staff names and phone numbers with information on when her next target contact is due
- (Optional) Any comments or suggestions from the participant on how to improve originating CC interactions with participants

Schedule a telephone call with the receiving CP or responsible staff to discuss the above information.

Data: Enter into WHILMA all data collected at the originating CC before sending the *Form 22 – Participant Transfer* is sent to the CCC. This includes all forms and any specimen or test results that have been done at the originating CC. Close out DM intervention participants from their originating CC intervention group. Study pill bottles dispensed to the participant do not have to be collected by the originating CC (unless you are doing a pill collection before dispensing more study pills to cover the transfer process time). Adherence on the current study pill bottle will be collected at the receiving CC once the transfer has been completed.

Reports: The *Form 22 – Participant Transfer* instructs the originating CC to run the following reports and fax them to the receiving CC:

- Personal Information Change Request (*WHIP 0441*)
- Missed Tasks at Visit (*WHIP 0618*) for CT participants for the last two annual visit contacts
- Members Outcomes Status (*WHIP 1215*) for CT and OS participants
- HRT/CaD Medication Adherence (*WHIP 1265*) for HRT and/or CaD participants
- Individual Progress report (*WHIP 0428*) for DM intervention participants
- Participant Contact Schedule (*WHIP 0472*)

Outcomes: All participant data, including outcomes data, disappear from the originating CC's database once a transfer is complete. Therefore, promptly enter completed outcomes tasks into WHILMA. Make every attempt to investigate, adjudicate, and close pending adjudications before a participant is transferred.

If an outcome is under investigation when the participant transfers, the receiving CC will complete the investigation and adjudication process. To ensure pending outcomes are investigated appropriately, it is recommended that the originating OCS contact the receiving OCS and discuss the status of pending investigations.

When one clinic begins an outcomes investigation and another completes the investigation and/or adjudication, simplify the transition by considering a "natural" stopping point, complete a particular outcomes task, key enter the appropriate information, and stop. Suggested stopping points include:

- *Form 33-Medical History Update* is completed by participant and scanned.

- *Form 33D-Medical History Update (Detail)* is completed by participant and key entered.
- Potential outcome is identified and a current Release of Information is obtained.
- Medical records documentation is requested, received, and key entered.
- Adjudication case packet is assembled and local adjudication is pending.

The participant's pending and closed adjudication case packets must be forwarded to the receiving CC for permanent archiving. Photocopy the case (medical record documents, *reports* [Member Outcomes Status Report *WHIP 1215*] and outcomes forms) and send the original documentation to the receiving CC. The originating CC keeps a copy of the case packet for their records or in accordance with local IRB guidelines.

Participant Contact: If the participant is planning to move but does not yet have a new address and phone number, instruct the participant to contact the originating CC as soon as she is settled in her new location. Confirm that the information on the Member Personal Information report [*WHIP 0441*] is correct in case she fails to establish contact and needs to be located through her personal information contacts.

Once a new address and phone number are obtained, provide the participant with the address, phone number, and name of a contact person at the receiving CC and inform her that the receiving CC will contact her. Give her an estimated timeframe as to when she should expect to be contacted by the receiving CC. A DM intervention participant should also be given the name and phone number of the receiving Lead DM Intervention Nutritionist.

The ancillary study PI will determine appropriate ongoing follow-up of ancillary study participants. Thus, for an ancillary study participant who is transferring to a CC that is NOT involved in the ancillary study, contact the ancillary study PI for specific transfer guidelines and discuss with the participant her ongoing participation in that study before completing the transfer.

Participant Files: Make copies of the participant file and send the original or copy to the receiving CC. Include any information, such as DM intervention notes, HRT notes or outcomes documents, that may be kept in separate files (DM Intervention notes may be sent in an appropriately marked separate envelope). To decrease the burden of copying and archiving the entire participant file, the originating CC may copy only the information required for archiving at their CC in accordance with local IRB and state laws. You do not need to copy or send the CC's internal tracking forms. Review the files for accuracy and completeness before sending them to ensure the transfer process goes smoothly.

17.5.2 Transfer Team Procedures (Receiving CC)

The receiving CC CM and/or transfer team will review the participant and her proposed transfer. During this review, complete the following tasks:

- Fill out and sign Part II of *Form 22 – Participant Transfer*.
- Discuss information currently available from the originating CC. Appropriate receiving lead staff should talk with appropriate originating staff (e.g., the receiving Lead Nutritionist should contact the originating Lead Nutritionist for DM intervention participants).
- Identify an appropriate receiving CC staff person (e.g., LN) to conduct a phone interview with the participant to establish continuing interest in study participation. This interview should take place as soon
  as it is feasible after the originating CC's initial contact. Include a discussion of such issues as travel distance and contact schedules. If a receiving CC cannot provide services that the originating CC has been providing (such as transportation, bone density scans, in-house mammograms, or non-English speaking staff), discuss these issues thoroughly with the participant to ensure they will not be barriers to her retention at the receiving CC. Schedule the next routine visit, even if the target date is sometime in the future.

The receiving CC should also establish if it is appropriate to have a CC visit before the transfer is approved

and/or before the next scheduled routine contact. Note that a visit to the receiving CC before the potential transfer participant is actually approved may not be practical and is not required. If it is decided to conduct a clinic visit before the transfer is completed, make sure you are aware of your local IRB guidelines for conducting a clinic visit with a participant without a signed consent. It is important that the receiving CC has sufficient contact with the participant by phone and/or mail to establish rapport and determine her interest in continuing in the study at the new CC. If a participant does not want to attend visits there, the originating CC can continue follow-up by mail and/or phone and attempt to schedule visits. However, you may need to "stop intervention" (on *Form 7 – Participation Status*) for those participants who cannot be seen at their assigned CC. Guidelines for determining minimum requirements for staying on "active intervention" are in *Vol. 2, Sect. 16.4.2 – Minimum Procedures Required For A CT Participant To Remain On Intervention* (Required) and *Vol. 2, Sect. 17.2.1 – Identifying Retention Challenges and Tracking Special Activities.*

Participant Contacts Before Transfer Procedures Initiated: If a participant contacts a receiving CC that has not yet been contacted by the originating CC to initiate a transfer, be cautious how you respond to the participant. Instead of telling the participant that you are not aware of her transfer (and can't help her), consider taking the following steps:

- Explain to the participant that information needs to be obtained from the originating CC.
- Obtain her address, phone number, and other contact information.
- Let her know who will be contacting her again.
- Contact the CM at the originating CC for more information and/or to formally initiate the transfer process (it is possible that the originating CC doesn't know that the participant has moved).

Nutrition: A DM Intervention participant retains the diet goals (fat, fruit/vegetable, grain) assigned at the originating CC. Attendance and performance data from sessions completed at the originating CC are also retained, except in the following situations:

- if the participant is assigned to an intervention group at the receiving CC before that group completes the sessions already completed by the participant at the originating CC, and
- if the participant repeats the session(s) at the receiving CC.

For both exceptions, data collected at the receiving CC become the participant's data. To avoid a break in the dietary intervention, DM intervention participants should be assigned to an active intervention group and resume session attendance as soon as possible after the transfer.

It is highly recommended that the LN or other designated nutrition staff person at the receiving CC make the initial contact with the DM Intervention participants.

HRT/CaD: The receiving CP (HRT, CaD) or appropriate other staff person (CaD) should complete the following tasks:

- Discuss participant's current status with the originating CP.
- Review information from the originating CC.
- Contact and welcome the participant soon after her arrival.
- Schedule her next appointment.
- Determine whether there are any problems, questions, or a need for more study pills.
- Continue any IAP activity that was initiated by the originating CC.

17.5.3 Procedures to Finalize Transfer (Originating/Receiving CC)

Each CC needs to approve the transfer and sign off on *Form 22 – Participant Transfer* before the participant can officially transfer (i.e., in WHILMA). Participants will need to sign a CT or OS consent (as appropriate) for the receiving CC at the first visit or before data is collected. It is recommended that participants signed HRT Update(s) sent from the originating CC be filed with the new HRT consent form the participant signs at the receiving CC.

Refusal of Transfer Participant: A receiving CC may refuse to accept a transfer for any one of the following three reasons:

- The participant refuses to attend clinic visits at the receiving CC.
- The receiving CC is unable to accommodate non-English speaking participants (assessed on a case by case basis by the receiving CC).
- The participant is an OS participant and has already completed AV3.
- The receiving CC has the option to accept an OS participant after AV3 has been completed if they choose to do so.

Issues that cannot be resolved on the clinic management level can be discussed between the respective PIs.

17.5.4 CCC Transfer Procedures

Send only the last page (page 3) of *Form 22 – Participant Transfer* to the CCC. The CCC will return the *Form 22 – Participant Transfer* to the originating CC if the last page of the form (page 3) is not complete. Once the CCC receives a completed *Form 22 - Participant Transfer* (page 3 only) from the receiving CC, the transfer will be considered to be approved, regardless of whether the participant ever visits the receiving CC. All WHILMA records for the participant will be removed from the originating CC's database and copied onto the receiving CC's database. Allow a minimum of one week from the time the CCC receives page 3 of *Form 22* for the WHILMA database records to be transferred from the originating CC to the receiving CC.

The CCC will notify both the originating and receiving CCs of the transfer when it is complete. Transferred participants will retain their original eight-digit member ID number (2-digit CC ID, 5-digit member suffix and check digit) following a transfer. The originating CC will retain credit for the randomization for any participants transferred after randomization.

Once the actual transfer of WHILMA data is completed, the receiving CC is responsible for follow-up and tracking of the participant. For DM intervention participants, the intervention group assigned at the originating CC will appear in the receiving CC's record of intervention groups, but only the data for that transferred participant's activity in that group will be transferred.

If any of the transfer participant's *Form 33s – Medical History Updates* have been analyzed in the WHILMA outcomes analyzer at the originating CC, the analyzer batch(es) from the originating CC with only the transfer participant's form(s) in it will be transferred to the receiving CC's database.

17.5.5 Ancillary Study Transfers

When a participant is transferred from one CC to another, all of her forms and other WHI data are moved to the receiving CC's database. However, her ancillary study enrollments are not transferred along with the rest of her WHILMA data. This is because only a subset of CCs participate in any given ancillary study. Thus, it is especially important that the originating CC and the receiving CC communicate about ancillary studies when initiating a transfer. If the receiving CC is not participating in the ancillary study, then no action is needed as far as WHILMA is concerned. If a participant is enrolled in an ancillary study and is being transferred to a CC that is also participating in that ancillary study, the receiving CC will need to enter the ancillary study enrollment into its database once the other WHILMA records are transferred. Please contact your CCC Data

Coordinator liaison for assistance with this. Originating CCs should remember to send ancillary study consents or data forms to the receiving CC along with the rest of the participant chart if the ancillary study is one in which the receiving CC is participating. You may also need to inform the ancillary study coordinating center of the transfer. Include the information on *Form 22 – Participant Transfer*.

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17.6 Participants Who Move To Area Without Local CC

If a participant has moved to an area without a local CC, she may still be able to continue to participate, if willing.

DM Participants - Because there are no required annual safety procedures for DM participants, it is possible for them to remain on full intervention participation status without coming to the CC for annual visits. However, their follow-up status would need to be changed to "partial follow-up", since they would be unable to come in for clinic visits. For these participants, every effort should be made to collect follow-up data by phone or mail for the duration of the study.

HRT Participants - Participants on HRT may remain on full intervention if they are willing to complete the required safety procedures outlined in *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*. For those who are unwilling or unable to complete the required procedures, indicate "Stop HRT Intervention" on *Form 7 - Participation Status* and retrieve study medications (see *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*). These participants, if willing, should remain on "partial follow-up" and every effort should be made to collect follow-up data by phone or mail for the duration of the study.

CaD Participants - Participants on CaD may remain on full intervention if they are willing to complete the required safety procedures outlined in *Section 16.4.2 - Minimum Procedures Required for a CT Participant to Remain in Intervention*. For those who are unwilling or unable to complete the required procedures, indicate "Stop CaD Intervention" on *Form 7 - Participation Status* and retrieve study medications (see *Section 17.4.4 - Retrieving Study Pills [HRT and CaD]*). These participants, if willing, should remain on "partial follow-up" and every effort should be made to collect follow-up data by phone or mail for the duration of the study.

OS Participants - OS Participants may remain on full follow-up if they have already completed their 3-year clinic visit and are not at a bone density site. Follow-up data collection (by mail and phone) will proceed as usual for these women. For those who have not completed all of the necessary clinic visits, change their follow-up status to "partial follow-up" and attempt to collect follow-up data by mail or phone for the duration of the study.

For all participants who move outside of the area, be sure to update and data enter *Form 20 - Personal Information*.

Figure17.1
Sample Form to Track Contact Attempts

1. Phone calls to the participant:

Phone Number	Date	Home or Work?	Time of Day	Outcome

2. Mailings to participant:

Date of Mailing	Details (what was mailed)?	Outcome

3. Phone calls to personal contacts

Name of first contact: _____

Phone Number	Date	Time of Day	Outcome

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Figure 17.1 (continued)

Phone calls to personal contacts

Name of second contact: _____

Phone Number	Date	Time of Day	Outcome

4. Phone calls to participant's personal health care provider:

Name of health care provider: _____

Phone Number	Date	Time of Day	Outcome

- Affix label here-

Clinical Center/ID: __ __ __ __ - ___ ___ ___ - ___

First Name _____M.I._____

Last Name _____

Figure 17.2
Intensive Adherence Program Checklist

1. Date IAP initiated: _____
2. IAP Coordinator: _____
3. Reason for enrollment: ___ Low adherence (____% adherence)
   ___ Staff referral

   Adherence problem (short description): _____

   _____

   _____

4. Steps of IAP:

   4.1 Nature of adherence problem (historical, current timing, cues, etc.)

   _____

   _____

   _____

   4.2 Self Monitoring: If Daily Diary assigned, date of recheck: _____

   4.3 Identify problem antecedents and reinforcers (symptoms, emotions, cognitions, behaviors, and/or difficult situations)

   _____

   _____

   _____

   4.4 Identify solutions

   _____

   _____

   _____

   4.5 Reinforce appropriate attributions

   _____

   _____

   _____

   4.6 Check for success

   _____

   _____

   _____

5. Date IAP ended: _____
6. Plan: _____

   ___ Return to routine follow-up ___ Refer to Retention Specialist for further evaluation

   ___ Re-evaluate in 6 months ___ Other: _____

Figure 17.3
IAP Participant Call Record

ATTEMPTS						
	Day	Date (MM-DD-YY)	Time (HR:MIN)	Spoke With	Comments	Date of Next Call
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

Figure 17.4
Daily Adherence Diary

Name: _____

Study: HRT CaD

Begin monitoring on:

Day/Date: _____

Day/Date	Took Pills?		Any unusual events today?	Any symptoms today?
	HRT _____ # of pills	CaD _____ # of pills		

Figure 17.5

Transfer Checklist*

(not data entered)

Instructions: This Transfer Checklist is an optional form to be used by both the originating and receiving CCs. Part I is completed by the originating CC and Part II by the receiving CC. Information on this form can be revised as often as necessary to communicate pertinent information between the originating and receiving CCs.

Part I Originating CC

Participant Name: _____ ID Number or ID Label: _ _/ _ _ _ _ _/ _

Date of participant's move: ___/___/___

Check all that apply:

❑ DM ❑ HRT ❑ OS ❑ CaD

❑ Subsample ❑ WHIMS ❑ Ancillary study: _____

Form 22—Participant Transfer Circulation:

	❑ CM	❑ CP	❑ OCS
	❑ LN	❑ DC	❑ Other
Exit interview conducted	❑ Yes	❑ No	___/___/___
Other: _____	❑ Yes	❑ No	___/___/___

Notes: _____

_____

Sent to receiving CC:

	Fax	Mail	Date Sent	Staff ID
Contact schedule (*WHIP 0472*)	❑	❑	___/___/___	___ ___ ___
Contact notes	❑	❑	___/___/___	___ ___ ___
Form 22 – Participant Transfer	❑	❑	___/___/___	___ ___ ___
Reports				
WHIP 0618- Tasks Missed at Visit	❑	❑	___/___/___	___ ___ ___
WHIP 1215-Outcomes Status	❑	❑	___/___/___	___ ___ ___
WHIP 1260-Pill Adherence	❑	❑	___/___/___	___ ___ ___
WHIP 0428-Individual Progress	❑	❑	___/___/___	___ ___ ___
WHIP 0441-Personal Information	❑	❑	___/___/___	___ ___ ___

Notes: _____

_____

*For CC use only. Do not send checklist to CCC.

Part II Receiving CC

Form 22—Participant Transfer Circulation:

❑ CM ❑ CP ❑ OCS

❑ LN ❑ DC ❑ Other

Participant Contact: ___/___/___ Staff ID: ___ ___ ___

❑ Yes ❑ No Willing to attend clinic visits

❑ Yes ❑ No Explained transfer process

❑ Yes ❑ No Appointment scheduled ___/___/___

❑ Yes ❑ No Sent welcome letter ___/___/___

❑ Yes ❑ No Concerns identified:

- ❑ Transportation
- ❑ Adherence
- ❑ Retention
- ❑ Other: Specify _____

❑ Form 22 signed by both CCs and sent to CCC on: ___/___/___ Staff ID: ___ ___ ___

Notes: _____

_____

Follow-up needed (include staff ID number and date):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Table 17.1
Summary of Retention Activities

Ongoing Retention Activities - All Participants (Refer to Vol. 2, Sections 2, 3, 4, 16, 17, and 20 for details)
CC Environment and Facilities (Sections 2, 17) • Make pleasant and appealing to participants • Provide convenient transportation and parking • Reimburse for travel expenses and parking, if necessary • Recruit volunteers to drive participants, if necessary • Post easy to follow signs and directions • Provide easy telephone access • Offer convenient clinic hours • Add weekend and evening hours, if necessary • Provide private area for interviews • Display health information materials in waiting area
Participant/Staff Relations (Sections 2, 17) • Maintain professional appearance • Use CC staff who have good interviewing skills • Make sure interactions are always pleasant and reassuring • Give clear and consistent instructions • Encourage active listening and open-ended questions to foster discussion • Enlist the help of a participant ombudsperson and/or advisory group
Tracking (Sections 4, 16, 17) • Use WHILMA tracking system • Send appointment reminders (include reminder phone calls 24-48 hours before appointment) • Follow-up on no-shows
Involvement of Family Members (Sections 2, 17, 20) • Invite family members to visits and special events • Encourage learning about study's purpose and design • Encourage proxy contact if participant dies or becomes ill
Participant Materials (Sections 3, 17) • Include logo and catch-phrase on recruitment and retention materials • Use at least 12-point font and sufficient white space • Make materials attractive and appealing • Make materials clear, consistent, and understandable • Prepare written materials at a 6th grade reading level • Spell and grammar check materials
During Screening (Sections 4, 17) • Effectively screen out of women who seem unlikely to stay in the trial (e.g., history of mental illness, substance abuse; negative attitudes about the study; non-compliant; confused by information; low literacy; transportation problems) • Send reminder letters for clinic visits • Conduct thorough informed consent discussions
During Enrollment/Randomization (Sections 4, 17) • Provide baseline welcome packet with folder, magnet, member ID card, "Welcome to" handouts, calcium handout, chart stickers, exercise brochure, other health education materials, appointment reminders, other component-specific information, CC contact information

Table 17.1 (continued)

Clinic Visits (Screening or Follow-up) (Sections 4, 16, 17)
• Send "Thank you" cards within a week of CC visits • Keep waiting and appointment times to a minimum • Conduct exit interviews to debrief and prepare for next contact • Have consistent contact person to ensure continuity during visit • Provide clear, easy-to-follow instructions for completing activities • Ensure materials are informative about the next contact/visit • Provide phone number and contact name in case participant has questions • Provide incentives, if available • Transfer participant if she moves to another area with a CC
Older Participants (Sections 2, 17, 20)
• Keep magnifying glass or reading glasses in form-completion area • Use large font-size in materials
Retention Incentives (Section 17)
• Provide annual follow-up visit and other incentives • Send Birthday, thank you, anniversary, bereavement, holiday cards • Annual participant newsletter mailed by CCC
Follow-up Contacts (Sections 16, 17)
• See "Clinic Visits" above for follow-up visits • Contact participants who are difficult to reach at several different times and days • Encourage some participation, even if participant is unwilling to stay on intervention or come in for visits • Initiate special retention activities for participants who are difficult to schedule for contacts • Ensure that minimum safety procedures are completed at follow-up contacts for participants on HRT and/or CaD intervention • Mail out a friendly postcard annually to participants who have requested "no follow-up" (but not to those who have requested "absolutely no follow-up") • Try to get participants who miss follow-up contacts back on schedule as soon as possible • Missed annual visits should be conducted even if the next scheduled contact is a semi-annual contact • Missed 1, 3, 6, and 9 should be conducted even if the next scheduled contact is a semi-annual contact or other annual visit • Missed OS third-year visit can be conducted for up to one year after the third-year target date • To discourage missed contacts/visits, send reminder cards and/or conduct reminder phone calls, or send second mailings to participants who do not respond
Maintaining Up-To-Date Addresses (Sections 16, 17)
• Maintain mailable addresses in WHILMA (*run WHIP 0611: Members with an Incomplete or Long Name/Address* monthly and correct any problems) • Maintain complete and deliverable addresses (run *WHIP 1211 - Undeliverable Address Report*) on an ongoing basis • Fix problem addresses as soon as possible; call participant or post office if necessary • Set "undeliverable address flag", if necessary • Contact CCC immediately if CC return address listed on newsletter changes

Table 17.1 (continued)

Searching for Lost Participants (Section 17)

- Initiate search for lost participants using *Form 23 - Search to Locate Participant* and data enter
- Conduct appropriate activities as necessary:
  -attempt to reach by phone
  -attempt to reach by mail
  -contact personal contacts
  -contact physician
  -contact other sources
- Continue to repeat attempts over a 6 month period if early attempts are unsuccessful
- Update WHILMA with any new contact information (e.g., new address)
- When search is completed, indicate search result on *Form 23 - Search to Locate Participant* and data enter
- Complete *Form 7 – Participation Status* if appropriate
- Periodically re-open search for "lost to follow-up" participants

Procedures for Conducting Special Activities for Retention Challenges (Section 17)

- Conduct all activities necessary and appropriate to situation and study component
  -see component-specific strategies summarized in tables below
  -refer to appropriate sections of Volume 2 for component-specific strategies: *Sections 5 (HRT), 6 (DM), 7 (CaD), 8 (OS), 15 (Medications), 16 (Follow-up Contacts), 17 (Retention)*
- Track activities by completing *Form 24 – Adherence and Retention Worksheet*
- Complete *Form 7 – Participation Status* if appropriate

Participation Status (Sections 16, 17)

- Initiate retention activities, if appropriate, before changing status
- Conduct search for participant, if appropriate, before changing status
- Complete *Form 7 – Participation Status* if participant's intervention or follow-up status change
- Periodically contact "no follow-up" and "no intervention" participants, as appropriate, to see if they are willing to change status

Table 17.1 (continued)

Summary of Specific Retention Activities - DM Participants (Refer to Vol. 2, Sections 4, 6, 16, and 17 for details)
CC Environment and Facilities (Sections 6, 17)
• Use comfortable classroom for DM Intervention sessions
Participant/Staff Relations (Sections 6, 17)
• Have investigators present study updates at DM Intervention potlucks • Have Nutritionists call DM Intervention participants when they miss sessions
Tracking/ (Sections 6, 17)
• Send reminders (e.g., postcards or letters) to attend DM Intervention sessions and follow-up visits • Use WHILMA reports to monitor DM Intervention participation and progress • Provide reminders for off-schedule mammograms
Involvement of Family Members (Sections 6, 17)
• Invite family of DM Intervention participants to DM Intervention potlucks and some session activities
Participant Materials (Sections 6, 17)
• Provide DM Intervention participants with session materials and binders • Provide DM Intervention participants with calculators
During Screening (Sections 4, 6)
• Use DM Eligibility Checklist • Provide DM participants with measuring cups and spoons, as needed
During Randomization (Sections 4, 6)
• Make sure that DM Control participants understand that they are in the study • Provide DM Control participants with USDA brochure of Dietary Guidelines for Americans • Provide DM Intervention participants with "Your New Eating Style" booklet 4 weeks after randomization if they have not yet started group sessions • Have Nutritionists contact DM Intervention participants monthly while they are waiting to start group sessions
Retention Incentives (Sections 6, 17)
• Provide/send DM Intervention newsletter to DM Intervention participants, Year 2+ (Maintenance years) • CC retention activities for DM Control participants are allowed, but not required
Activities for Retention Challenges (Sections 6, 17)
• Have Nutritionists contact DM Intervention participants after they miss sessions to schedule make-up sessions • Use high intensity Intensive Intervention Protocol (IIP) procedures for Level 2 and Level 3 participants having difficulty meeting Dietary Change goals • Use low intensity Interrupted DM Intervention Participation procedures for Level 4 participants having difficulty completing Dietary Change sessions

Table 17.1 (continued)

Summary of Specific Retention Activities - HRT and CaD Participants (Refer to Vol. 2, Sections 4, 5, 7, 15, 16, and 17 for details)
CC Environment and Facilities (Sections 4, 17) • Have BSE audiovisuals available • Don't have articles promoting/discouraging HRT or CaD use in waiting area • Make sure GYN exam room is clean, well-lit, secure, "friendly"
Participant/Staff Relations (Sections 15, 17) • Provide participant with a contact phone number to call if she has questions or concerns • Ensure that a clinician is available to respond to participant questions and concerns • Promote bonding by having all HRT contacts with the same knowledgeable staff members
Tracking (Sections 16, 17) • Provide reminders for off-schedule mammograms • Use reports and a tickler system for routine and non-routine calls/visits
Involvement of Family Members (Section 17) • Provide explanations and incorporate support for pill-taking
Participant Materials (Section 17) • Keep participant up-to-date on science of HRT • Develop materials that explain what recent studies about HRT really mean, in lay language
Before Randomization (Sections 4, 5, 7, 15) • Treat enrollment pills as regular study pills • Stress need for adherence and retention • Assess potential for bleeding (e.g., pre or perimenopausal) and its impact on participant's willingness to stay on HRT intervention • Ensure participant is willing to be randomized to active or placebo study pills • Clarify possibility of side-effects and stress availability of methods to deal with them
Follow-up Contacts (Sections 5, 7, 16) • Maintain schedules to ensure safety • Offer HRT Handbook and/or CaD Instruction Sheet at each contact • Offer pill organizer at each contact • Premedicate and/or use local anesthesia for participants who undergo endometrial aspirations
Identifying Retention Challenges (Sections 5, 7, 15, 17) • Complete *Form 10* and/or *17* at each participant contact and assess indicators of adherence • Discuss difficulties with adherence with participants during visits
Activities for Retention Challenges (Sections 5, 7, 15, 17) • Ensure participant has pill organizer, HRT Handbook, or any other relevant materials • Provide participant with cues for pill taking (e.g., at bedtime, when you get up, with meals) • Emphasize importance of answering the study's scientific questions and how no one can take her place • Offer to discuss concerns with participant's personal physician • Initiate the Intensive Adherence Program for those with <80% adherence
Changing Participation Status (Sections 5, 7, 15, 16, 17) • Offer participant self-management and/or step-down of study pills, rather than immediately discontinuing pills for symptoms (e.g., breast tenderness, bloating, hot flashes, GI discomfort) • Utilize algorithms and alternative dosages to decrease side effects • Stop intervention if participant is not meeting safety requirements • Retrieve study pills if intervention is stopped • If participant is willing, re-initiate study pills in women who have previously stopped, even at a minimal level

Table 17.1 (continued)

Specific Retention Activities - OS Participants (Refer to Vol. 2, Sections 4, 8, 16, and 17 for details)
Tracking (Section 16) • Indicate returned packets by either: scanning barcode in receipt screen or key-entering returned forms • Run *WHIP 1207 - Returned Packet with Missing Form* monthly to identify packets with missing Form 33 needing follow-up or track for data entry
Maintaining Up-To-Date Addresses (Sections 16, 17) • Maintain addresses in WHILMA (*run WHIP 0611: Members with an Incomplete or Long Name/Address* monthly and correct problems) • Update WHILMA if Post Office notifies of address change following non-delivery of OS mailing • Maintain complete and deliverable addresses (run *WHIP 1211 - Undeliverable Address Report*) on an ongoing basis • Fix problem addresses identified by *WHIP 1211* as soon as possible; call participant or post office if necessary • Set "undeliverable address flag" if necessary • Initiate search for lost participants using *Form 23 - Search to Locate Participant*
Materials (Section 16) • Contact CCC immediately if CC return address on OS mailing envelopes used by the CCC needs to be changed
During Enrollment (Sections 4, 8) • Make sure OS participants understand that they are in the study
Follow-up of Non-Respondents (Sections 16, 17) • Run *WHIP 1206 - OS Enrolled Members Needing CC Follow-Up* monthly for list of non-respondents requiring CC telephone data collection • Make telephone contact to ascertain correct address and collect *Form 33 - Medical History Update* • Update address in WHILMA, as appropriate • Collect data from proxy, if participant is deceased, unable to communicate, has poor cognitive functioning • Complete *Form 7 - Participant Status* if participant, as appropriate (e.g., if participant is deceased)

Table 17.2
Summary of Clinical Center Activities for Retention Challenges

		Retention Challenges	Identifying Retention Challenges	Special Activities for Retention Challenges	Documenting Special Activities	Tracking Special Activities	Ending Special Activities
Intervention	**HRT/CaD**	Low or non-adherence to pill taking regimen	• Pill count • Ppt self-reports low adherence • Ppt comments indicate low adherence • Ppt refuses pills *HRT/CaD Medication Adherence* (*WHIP 1260*) *CaD Management Recontact* (*WHIP 1048*)	IAP (Section 17.2.2.2.1)	• *Form 10 – HRT Management and Safety* • *Form 17 – CaD Management and Safety* • *Figure 17.2 – IAP Checklist* • *Figure 17.3 – IAP Participant Call Record* • *Form 24 – Adherence and Retention Worksheet* • Clinical Contact Notes	*Member Adherence and Retention Activity Tracking* (*WHIP 1238*)	• Adherence improves. • Adherence doesn't improve, but all special activities have failed. • Participant refuses study pills, and all special activities have failed.
	DM	Not meeting Dietary Change goals (Level 2 + Level 3)	*IIP Triage & Tracking (WHIP 0444)* *Individual Progress* (*WHIP 0428*)	Intensive Intervention Protocol (IIP) (Section 6.11)	• *Form 64 – Individual Data Sheet* • GN Progress Notes	*IIP Triage & Tracking (WHIP 0444)*	Participant refuses contact with nutrition staff, and all special activities have failed.
		Not completing Dietary Change sessions (Level 4)	*IIP Triage & Tracking (WHIP 0444)*	Interrupted DM Intervention Participation (Section 6.10.8)	• *Form 24 – Adherence and Retention Worksheet* • GN Progress Notes • *Figure 6.3 – Interrupted DM Intervention Worksheet*	*IIP Triage & Tracking (WHIP 0444)* *Member Adherence and Retention Activity Tracking* (*WHIP 1238*)	Participant refuses contact with nutrition staff, and all special activities have failed.
Follow-up	**CT and OS**	Not attending follow-up visits Not accepting f/u phone	*Missed Scheduled Visit (WHIP 0799)* *OS Enrolled Members Needing OS Follow-up*	16.4 16.5 16.6 16.7	*Form 24 – Adherence and Retention Worksheet*	*Member Adherence and Retention Activity Tracking* (*WHIP 1238*)	Participant refuses all follow-up participation (including safety procedures for HRT and CaD), and all special

		calls/mail	*(WHIP 1206)*				activities have failed.

Table 17.3
Reasons for Poor Retention and/or Adherence

Interactions between participants and study staff are critical to maintaining or regaining retention and/or adherence and performance. During these interactions, staff may discover the participant's reasons for wanting to change her participation status, or for low adherence to the intervention. Learning the reasons for wanting the change may help you determine your strategy to help keep the participant in the study. Some common reasons are:	
Lack of Knowledge	The participants may not have the knowledge necessary to fully participate. Participants forget instructions and may not remember what to do if something goes differently from the standard procedures. Participants may also change their behavior based on incorrect knowledge. Never assume that the participant understands and knows what to do without some form of check and review of the activities necessary to follow the regimen.
Lack of Long-Term Cues	The participant may drift off the intervention due to boredom, lack of reminders, or no recall as to why she joined in the first place.
Lack of Skills	The participant may not have the necessary skills to carry out the intervention procedures. For example, memory skills are critical to good adherence and retention. Participants may not know how to set up a personalized reminder system to cue activities, for example, to help remember to take their study pills. Discussing and even practicing the steps of a reminder system may help some participants. Assertiveness skills may be necessary for some activities. Participants need to feel comfortable calling the CC to ask questions, to report problems, or to reassure themselves that they are not harmed by the intervention. Make it clear that calling is appropriate and not a burden.
Conflicting Beliefs About the Intervention	The participant may hold a set of beliefs or ideas that are different from either the standard medical knowledge or from the study staff. Examples of these beliefs include the idea that the CC staff is not helpful or honest, that the participant is on an incorrect or inappropriate intervention, that she has received contradictory advice from friends, that she has incorrectly attributed symptoms or health problems to the intervention, or the she misunderstands what the intervention was supposed to do for her (e.g., lose weight, feel better, etc.).
Fear of Negative Health Consequences Due to Participation	The participant may hold beliefs and feelings about the intervention that interfere with adherence and/or retention. The most common of these is fear, including fear of the meaning of current symptoms, fear of future health problems, and fear of other negative consequences of study activities or procedures. Participants may worry that the intervention (or lack of intervention, if they are in the control group) will have a negative impact on their health.
Adverse Physical Reactions or Symptoms Resulting from the Intervention	Some women will experience symptoms as a result of the intervention, especially those women in the HRT or CaD components. These symptoms may make a participant so uncomfortable that she is unwilling to continue her participation in the intervention. Participants in the DM dietary change component may also incorrectly attribute health symptoms to be a result of changes in their diet.
General Health Issues	A participant's health may deteriorate over the course of the study, which may change her priorities.
Environmental Issues	The participant's environment may not be supportive of or may actively discourage full participation. Changes in home and family priorities, lack of time, logistical difficulties, unemployment, financial needs, stress, and other life changes may interfere with adherence and retention. There may be a lack of support from family or CC staff or a feeling that their participation doesn't contribute to science or the good of others. For example, the participant may inform her spouse of symptoms and the spouse may respond, "That hormone study is no good for you."
Life Events	Often life events may occur that can get the participant off the track and she may forget to get back into the intervention. These types of events tend to be more episodic than environmental issues.

Table 17.4
Strategies to Retain Full Participation in CT and OS

There are several activities that CC staff can use when encouraging participants to fully participate in the component to which they have been assigned. You may use these activities during regularly scheduled follow-up contacts, or with participants who are expressing reluctance to continue to fully participate or who are having adherence problems. You may need to make special attempts, either by mail, phone, or both, to contact those participants who have not shown up for regular intervention and/or follow-up activities.

Reinforce the Importance of WHI and Remind Participants of Their Original Commitment to WHI

- Reinforce the contributions made to-date and thank the participant for her participation.
- Remind her that her contribution is valuable and that every person's information will be necessary to reach the goals of WHI.
- Revisit the larger scientific goals and the exciting potential of WHI to answer critical questions about the health of women of all ages.
- Remind her of the contribution she is making to future generations of women.

Identify and Update Participants' Competing Beliefs and Motives

Participants join and maintain their activity in studies like the WHI for a variety of reasons. They also hold beliefs about the study and procedures that may or may not fit with current medical knowledge. These beliefs may have come from well-meaning family or friends and may not be accurate. In the face of ambiguous information in the press (for example, about HRT), participants may develop certain beliefs to explain sensations or observations about the effects of the intervention.

- Talk with the participant to uncover her beliefs about the study that may be causing her to limit or stop her participation. Discuss these beliefs without discounting what the participant is saying.
- Tell her about new studies that contradict these beliefs. Explain how she could have come to conclusions based on the evidence and show her how alternative explanations for what she has observed can also be true.
- Try to chip away at these beliefs using existing evidence to remove barriers to adherence.
- Ask the participant to discuss the problem with her primary care provider, since her problems might be due to other health problems.
- Consider having the Principal Investigator contact the participant's primary care provider to discuss the issue.

Identify Participant's Fears and Concerns

Participants may have fears or worries about the study that they do not volunteer at first.

- Probe to find these fears and discuss the reasons for them. Reassure participants when possible, especially if there is medical evidence to refute the fear.
- Do not brush away fears and concerns. Instead, explain how current medical knowledge has uncovered information she will want to consider when making her decision. For example, if a participant mentions her fear of breast cancer while taking hormones, discuss the fact that information from other studies suggest that the benefits of preventing heart disease and osteoporosis may outweigh any increase in risk of breast cancer for most women and remind her that we will monitor her throughout the study to help ensure her safety.

Anticipate and Reduce Negative Effects of Participation

One of the predictors of adherence and retention problems is the negative events (e.g., symptoms) that come from participation. These include symptoms that are caused by the study pill preparation, interference of the intervention with other activities, social barriers, etc.

- Discuss all barriers, whether experienced or anticipated, with the participant.
- Participants may need reassurance that symptoms are a normal part of getting used to the intervention (e.g., study pills).
- Interference and social difficulties resulting from participation should be addressed immediately. Probe for these at all visits. For example, participating in DM intervention may cause problems in family and social situations for dietary change participants. Try to help the participant find methods of reducing these difficulties.

Identify Problems with Convenience and Accessibility

Often participants will not stay with the study due to the inconvenience of visits or inaccessibility of the CC. If these are a problem, try to work with the participant to arrange a schedule of visits that fits with her schedule. Try to make transportation arrangements for the participant, if possible. If she is unable to attend CC visits on a regular basis, try to conduct as much of the follow-up as possible by telephone and mail.

Identify Sources of Social and Emotional Support for Participant

The relationship between the Clinic Practitioner (CP) and other clinic staff (e.g., the group nutritionist for DM dietary change participants) and the participant can be a source of social and emotional support for participation. Indicate at every reasonable opportunity that you appreciate the participant's efforts, that you are there to help her, and that you know that she can succeed in her study participation. The latter is critical, because she will likely interpret any silence on the CP's part as evidence of lack of confidence. Ask her if she has any other sources of support and encourage her to use these in addition to using CC staff.

Negotiate Any Level of Activity Possible Within the Confines of the Protocol

If you have exhausted retention activities and the participant still wants less than full participation in the study, try to keep her involved in study activities to the extent possible. Some activity is better than no activity. For example, a participant may be willing to complete forms by mail, but unwilling to come in for clinic visits or take phone calls. It is much better to collect data by mail than to not collect any data at all.

Always Leave the Conversation Open to Future Contact

If you are unable to convince the participant to continue as a full participant, keep open the possibility of future contact. Say "I'll be calling you every so often to see how you are doing", if appropriate. Never close the door to a future contact opportunity. Encourage the participant to take a break from the study and that you'll get back to her at a later time. Try to find ways to maintain period contact with participants: send postcards or call her occasionally to let her know you're interested.

Table 17.5
Strategies for Adherence to CT Intervention

Involve the Participant in Improving Her Adherence	The participant must be involved in decisions about strategies to improve adherence. The participant will be more likely to use a strategy for improving adherence if she identifies it herself, rather than receiving it from the CC staff. Ask the participant, "How can you overcome this problem?" rather than, "Here is what you should do to overcome this problem."
Be Concrete and Specific About Steps to Improve Adherence	Be very specific about the steps needed to change behavior when deciding with the participant on a course of action to improve adherence to the intervention. Set a concrete behavioral goal (e.g., "I will put this sign up on my bathroom mirror to remind myself to take my HRT study pills"), then review with her the steps needed to achieve the goal. For this example, the steps could include making the sign, deciding on its placement, discussing it with other bathroom users, hanging the sign in the bathroom, and checking in at the next clinic contact about how the sign is working.
Test to Make Sure That the Communication Exchange Has Been Clear	After every discussion, no matter what the topic, ask if the participant has any questions and give her a few moments to think about it. If there are no questions, ask her open-ended questions to review the topics discussed and the decisions made. Go beyond a simple review of the facts and statements. Attempt to question the participant as to how the discussion will affect the ways she behaves and feels. Review is particularly important when discussing instructions for conducting specific intervention activities or a new procedure.
Give Direct Skill Training and Rehearsal When Necessary	When you identify new activities and skills to improve adherence, practice them with the participant to ensure clarity and her comfort in conducting them. For example, if you and the participant have identified assertiveness as a needed skill, practice what the participant will say in the problem setting. If you both have identified a method for reminding her to take her pill every day that involves a change, rehearse it out loud during the visit or telephone call. Talk through the steps one-by-one until both of you are convinced that the participant has a clear vision of what needs to change. Begin by saying, "Let's run through it here in the office so that when you get home it will be easy."
Design Reminder Systems	Designing reminder systems may help the participant adhere to her intervention activities. Discuss with the non-adherent participant the reasons why she seems to be forgetting to follow the intervention and help her design a set of reminders that will help her stick to it (e.g., to take her daily pill). Remember to design the reminder system so that unusual days (e.g., vacations or traveling) are incorporated. Have the participant rehearse the steps to implement and use the reminder system before she leaves the clinic. Refer to other sources for strategies to remember to follow the intervention, for example, HRT participants should refer to the HRT Handbook and DM intervention participants should refer to their study manual.
Use Cognitive Rehearsal Strategies	Have the participant take time in the clinic to visualize herself carrying out the steps to good adherence that you have just discussed with her. The common steps in cognitive rehearsal are 1) Relax for a few minutes, 2) Imagine herself actually performing the activity, and 3) Visualize the success of the strategy or activity. Ask her what it will look like and how it will feel. This is a good method for identifying problems that might come up during the course of the activity.
Provide Support	Reinforce the participant's efforts, no matter how small. Help her to feel needed by indicating that her participation is valued and critical. Listen to her problems and indicate that her concerns are real and important. Reinforce the presence of the CC staff in helping to solve problems related to WHI.

Table 17.6
Examples of Retention Strategies

The following is a list of strategies that CC staff may use in an attempt to keep the participant fully participating. Use any strategies that seem appropriate. None of the activities are required and CC staff are encouraged to design their own activities.

- Initiate contacts with the participant:

  Emphasize the participant's important personal contribution to WHI: Make participant feel important and valuable to the study.

  Describe the scope and significance of WHI: Review the WHI goals and participant's contribution to goals.

  Emphasize the importance of participant: Remind participants of early commitment and consent.

  Remind the participant that WHI is research, not health care: Remind participants to see primary care provider.

  Express appreciation for the participant's effort in the project so far: Thank participant at every opportunity.

  Invite participant to talk with Clinic Practitioner: Schedule the Clinic Practitioner to discuss issues with participant.

  Remind the participant of the careful monitoring for side effects during visits and phone calls: Try to calm any fears about side effects that may result from participation.

  Remind the participant of the careful monitoring for side effects during the visits and phone calls: Try to calm any fears about side effects that may result from participation.

  Invite family or friends to CC with participant for discussion: Discuss problem issues as a group to help participant with social problems.

  Ask participant to discuss study participation with family or friends: Encourage participant to tell others of her commitment to WHI.

  Invite the participant to talk with CC Manager about questions/concerns: Schedule a time for participant to discuss with the Principal Investigator.

  Ask if the participant wants the Principle Investigator to talk with her personal physician: Schedule the Principle Investigator to call the participant's health care provider.

  Discuss fears about consequences of intervention and reassure as appropriate: Probe for fears and discuss reasons for them. Reassure participant when possible, especially if there is medical evidence to refute the fear.

  Probe for and clarify misconceptions about the study: Provide literature, as appropriate. Clarify misconceptions about symptoms, risks, etc.

  Discuss barriers to participation and help find ways to reduce: Brainstorm with the participant to address barriers.

  Anticipate and reduce negative effects of retention/adherence: Probe for negative effects, such as barriers, symptoms, time factors. Help the participant find ways to reduce these difficulties.

- Discuss alternatives to make participation easier:

  Convenient appointment days and times: Discuss alternative visit times or days to make participation easier.

  Annual visits instead of semi-annual: Offer to drop the semi-annual contact, if possible.

  Help with filling out forms during the visit: Provide assistance with WHI procedures, if available.

  Coordinate with other participants: Offer to request carpool participants and to schedule visits with others.

  Help with transportation: Offer compensation for transportation, if available.

Free, safe, or more convenient transportation suggestions: Help participants to identify transportation alternatives.

Security assistance: Offer an escort to the parking lot, if available.

Offer telephone only contact substitution (as last resort): Offer to collect data over the telephone, if possible. No blood draw (as last resort): Offer to reduce or eliminate the blood draw, if possible.

No blood draw (as last resort): Offer to eliminate the Bone Density measure.

Review instructions for required activities: Make sure the participant clearly understands what is expected of her and that she isn't dropping out due to confusion or frustration.

Help design reminders to follow intervention: Work with the participant to design reminder systems (e.g., note on bathroom mirror to help remind to take study pills).

Provide skills training and rehearsal when necessary: Talk with her about the areas she is having problems with and provide skills training, if appropriate.

- Give informational materials/referrals:

Retention incentives: Provide the participant with whatever retention incentives are available at the CC.

Disease prevention literature: The participant may want to stop participating because of misconceptions about the intervention. Provide her with relevant information about the intervention and diseases being studied in WHI, as well as other prevention literature (e.g., quitting smoking), as appropriate.

Disease etiology literature: Provide participant with any available interesting and relevant literature on the causes and prevention of disease.

Tip sheets and other health information: Provide any general health information or information specific to successful WHI participation, as available and appropriate.

Health care referrals: Provide participant with a list of other health care referrals, if appropriate, to help address her health concerns, even those not related to WHI (e.g., referrals for domestic abuse, smoking cessation, etc.).

Physician letter: Provide participant with letters of support from physicians or other health care providers in the community. Or, give her a letter to take to her own physician explaining WHI and have her discuss her participation with him/her, appropriate.

HRT/CaD handouts: Provide participants with any written information about HRT and/or CaD. This the materials provided at any of the screening or randomizations contacts or any other written material, such as brochures, articles, etc.

Review consent form/video: Show the participant the consent video and/or review her consent forms with her if she has questions or concerns about her original consent process. Discuss the issues with her.

New pill dispenser: Provide the participant with a new pill dispenser, if appropriate.

New HRT Handbook: Provide the participant with a new HRT Handbook, if appropriate.

Section 17
Retention

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