

Section 9

Retention

Introduction

Retention in the Women's Health Initiative (WHI) Extension Study is crucial to the success of the study. Retention refers to the overall strategies and procedures used to assure a participant's participation and contact in the study. Retention of study participants as defined by the study protocol is the dominant focus after the participant is enrolled.

This section describes study-wide and local retention activities designed to keep participants interested and active in the study. These activities include having regular, ongoing contact with study participants and continuing a professional, caring relationship with participants during all study contacts.

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, Field Center (FC) staff should conduct specific retention activities to encourage the participant to continue. Suggestions for dealing with those who are reluctant to continue in the study ("retention challenges") and procedures for locating hard-to-find or "lost" participants are included in this section.

Occasionally a participant will become unable or unwilling to fully participate in the study, necessitating a change in her participation follow-up status. 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. Procedures for changing participation follow-up status are described in this section.

9.1 General Activities to Promote Retention

Retention of study participants is the primary focus of activity following enrollment in the WHI Extension Study. Retention activities in the Extension Study consist of collecting the annual data forms and tracking hard to find and lost participants. Strategies and procedures to assure a participant's retention and identification with WHI must be used throughout the course of the study, from the initial consent 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 FC use (personal information updates).

A table at the end of this section (*Table 9.1 – Summary of Retention Activities*) summarizes retention activities for WHI.

9.1.1 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. During all contacts, the participant should be helped to understand the beneficial nature of participation in the study. Encourage her to call to clarify questions and problems that may arise. Assure participants that they should not hesitate to bring up any issues of concern. If a participant calls and leaves a message, be sure to get back to her promptly. Delays in returning phone calls may alienate participants. Also, be sure that the message on the FC answering machine clearly identifies the number as reaching the WHI center. It can be confusing to participants if the message refers to a more generic organization (e.g., "University Medical Center").

9.1.2 Promote Identification with WHI During Routine Contacts

All FC staff should focus on continuing to promote the participant's identity with WHI. Participants already have a strong affiliation with WHI through their years of participation, and this should continue through the end of the Extension Study. The following are suggestions for activities to promote identity with WHI.

During Enrollment

During enrollment into the WHI Extension Study, it is important to fully explain the expectations of participation in the Extension Study. At enrollment, participants receive a packet of materials designed to help them understand the requirements of the Extension Study (see *Section 6 – Enrollment.*) These materials should include a cover letter explaining the study (HT and non-HT participant versions), the Extension Study consent form, and FC contact information. Enrollment is conducted in person for most Clinical Trial (CT) participants, and by mail for Observational Study (OS) participants and those CT participants who did not attend a close-out clinic visit.

During Follow-up

During follow-up, maintaining identification with the study is particularly important for retention. Identification is promoted by regular contact with WHI 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 or telephone. These contacts help promote retention in study activities. Identification after enrollment is achieved through several activities:

- Annual follow-up mailings to collect study data (See *Section 7 – Follow-up Contacts*)
- Participant Newsletter (See *Section 9.2 – Participant Newsletter*)
- Birthday, thank you, anniversary, bereavement, and holiday greeting cards – FCs are encouraged to maintain contact with participants by sending greeting cards to mark special occasions in the participant's life. Purchasing/designing and distributing greeting cards are entirely at FC discretion.

9.1.3 FC Group Events and Activities

Field Centers are allowed to plan events and activities to promote retention, although most are not likely to hold such events during the Extension Study. For example, FCs may choose to invite participants to an event to disseminate CT and OS findings with the goal of promoting retention in the Extension Study. The occurrence of retention events and activities is completely at the discretion of the FCs.

9.1.4 Health Information and Education

Another optional FC activity is to compile a list of local services and programs for health promotion (e.g., smoking cessation) and for special support groups (e.g., bereavement, cancer). Have this available for participants if they call requesting information about resources in your area.

9.1.5 Tracking System for Participants Requiring FC Follow-Up

Several WHIX reports help track a participant's progress in the Extension Study. FCs are required to run these reports, some weekly and some monthly, to see which participants need follow-up. Follow-up may include calling participants who did not respond to the annual mailing, sending out Personal Information Updates (PIU) to participants who have recently moved, and tracking down up-to-date addresses for participants with undeliverable addresses. See *Sections 7.1.2.1 – Running Monthly Follow-up Reports from WHIX, Section 9.1.6 – Maintaining Complete and Deliverable Participant Addresses, and Section 9.2.3 – Updating Addresses for Undeliverable Newsletters.*

FCs are also encouraged to develop a system for tracking contacts and progress with "retention challenges", e.g., using the *Form 24 – Retention Worksheet* and *WHIX1238 – Member Retention Activity Tracking Report* (see *Section 9.3.3 – Documenting and Tracking Special Activities for Follow-up Retention Challenges*).

9.1.6 Maintaining Complete and Deliverable Participant Addresses

When a participant's address is found to be no longer valid (either by the Clinical Coordinating Center [CCC] or the FC), 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 9.4 – Locating "Hard to Find" Participants*). Each month, FCs should run *WHIX0611 – Address Problems* to help maintain up-to-date and

deliverable addresses in WHIX (see *Sections 10 – Data Management* for information on running these reports).

This report provides a list of all participants (or their proxies) with undeliverable addresses (indicated by the undeliverable address flag) in the FC's database. The report does not include those with participation status of "deceased," "no follow-up," or "absolutely no contact". 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.

This report also provides a list of all 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 WHIX. This will prevent follow-up mailings and participant newsletters 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.

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 9.4 – Locating Hard to Find Participants*).

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.

9.1.7 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. 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 always be reviewed with any participant who is known to have moved. Participants should be asked to provide the name of a new proxy and/or personal contact if either the proxy or the personal contacts named at the start of the study are no longer suitable to act as contacts.

FCs should use any telephone contact (e.g., to collect follow-up data) as an opportunity to review the personal information. FCs also has the option of conducting periodic mailings of the PIU to all participants to confirm that the information on file is correct.

9.1.8 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 National Institute of Health (NIH) Project Office is likely to supply talking points and a referral list of national WHI spokespersons to the FCs.

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 FC. 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.

9.2 Participant Newsletter

All participants receive a trial-wide WHI newsletter (*WHI Matters*) once a year during approximately the sixth month after the anniversary of their enrollment 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. Field Centers are responsible for documenting on *Form 9 – Participation Status* those participants who request to be deleted from the newsletter mailing list.

9.2.1 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 (GPO). Staff members at the CCC or any of the FCs are welcome to contribute ideas or articles for consideration.

9.2.2 Content

Newsletters include both project-specific and general health-related information in the following general content areas:

- Information from the WHI Director at the NIH describing the progress and importance of the WHI.
- Articles on relevant health topics.
- Description of overall progress on study activities.
- Features and interviews of WHI participants.

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 at the CCC make initial discretionary decisions regarding newsletter content, appropriateness of articles, readability level, layout, and emphasis in coverage. Before printing, a draft of the newsletter is sent to the Project Office and Executive Committee for final approval.

9.2.3 Updating Addresses for Undeliverable Newsletters

One purpose of the participant newsletter is to make sure that the address is current 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 WHIX. When the address on the mailing label is incorrect and the newsletter is not deliverable, the local Post Office will notify the CCC. 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 CCC is charged for each notification of an undeliverable address (\$.70 per address as of 6/05). The CCC will update the contact information screen in WHIX 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. A Personal Information Update will automatically be sent by the CCC to the participant's new address, in case any of the contact information has changed.

If a participant has a changed address, the Post Office does not forward the newsletter. The CCC will send another newsletter to the participant when a change of address is provided.

If address correction information is not available (i.e., "forwarding address unknown"), the CCC will set the undeliverable address flag on the "Contact Information Screen" in WHIX. Participants with an undeliverable address will appear on the *Address Problems (WHIX0611)* the next time it is produced (see *Section 9.1.6 – Maintaining Complete and Deliverable Participant Addresses*). FCs should immediately 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 9.4 – Locating Hard to Find Participants*).

If the Post Office indicates that the participant is deceased, the CCC will initiate a *Form 120 – Initial Notification of Death* and contact the FC. The FC should take steps to confirm the death and, if confirmed, process according to procedures outlined in *Section 8 – Outcomes*.

9.3 Field Center Activities for Retention Challenges

Field 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 is no longer willing to fully participate in follow-up activities. Participants who refuse follow-up contacts are considered to be retention challenges, as are those who do not complete their forms without actually refusing to participate. Both types of follow-up retention challenges require special retention activities.

A participant's follow-up participation status is the degree to which she is willing to participate in follow-up activities. Before changing a participant's follow-up status, FC staff should conduct special retention activities to try to reverse the participant's decision to reduce participation. Follow-up status should be negotiated directly with the participant. A participant who decides to reduce her participation level can usually continue to participate at some level, e.g., she may refuse to complete forms by mail but be willing to complete them by telephone.

Refer to *Section 9.5 – Changes in Participant Status* and *Form 9 – Participation Status* for information about changing participation status.

9.3.1 Identifying Retention Challenges

Most participants will perform their WHI follow-up activities as planned with no retention difficulties. Some participants, however, will want to reduce or eliminate their follow-up participation status due to a variety of reasons. A participant becomes a follow-up retention challenge and requires special activities when she is unwilling to participate in follow-up activities, including phone calls or mailings. These retention challenges need more attention and motivation strategies from FC staff.

Try to identify participants who are retention challenges before they are lost to follow-up or decide to drop out of the study. Regularly review WHIX reports that may identify challenges, such as *WHIX1206 – Enrolled Members Needing FC Follow-up*, and initiate special activities as soon as possible. See *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings* for procedures on initiating contact with participants who have not responded to data collection attempts by mail.

9.3.2 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. The FC should develop its own list of possible special retention activities that fit within the FC budget, preferences, and judgments. Try different activities for each participant, depending on previous experience with the participant and with her particular problems. In addition to the special activities described below, refer to *Table 9.2 – Reasons for Poor Retention* to help better understand some of the reasons participants may have with staying in the study, and *Table 9.3 – Examples of Retention Strategies*.

When speaking with a retention challenge, reinforce the importance of WHI and our appreciation for her contributions to date. Remind her that her contribution is valuable and that every person's information will be necessary to reach the goals of WHI. Negotiate any level of activity she is willing to do – some activity is better than no activity.

It is at the FC's discretion to decide whether or not to complete retention activities in specific situations or for certain women. For example, when a woman says she is too ill to continue in WHI, the FC 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, FC staff may attempt to dissuade her from inactivation. Each FC should develop a system for tracking participants during this period.

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.

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

When a contact has been made to conduct special retention activities with a participant who has a retention problem, complete and data enter a *Form 24 – Retention Worksheet* to help document and track activities (refer to *Appendix A – Forms, Instructions for Form 24 – 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 "recontact date" portion of *Form 24*. The names of participants

needing additional contact, as indicated on *Form 24*, will then appear on the *Member Retention Activity Tracking Report (WHIX1238)* 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 FC contact; *Form 24* does **not** need to be completed for routine retention activities.

Although use of *Form 24* is optional, its use is strongly encouraged as a way to help track activities, especially by FCs 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*. FCs should use the form in whatever way it is most useful in helping them track retention activities.

Keep detailed progress notes and flag charts of participants who, through their comments or actions, suggest a possible future problem with retention. For example, if *Form 24* is used, keep a copy with detailed notes in the chart, along with some type of sticker on the outside that indicates that this woman has retention challenges. [Have the participant’s chart in front of you when you talk with her on the phone. With the chart readily at hand, staff can easily document appropriate progress notes that can be](#) useful in future contacts.

9.3.4 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 WHI.

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” or less than full follow-up), complete *Form 9 - Participation Status* to indicate the change. See *Section 9.5 - 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 9.4 – Initiating a Search to Locate Participants [Form 23]*).

9.3.5 Re-Contacting 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 9.5.3 – Reactivation of Participants with Changes in Participation Status*).

9.4 Locating "Hard to Find" Participants

The term “hard to find” is used to designate a participant the FC has lost contact with and is searching for.

9.4.1 Initiating a Search to Locate Participant (*Form 23*)

If at any stage in the study a WHI participant misses a scheduled contact for an unknown reason, it is important for the FC 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 fails to respond to mailed questionnaires and FC staff cannot make contact with the participant either by phone or 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 *WHIX1592 – 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 FC 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*.

9.4.2 Strategies to Locate “Hard to Find” Participants

FCs should develop their own forms and procedures for tracking attempts to locate participants once a *Form 23 – Search to Locate Participant* has been initiated. For a list of participants with “open” *Form 23*s, run *WHIX1237 – Call List for Form 23 – Search to Locate Lost Participant*. A record of attempts to locate the participant should be kept in her file (refer to *Figure 9.1 – 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.

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 FC, depending on local circumstances and accessibility of useful sources of information. However, all FCs are required to meet the overall retention goals (refer to *Section 11 – Quality Assurance* for 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 FC. You can also try reverse telephone number assistance offered through directory assistance. For unlisted numbers, this service allows you to request the operator leave a message be left with the resident at the residence by the operator (for a fee).
- Attempt to contact the participant by mail. Send her a letter with “Address Correction Requested” printed on the envelope (check with the Post Office for the current appropriate terminology), requesting that she contact the FC.
- If the above is unsuccessful, send a Federal Express or certified letter to the participant’s last known address requesting that she contact the FC. Using the restricted delivery option will ensure that the participant is the one who signs for and receives the letter.
- Contact personal contacts and medical care providers 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).

- Try using people-finder search engines on the internet. See the WHI Staff home page of the website for a list of search sites.
- If the address correction information has expired, try contacting the Post Office to determine if they have a record of the forwarding address.
- Check with state and local public agencies, 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.

9.4.3 Ending the Search to Locate Participant

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 WHIX to close out the search.

If the participant is found:

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

Once contact is made with the “hard to find” participant and/or you have updated phone/mail information, data on missing forms should be collected, especially the *Form 33 – Medical History Update*. Once collected, the forms should be data entered immediately to prevent additional forms from being mailed by the CCC. 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.

If the participant is found to have moved to an address far from the FC, follow-up by mail and phone should still continue.

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 *Section 8 – Outcomes*.

If the participant is not found:

Start a new *Form 23* to conduct a search at least once every twelve months for those participants who continue to be “lost”.

The CCC will routinely request searches of the National Death Index for all participants with follow-up status “lost to follow-up” (see *Section 9.4.5 – Searches of the National Death Index*).

9.4.4 Procedures for Study-Wide Vital Status Ascertainment

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 and 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.

WHIX 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 WHIX1591 under the following circumstances:

- 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 criteria for “lost” 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 WHIX1591 under these circumstances:

- *Form 120 – Initial Report of Death* and/or *Form 124 – Final Report of Death* have 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 completed other forms in the previous 24 months, excluding *Form 33*. By definition, this participant will be included on *WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up* because outcomes data are missing. For this reason, FCs 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. Participants Who Are Lost-to-Follow-up (WHIX1591)

WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up, lists all 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 9 – Participation Status* and *23 – Search to Locate Participant* information, and prior follow-up status. For each participant listed on the report, FCs are required to conduct a search to locate the participant.

WHIX1591 – Participants Who Are Lost-to-Follow-up and Participants Requesting No Follow-up also includes participants 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 WHIX1591 – Participants Who Are Lost-to-follow-up and Participants Requesting No Follow-up

For each participant listed on the *WHIX1591*, 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 *Section 9 – 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 Observational Study Monitoring Board (OSMB) database freezes. (Notification of freeze dates is 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 24 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 FC 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 9* to change a participant’s follow-up status by using the “prior status” listed on *WHIX1591* 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 sear*-ch 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 9 – Participation Status, if appropriate*.

For any participant listed on *WHIX1591*, you need to update the participant’s follow-up status on *Form 9*, 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 *WHIX1591* who have a follow-up status set to “lost-to-follow-up,” based on the criteria described in *B.1. Participants Who Are Lost-to-Follow-up* 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 *WHIX1591* unless a new follow-up status is negotiated directly with the participant. To do this, complete *Form 9*, 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 9*. Instead complete *Form 120 – Initial Notification of Death*.

5. Data enter the *Form 23*, *Form 9* and *Form 33* before the OSMB database freeze dates, when possible.

9.4.5 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 WHIX 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 WHIX 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 FC 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 FC will then be responsible for completing *Form 120 – Initial Notification of Death* and processing according to procedures outlined in *Section 8.5 – Fatal Events – Special Considerations*.

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 who are lost-to-follow-up, if resources permit.

9.5 Changes in Participation Status

Participants are assumed to be on full participation in WHI, unless a change is indicated using *Form 9 – Participation Status*. Participation status indicates the degree to which a participant is willing or able to participate in the WHI Extension Study follow-up activities. A participant changes her follow-up status if she becomes unwilling or unable to participate in full follow-up (e.g., if she refuses 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 type of follow-up the participant is willing and/or able to have. Temporary changes, such as the inability to respond to one of her annual forms due to an illness or family problem, do not change her participation status. Similarly, ambiguous situations such as a participant failing to return her forms after several mailings does not change her status unless she actually states that she is no longer willing to participate.

Every effort should be made to encourage full participation throughout the study (see *Section 9.1 – General Activities*). Before a woman voluntarily changes status, specific retention activities should be conducted (see *Section 9.3 – Field 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. For a woman who refuses to complete forms by mail, it is important to at least get agreement to contact her by phone once a year 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 full participation. Procedures for contacting and reactivating participants are in *Section 9.5.3 – Reactivation of Participants with Changes in Follow-up Status*. *Form 9 – Participation Status* is also used to resume those aspects of participation that were formerly limited on *Form 9 – Participation Status*.

When a participant’s follow-up status changes, complete a new *Form 9 – 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.

9.5.1 Changing Follow-Up Status

Follow-up status refers to the participant’s ability or willingness to participate in WHI mailings and /or phone calls to complete annual forms. Below are the definitions and procedures relating to change in follow-up status.

9.5.1.1 Full Follow-Up

Use to indicate/resume full follow-up (mail and phone contact permitted).

9.5.1.2 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. Most women have identified a proxy, who is listed on the Personal Information Screen in WHIX. If a proxy has not been identified, the order of priority for selecting a proxy respondent is: 1) spouse or partner; 2) nearest relative; 3) friend; 4) physician. If a participant requests proxy follow-up, indicate “proxy follow-up” on *Form 9 – Participation Status* and identify the name, relationship, address, and phone number of the proxy, as well as the reason the participant is on proxy follow-up. If applicable, check the appropriate box to indicate either no phone calls or no mailings.

9.5.1.3 Partial or Custom Follow-Up

Partial or custom follow-up means that the woman is not able or willing to continue receiving either mail or phone, but is willing to receive the other (e.g., she will complete forms by phone but not by mail).

9.5.1.4 No Follow-Up

“No follow-up” status is used when a participant wants no follow-up (no phone and no mail contact), and retention activities have failed. Retention activities must be conducted before changing status to no follow-up. Only participants who verbally refuse follow-up should be classified as no follow-up. Failure to participate (i.e., consistent failure to complete and return the mailed forms) should not be used to classify a participant as no follow-up.

Contact 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 contact” and do not attempt further contacts.

9.5.1.5 Absolutely No Contact

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 contact” 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.

9.5.1.6 Lost to Follow-Up

A participant automatically becomes lost-to-follow-up when a *Form 33 – Medical History Update* has not been data entered in WHIX for at least 24 months and a *Form 23* has not been entered in the past 12 months.

See *Section 9.4 – Locating “Hard to Find” Participants* and *Form 23 – Search to Locate Participant*.

9.5.1.7 Deceased

When a woman has died and a *Form 120 – Initial Notification of Death* has been data entered, WHIX will automatically change her participation status to “deceased”. See *Section 8 – Outcomes* for the remaining procedures.

9.5.2 General Steps in Changing Participation Status

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

- Identify the problem— What aspects of the participant’s WHI participation does the participant or FC staff want to change? What are the reasons?
- Determine if retention activities need to begin by evaluating if this is a temporary problem or an ongoing one. If ongoing, conduct retention activities as described in *Section 9.3 – Field Center Activities for Retention Challenges*. If, following the retention efforts, the participant still requires a change in participation status, thank her for her WHI activity to date and complete *Form 9 - Participation Status*.
- Determine if a search for a lost participant is needed. If so, complete and data enter a *Form 23 – Search to Locate Participant* as described in *9.4 – Locating Hard to Find Participants*.

As noted above, when a problem with participation status has been identified, one of three forms may be used: *Form 23 – Search to Locate Participant* (upper part), *Form 24 – Retention Worksheet* or *Form 9 – Participation Status*. In this way, those women with less than full participation status can be tracked.

9.5.3 Reactivation of Participants with Changes in Participation Status

Reactivation is the procedure by which participants who have changed their follow-up status are re-contacted to increase their follow-up activity and/or to obtain follow-up information. The purpose of reactivation is to:

- 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

All enrolled participants will be included in data analysis; ensuring that WHI participants continue appropriate follow-up contacts is important. Thus, participants who change their follow-up status will be allowed, and even encouraged, to return to active participation in the study whenever feasible.

9.5.3.1 Eligibility for Reactivation

All participants who have less than full follow-up status are eligible for reactivation of activities. Participants on less than full follow-up status should be contacted periodically by mail or phone to see if they would be interested in resuming follow-up 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. You may reactivate these participants, however, if they initiate the process and are otherwise eligible.

When a participant changes her follow-up status, the FC staff can note the reasons for the change on *Form 9 – 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.

9.5.3.2 Reactivation From No Follow-Up Status

When a participant, who has previously requested no follow-up, shows interest in returning to the study, schedule reactivation as soon as possible. Do not wait for the next usual contact window.

- For a participant who has had no phone or mail contact for one year or more, schedule a telephone appointment to complete a *Form 33 – Medical History Update*, as soon as possible. Following reactivation, she will resume her normal follow-up schedule.
- 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. Give the FC phone number to the participant.
- Thank the participant for her time, tell her that you enjoyed talking with her and that you hope she participates in future follow-up activities.

9.5.3.2.1 Reactivation From “No Phone” Contacts

If a participant calls or writes to indicate that she might be interested in resuming phone contacts, discuss the possibility with her by phone and ask if her concerns have changed since she requested the “no phone” contact. If she agrees that phone contact is now okay, complete a *Form 9 – Participation Status* to indicate the change in her status.

9.5.3.2.2 Reactivation From “No Mail” Contact

If a participant indicates that she might be interested in resuming mailed contacts, discuss the possibility with her by phone and ask if her concerns have changed since she requested the “no mail” contact. If she agrees that mailings are now okay, complete a *Form 9 – Participation Status* to indicate the change in her status.

9.5.3.2.3 Reactivation From Proxy Follow-up

If a participant or her proxy indicate that proxy follow-up is no longer needed (e.g., she recovers from an illness that prevented her from completing the forms), complete a *Form 9 – Participation Status* to indicate the change in her status.

**Figure 9.1
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

Figure 9.1 (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

**Table 9.1
Summary of Retention Activities**

Ongoing Retention Activities - All Participants
<p>Participant/Staff Relations</p> <ul style="list-style-type: none"> • Use FC staff with good interviewing skills when making phone contacts • Make sure interactions are always pleasant and reassuring • Give clear and consistent instructions
<p>Participant Materials</p> <ul style="list-style-type: none"> • 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 • Provide clear, easy-to-follow instructions for completing activities • Provide phone number and contact name in case participant has questions
<p>Enrollment</p> <ul style="list-style-type: none"> • Conduct thorough informed consent discussions • Provide enrollment packet that describes study expectations and FC contact information
<p>Follow-up Contacts</p> <ul style="list-style-type: none"> • Contact participants who are difficult to reach at several different times and days • Encourage some participation, even if participant is unwilling to stay on full follow-up • Initiate special retention activities for participants who are difficult to schedule for contacts • Mail out a friendly postcard annually to participants who have requested “no follow-up” (but not to those who have requested “absolutely no contact”) • Try to get participants who miss follow-up contacts back on schedule as soon as possible • Encourage proxy contact if participant dies or becomes ill • Send Birthday, thank you, anniversary, bereavement, holiday cards (optional) • Annual participant newsletter mailed by CCC
<p>Maintaining Up-To-Date Addresses</p> <ul style="list-style-type: none"> • Maintain deliverable addresses in WHIX (run <i>WHIX0611 – Address Problems</i> monthly and correct any problems) • Fix problem addresses as soon as possible; call participant or post office if necessary • Set “undeliverable address flag”, if necessary

Table 9.1 (continued)

<p>Searching for Lost Participants</p> <ul style="list-style-type: none"> • Initiate search for lost participants using <i>Form 23 – Search to Locate Participant</i> and data enter • Conduct appropriate activities as necessary: <ul style="list-style-type: none"> - 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 WHIX with any new contact information (e.g., new address) • When search is completed, indicate search result on <i>Form 23 – Search to Locate Participant</i> and data enter • Complete <i>Form 9 – Participation Status</i> if appropriate • Periodically re-open search for “lost-to-follow-up” participants
<p>Procedures for Conducting Special Activities for Retention Challenges</p> <ul style="list-style-type: none"> • Regularly review reports that may indicate retention problems • Conduct all activities necessary and appropriate to the situation • Track activities by completing <i>Form 24 – Retention Worksheet</i> • Complete <i>Form 9 – Participation Status</i> if appropriate
<p>Participation Status</p> <ul style="list-style-type: none"> • Initiate retention activities, if appropriate, before changing status • Conduct search for participant, if appropriate, before changing status • Complete <i>Form 9 – Participation Status</i> if participant’s follow-up status changes • Periodically contact “no follow-up” participants, as appropriate, to see if they are willing to change status
<p>Follow-up of Non-Respondents (See Section 7 – Follow-up Contacts)</p> <ul style="list-style-type: none"> • Run <i>WHIX1206 – Enrolled Members Needing CC Follow-Up</i> monthly for list of non-respondents requiring FC telephone data collection • Make telephone contact to ascertain correct address and collect <i>Form 33 – Medical History Update</i> • Update address in WHIX, as appropriate • Collect data from proxy, if participant is deceased, unable to communicate, has poor cognitive functioning • Complete <i>Form 9 – Participant Status</i> if participant, as appropriate (e.g., if participant is deceased)

Table 9.2
Reasons for Poor Retention

<p>Interactions between participants and study staff are critical to maintaining or regaining retention and performance. During these interactions, staff may discover the participant’s reasons for wanting to change her participation status, or for lack of response to the mailed questionnaires. 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:</p>	
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.
Lack of Long-Term Cues	The participant may drift from the study because of infrequent contact, or no recall as to why she joined in the first place.
Lack of Skills	The participant may not have the necessary skills to complete the forms. For example, memory skills are critical to completing information about health outcomes. They may also suffer from loss of vision and/or hearing. Participants need to feel comfortable calling the FC to ask questions and to report problems. Make it clear that calling is appropriate and not a burden.
General Health Issues	A participant’s health may deteriorate over the course of the study, which may change her priorities. Or, she may think that her participation is not needed, now that her health is declining.
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 retention. There may be a lack of support from family or a feeling that their participation doesn’t contribute to science or the good of others.
Life Events	Often life events may occur that can get the participant off the track and she may forget to complete her study forms. These types of events tend to be more episodic than environmental issues.

Table 9.3
Examples of Retention Strategies

<p>The following is a list of strategies that FC 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 FC staff is encouraged to design their own activities.</p>
<ul style="list-style-type: none"> • Initiate contacts with the participant: <ul style="list-style-type: none"> <u>Emphasize the participant’s important personal contribution to WHI</u>: Make participant feel important and valuable to the study. <u>Describe the scope and significance of WHI</u>: Review the WHI goals and participant’s contribution to goals. <u>Emphasize the importance of participant</u>: Remind participants of early commitment and consent. <u>Remind the participant that WHI is research, not health care</u>: Remind participants to see a primary care provider. <u>Express appreciation for the participant’s effort in the project so far</u>: Thank participant at every opportunity. <u>Ask participant to discuss study participation with family or friends</u>: Encourage participant to tell others of her commitment to WHI. <u>Invite the participant to talk with FC Staff or PI about questions/concerns</u>: Schedule a time for participant to discuss with the Principal Investigator. <u>Ask if the participant wants the Principle Investigator to talk with her personal physician</u>: Schedule the Principle Investigator to call the participant’s health care provider. <u>Discuss barriers to participation and help find ways to reduce</u>: Brainstorm with the participant to address barriers. <u>Anticipate and reduce negative effects of retention</u>: Probe for negative effects, such as barriers, time factors. Help the participant find ways to reduce these difficulties.
<ul style="list-style-type: none"> • Discuss alternatives to make participation easier: <ul style="list-style-type: none"> <u>Help with filling out form</u>: Provide assistance by telephone, if needed. <u>Offer telephone only contact substitution (as last resort)</u>: Offer to collect data over the telephone, if possible. <u>Review instructions for required activities</u>: Make sure the participant clearly understands what is expected of her and that she isn’t dropping out due to confusion or frustration.
<ul style="list-style-type: none"> • Give informational materials/referrals: <ul style="list-style-type: none"> <u>Disease prevention literature</u>: Provide participant with relevant information about some of the diseases being studied in WHI, as well as other prevention literature (e.g., quitting smoking), as appropriate. <u>Disease etiology literature</u>: Provide participant with any available interesting and relevant literature on the causes and prevention of disease. <u>Tip sheets and other health information</u>: Provide any general health information or information specific to successful WHI participation, as available and appropriate. <u>Health care referrals</u>: 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.). <u>Physician letter</u>: 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.

**Section 9
Retention**

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