Section 7

Follow-Up Contacts

Introduction

Follow-up contacts with Women's Health Initiative (WHI) Extension Study participants occur to collect follow-up data, maintain current contact information, follow participants for study outcomes, and promote retention. These contacts provide an opportunity for Field Centers (FCs) to continue a professional, caring relationship with the participant throughout the duration of the study. Follow-up contacts include the following:

- Annual mail contacts (CCC).
- Annual phone contacts to participants who do provide data by mail (FC).
- Non-routine contacts (FC).

Required forms for follow-up data collection are identified in *Appendix A – Forms*. All Clinical Trial (CT) participants who were not enrolled in the HT receive the same follow-up data collection forms as Observational Study (OS) participants; participants who were enrolled in the HT receive additional data collection forms. The target dates for the routine annual follow-up contacts (mailings or phone calls for those on "no mail") and newsletter mailings are based on the original WHI randomization or enrollment date. Changes in participation status do not alter these target dates.

This section describes the required and recommended procedures for carrying out routine and non-routine follow-up contacts for all WHI participants. Refer also to *Section 5 – Guidelines for Interactions with Participants* for information on interviewing procedures and dealing with special situations that may be encountered during follow-up contacts (e.g., domestic violence, cognitive decline).

7.1 Annual Mail Contact and Follow-Up of Non-Responders

Follow-up data are collected annually from participants enrolled in the WHI Extension Study. Activities to collect the data consist of a series of mail and telephone contacts during the follow-up period. Data collection attempts by mail (Contacts 1-3) are conducted by the Clinical Coordinating Center (CCC) on an annual basis. For participants who do not respond to Contacts 1-3, data collection attempts by telephone (Contact 4) are conducted by FC staff.

Annual mailings to OS participants began the first week of May, 2005, and to CT participants in October, 2005. The timing of mailings is determined by the participant's original enrollment/randomization date in WHI. For the first year (2005-2006), the mailing schedule is slightly different, and is based on whether the participant's close-out visit was an annual or semi-annual visit. By August 2006, all participant mailings follow the regular mailing schedule as described below.

7.1.1 CCC Responsibilities for Annual Follow-Up

A series of mail contacts to collect follow-up data from WHI Extension Study participants is conducted annually by the Clinical Coordinating Center (CCC). The CCC is responsible for all printing (through the Government Printing Office [GPO]), assembly, and outgoing postage costs for the mail contacts. The three mail contacts include:

- An initial mailing of the entire questionnaire packet (Contact 1), mailed 2 months before randomization/enrollment date.
- A second mailing of the entire questionnaire packet to those who do not respond to Contact 1 (Contact 2), mailed 3 months after the first mailing.
- A third mailing of the entire questionnaire packet to those who do not respond to Contacts 1 or 2 (Contact 3), mailed 2 months after the second mailing.

Spanish-language versions of the contact materials are mailed to participants whose primary language is Spanish, as indicated by the "Preferred Language" flag on the Contact Information Screen in WHIX (see *Section 10 – Data Management*).

CCC staff will mail Personal Information Updates (PIU) to participants when they learn of address changes (via the US Post Office), and will complete a *Form 120 – Initial Notification of Death* when they are notified that a participant is deceased.

7.1.1.1 Mailing of Annual Questionnaire Follow-Up Packet 1 (Contact 1)

A follow-up packet is mailed annually by the CCC to all WHI Extension Study participants (except those with an invalid address or whose participation status in WHIX is set to no CCC mail contact, no follow-up contact, absolutely no contact, or deceased) two months before the participant's enrollment/randomization anniversary month.

If a participant does not meet the criteria at the time of her scheduled mailing, WHIX will continue to check her status each month to see if she is eligible for a mailing. For example, if she has an undeliverable address when she is first due and then the address is corrected, she will receive a mailing the following month. The CCC will try monthly for seven months to send a Contact 1 mailing to a participant. If, after seven months, the participant still does not meet the criteria to receive a mailing, the FC is responsible for attempting to collect the forms that would have been sent in the packet.

If a participant enrolls in the WHI Extension Study after her scheduled mailing would have occurred for that year, she will appear on *MAIL003 – Members Needing FC Follow-Up* for that year, and will resume the normal mailing schedule the next year.

The Contact 1 packet includes:

- A cover letter with the FC telephone numbers listed (see *Figure 7.1 – Cover Letter for Contact 1)*;
- A postage-paid, CCC-addressed return envelope with business reply information;
- A sharpened #2 pencil;
- Data collection forms. All participants receive a *Form 33 – Medical History Update* and a *Form 151 – Activities of Daily Life* annually. In addition, participants who were enrolled in HT receive *Form 150 – Hormone Use Update* annually. All participants receive a one-time form, *Form 134 – Addendum to Medical History Update*, in their first annual packet.

The *Form 33* has two labels:

1) **Date Label**: a Date Label with date of the last WHI Medical History Update (finished date of last *Form 33*), contact number (C1, C2, or C3), and participant ID.
2) **Participant ID label:** a Participant Identification Label with participant name, participant ID and barcode, contact number (C1, C2, or C3), and form number.

All other forms have only a Participant Identification Label, with participant name, participant ID and barcode, contact number, and form number.

The packet is sent third-class (bulk) mail in a mailing envelope printed with the CCC's return address, the CCC bulk mailing permit number, and a request for notification of change of address.

7.1.1.2 Second Mailing of Entire Follow-Up Packet (Contact 2)

A second complete follow-up packet is mailed the month after the participant's enrollment/ randomization anniversary month (three months after the mailing of Contact 1) to those participants who did not respond to the first mailing (i.e., those who did not complete and return the forms sent in Contact 1). If a participant does not complete all of the forms originally mailed in Contact 1, the Contact 2 packet includes only those forms not returned in response to the first mailing.

The Contact 2 packet includes:

- A cover letter (different from the Contact 1 cover letter--*see Figure 7.2 – Cover Letter for Contacts 2/3*) with FC telephone number listed;

- A postage-paid, CCC-addressed return envelope with business reply information printed on the envelope;
- Any data collection forms that were not completed and returned in response to the first mailing.

The packet is sent third-class (bulk) mail in a mailing envelope printed with the CCC's return address, the CCC bulk mailing permit number, and a request for notification of change of address.

7.1.1.3 Third Mailing of Entire Follow-Up Packet (Contact 3)

A third packet (identical to the Contact 2 packet) is mailed three months after the enrollment/ randomization anniversary month (two months after Contact 2) to non-responders only (i.e., those who have not completed and returned all of the forms sent during earlier contacts). Only those forms that were not completed during earlier contacts are included in the Contact 3 packet.

7.1.1.4 Processing Returned Packets (Contacts 1-3)

CCC staff is responsible for indicating in WHIX that packets have been returned. When a packet of forms is received at the CCC, the forms are scanned immediately, which prevents those forms from being sent to the participant again. Return of a form is indicated by scanning the entire form in WHIX. The scanned form data and image will be available to the FC within two weeks of the form arriving at the CCC.

When possible, the CCC will correct errors, such as light bubbles. Forms with data errors such as multiple marks, missing data, or incorrect skip patterns will be scanned as usual, but FC staff will be responsible for contacting participants by telephone to resolve problems (e.g., missing data) on *Forms 33* and *134*. Problems needing resolution by the FC will be identified at the CCC and will appear on *QA001 – Unresolved Alerts*.

Participant Comments on Forms:

CCC staff will also review the form for any handwritten comments, post-it notes, or letters. When notes are written on the form, they will be scanned along with the form. If there are comments on the form, the CCC will bubble in the FCA (Field Center Alert) bubble on the form. The FC can check for comments on the form by looking at the FCA field on the encounters screen. Forms with the FCA bubbled in will appear on *FCA001 – Forms with Comments to Review*. The CCC flags any health or study-related note written on a form, or any personal note that is a request for FC attention. The CCC does not take action if a participant requests to be taken off the study; in these cases, the FC must follow-up with the participant. Comments are not always written in the "comments" section of the form; sometimes they are written in the margins, so FCs should be sure to review the entire form for comments. Post-its, letters, or other communication enclosed with the forms are sent to the FC in the weekly mailing.

Unscannable Forms:

If a form cannot go through the scanner (e.g., because it's torn or crumpled) the form will be key-entered by the CCC. No images will exist for key-entered forms. The CCC will send the originals to the FC.

Incomplete Packets and/or Non-Response:

If a packet containing only one form is returned, the CCC scans the form to indicate that it has been received. If any of the forms were not returned in the packet or they were returned blank, they will be resent as part of the Contact 2 and possibly Contact 3 packets.

Following the three mailings, if a participant still has a missing form(s) or has not responded to any of the mailings, she will appear on *MAIL003 – Members Needing FC Follow-Up* (see *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*).

7.1.1.5 Making Address Corrections and Updating Personal Information

Each packet mailed out to WHI Extension Study participants has the CCC's return address in the upper left-hand corner, with the line "Change Service Requested" printed underneath. In the event that the participant's address on the mailing envelope is incorrect, the U.S. Post Office (USPO) will provide the CCC with a photocopy of the envelope and a statement as to why it was not delivered. If the address has been changed, the new address will be provided. If the address has changed and no forwarding address is available, it will be marked "undeliverable". An envelope may also be returned with a "deceased" stamp (See *Section 7.1.1.6 – Completing Form 120 for Deceased Participants*).

For **changed addresses where the new address is provided by the USPO**, the CCC will update the address in the "Contact Information Screen" in WHIX immediately. This will prevent future mailings from being sent to the old address. The CCC will mail a *WHIX0441 – Personal Information Update* (PIU) to the participant and ask her to review and update any incorrect information. The participant will return corrected PIUs to the CCC in a postage-paid envelope.

When a participant has an **undeliverable address and a new address is not available**, the CCC will set the "undeliverable address" flag on the "Contact Information Screen" immediately (see *Section 10 – Data Management*). This will prevent future mailings from being sent to the undeliverable address. The FC should run *WHIX0611 – Address Problems* monthly and obtain correct addresses for participants who are listed on the report.

The CCC does not change address information or mail out a PIU to participants who have sent in an address change as a handwritten note on a form. These notes are sent to the FCs for FC staff to take the appropriate steps to follow up (i.e., contact the participant to confirm the change and send out a PIU for review).

7.1.1.6 Completing *Form 120 – Initial Notification of Death* for Deceased Participants

In the event that the CCC learns that a participant is deceased, the CCC will complete and key enter a *Form 120 – Initial Notification of Death* with the date of death only. This will prevent additional mailings to that participant and will automatically set her participation status to "deceased". The CCC will notify the FC by e-mail and send the *Form 120* and any notes, comments, or letters from family members or the USPO to the FC. FCs will process these participants according to procedures in *Section 8 – Outcomes*.

7.1.2 FC Responsibilities During Annual Follow-Up Mailings (Required)

The FC's responsibilities during the follow-up mailings include:

- Running weekly and monthly follow-up reports in WHIX.
- Following-up with participants who do not respond to the mailed packets.
- Following-up with participants who have missing data or multiple marks on a form.
- Reviewing forms with comments to see if action is needed.
- Collecting a *Form 33D – Medical History Update (Detail)* when indicated by data provided on *Form 33 – Medical History Update*.
- Completing procedures outlined in *Section 8 – Outcomes* when notified that a participant is deceased.
- Sending out Personal Information Updates to participants with address changes, if the FC learns of the address change.
- Conduct participant searches as needed.
- Making address and other contact information corrections as soon as they become available.
- Collecting mammograms and data entering *Form 85 – Mammogram*.

7.1.2.1 Running Monthly Follow-up Reports from WHIX

Several reports are available to help FCs keep track of the status of participant follow-up. Detailed instructions for running these reports in WHIX are given in *Section 10 – Data Management*.

Every month, each FC should run the following reports:

1. *WHIX0611 – Address Problems*. This provides a list of all participants (or their proxies) with undeliverable addresses in the FC's database. It does not include those with follow-up status of no follow-up, deceased, or absolutely no contact. Included on the report are the participant's name and (undeliverable) address; member ID; home phone; work phone; applicable notes; best time to call; telephone numbers for other contacts; follow-up status; and date marked (i.e., the date the undeliverable address flag was set).

   Undeliverable addresses should be updated as soon as possible, since a participant will not receive any mailings until the address is fixed. If the participant does not receive her mailings, the data will eventually need to be collected by FC staff (see *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*). Also, the sooner you try to get an address correction, the more likely it is that you will be able to locate the participant. Undeliverable addresses should be corrected within one month of appearing on *WHIX0611*. Participants will continue to appear on this report until the "undeliverable address" flag has been removed or follow-up status changes.

   This report also provides a list of participants (or their proxies) with problem addresses (e.g., the address is incomplete or will not fit on a mailing label). Address lines that are too long should be fixed immediately. An address line is too long if it appears on this report as more than one line. To fix the problem, use Address Line 2 for the second line of the address, or abbreviate words in the first line so that they stay within the 30-character width limit of the mailing labels.

   Addresses that are incomplete should be resolved as soon as possible. If the zip code is missing, try calling the USPO or the participant to obtain the complete/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 mailings from being sent to an undeliverable address. Incomplete addresses should be fixed within two weeks of appearing on *WHIX0611*. Participants will continue to appear on this report until either the address has been fixed or the "undeliverable address" flag has been set. Once you have made all of the necessary edits indicated on the report, run the report again to confirm that problems have been cleared. Note: You do not need to correct international addresses that appear because they have no zip code, etc.

2. *MAIL003 – Members Needing FC Follow-Up*. The purpose of this report is to provide a list of those participants who have not completed all of the required data collection forms (i.e., *Form 33 – Medical History Update* [collected annually], *Form 150 – Hormone Use Update* [HT only] and *Form 134 – Addendum to Medical History Update* [collected during first year of follow-up only]) following the three CCC mailings. A participant appears on this form two months after the mailing of Contact 3 if no *Form 33* has been data entered since Contact 1 was initiated and if her follow-up status is not any of the following: no follow-up, deceased, or absolutely no contact. Participants also appear on this report if the CCC was unable to mail the data collection packets (i.e., if they are on "no mail" follow-up or if they have an undeliverable address). FCs should not attempt to contact participants to collect annual form data until they appear on the report.

   This report lists participant name, participant ID, home phone number, work number, best time to call, phone numbers of other contacts, and follow-up status. As described below in *Section 7.1.2.2 – FC Data Collection for Non-Respondents to Mailings*, FCs should use this report as a prompt to initiate follow-up contacts to participants who have not completed a *Form 33*.

   Participants remain on this report until one of the following occurs: either a *Form 33* has been completed; follow-up status changes; or the next year's contacts begin.

3. *FCA001 – Forms with Comments to Review*. This report lists the participants with handwritten comments on their forms requiring FC review.

4. *WHIX0621 – Outcomes Screening Action Required*. The purpose of this report is to provide a list of participants who need a phone contact to clarify data received on their outcomes follow-up forms (*Forms 33* and *134)*. This contact may be necessary in the case of missing data, multiple marks on an item, or incorrect skip patterns.

5. *WHIX0622 – Members with Potential Outcomes*. This report identifies participants who need a *Form 33D* (see *Section 8 – Outcomes*).

6. *QA001 – Unresolved Alerts*. This report provides a list of participants who need a phone call to correct forms that have missing or inconsistent data on any of the follow-up forms.

7.1.2.2 FC Data Collection for Non-Respondents to Mailings

FCs are required to attempt to collect *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update* (collected during first year of follow-up only), and *Form 150 – Hormone Use Update (HT only)* for participants who have not responded to that year's mailings. If a participant has not responded to Contacts 1-3, FC staff should initiate telephone contacts to collect the data. This is done through a series of attempts to reach the participant or her proxy to collect the data. Non-respondents needing follow-up data collection are listed on *MAIL003 – Members Needing FC Follow-Up*.

FC follow-up data collection activities consist of two types of contacts: a phone contact to ascertain correct address and to collect *Form 33 – Medical History Update* from the participant or proxy (Contact 4), and, if needed, mail or phone contacts with the personal contacts to trace participants.

FC attempts to collect *Form 151 – Activities of Daily Life* from non-respondents are optional.

Any data forms collected by FC staff will be data entered at the FC.

7.1.2.3 Telephone Contact to Ascertain Correct Address and to Collect Medical History Update (Contact 4) (Required)

If *Form 33* has not been returned by two months after the third mailing of the follow-up packet (CCC Contact 3), the FC should attempt to reach the participant by telephone. The purpose of this call is to confirm that the correct address is shown in WHIX and to complete *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update (first annual follow-up only),* and *Form 150 – Hormone Use Update (HT only)*. Use *MAIL003 – Members Needing FC Follow-Up* to determine which participants require follow-up telephone contacts.

Direct contact with the participant or other personal contact is preferable at this point to confirm that we have the correct address and phone number for her (e.g., a message left on an answering machine reminding her to mail in the packet is not sufficient since there is no way to confirm that she has received the packet or the phone call).

When calling, make at least 8 telephone attempts the first month and 4 attempts the second month during the "best times to call" (identified on *Form 20 – Personal Information*). Refer to *Figure 7.4 – Suggested Script for Contact 4 Telephone Contact*. If contact is made with the participant, verify the address and complete *Form 33* over the telephone. *WHIX0441 – Personal Information Update*, can also be completed at this time. Completion of any other forms (i.e., *Form 151*) is optional, depending on the willingness of the participant to complete additional forms by phone.

If you determine that the telephone number and/or address have changed, update WHIX accordingly. If a participant requests a change in her participation status, you may initiate a *Form 24 – Retention Worksheet* (see *Section 9.3 – FC Activities for Retention Challenges*), if appropriate. If you find out that she is deceased,

complete a *Form 120 – Initial Notification of Death* and process according to *Section 8 – Outcomes*. Data entry of *Form 120* will automatically set her participation status to "deceased".

FCs have the option of mailing the forms to participants who, as determined by the phone contact, are willing to complete the forms but are unwilling to complete them over the phone. These forms should be data entered at the FC upon receipt.

If you are unable to make contact with the participant, contact her proxy or one of her personal contacts to determine the location and vital status of the participant. After this contact, continue to try to reach and interview the participant, if appropriate. If you learn during this process that the participant is unable to complete the forms herself, attempt to collect the data from her proxy. Do not interview the proxy unless the participant is deceased, unable to communicate, or has poor cognitive functioning. (See *Section 7.2 – Follow Up by Proxy.*)

7.1.2.4 Making Address Corrections and Collecting Personal Information Updates

For **changed addresses where the new address is provided by the USPO in response to a mailing**, the CCC will update the address in the "Contact Information Screen" in WHIX. The CCC will mail a *Personal Information Update* to the participant at her new address, along with a postage paid return envelope addressed to the CCC. The CCC will enter any changes the participant has written on the returned PIU and send the form to the participant's FC.

When a participant has an **undeliverable address and a new address is not available**, the CCC will set the "undeliverable address" flag on the "Contact Information Screen" immediately. This will prevent future mailings from being sent to the undeliverable address. Participants with an undeliverable address will appear on the *WHIX0611 – Address Problems* the next time it is produced (see *Section 7.1.2.1 – Running Monthly Follow-up Reports from WHIX (Required)*). FC staff should initiate a search to find the correct address by contacting the participant. Refer to *Section 9.4 – Locating "Hard to Find" Participants* for instructions on conducting searches for lost participants. Try to update the address as soon as possible, so as not to lose permanent contact with the participant.

When the FC learns of any change to personal information that comes from a source other than the CCC (e.g., the participant calls the FC directly or they learn of the change during a data collection phone call), the FC needs to either mail out a Personal Information Update for the participant to review, or needs to review the information with the participant by telephone. The CCC will automatically mail PIUs to participants if it learns of an address change through the annual mailings.

7.1.2.5 Processing Information on Deceased Participants

When the FC learns that a participant is deceased (either from the CCC or a family member), FC staff should initiate contact with persons listed her Personal Information Update. If a death is confirmed, complete and data enter a *Form 120 – Initial Notification of Death* and process according to procedures outlined in *Section 8 – Outcomes*. This will automatically change her participation status to "deceased".

7.1.2.6 Handling Mailings to Snowbirds

There are two address options in WHIX for each participant. FCs can change the "current address flag" to indicate which address is to be used for mailing during a particular time period. This is useful for participants who are known to be away for a predictable portion of the year. Dates are included on the screen to help remind the FCs of the participant's location during that time. FCs are responsible for indicating which address is the best one to use by setting the flag next to that address. If the alternate address becomes the better address, FCs can set the flag to indicate that the alternative should be used for mailings. FCs can run the *ADR001 – Addresses for Members with More Than One Address* report to help remind them when the flags should be reset for a particular participant. If FCs don't get a chance or don't wish to change the flags for a participant with more than one address, participants are still likely to eventually receive the packet, since packets are mailed up to 3 times over a period of 7 months.

7.2 Follow-Up by Proxy

Some follow-up contacts, because of a participant's illness, disability, or death, may need to be conducted with a proxy. A proxy "stands in" for the participant and provides information about her health. The proxy should be someone who has frequent contact with the participant and knowledge of her health status. Use *Form 20 – Personal Information* for information on where to locate proxies. When contacting proxies, use the following order of priority: 1) proxy identified on Personal Contact Screen; 2) spouse or partner; 3) nearest relative; 4) friend; 5) physician. Refer to *Figure 7.5 – Suggested Script for Proxy Telephone Contact*.

If the participant is deceased, unable to communicate, or has poor cognitive functioning, *Form 33* data are collected from the proxy by either telephone or mail. If data are to be provided by a proxy, complete *Form 9 – Participation Status* to change the follow-up status to "proxy" (except if the participant is deceased). When a proxy is identified, confirm that the proxy contact information on the "Contact Information Screen" in WHIX is correct and make corrections as needed.

7.2.1 Designating a Proxy

FCs must have Institutional Review Board (IRB) approval to collect participant data from a proxy if the participant's consent form does not include explicit approval for contact of personal contacts.

Approval to conduct follow-up contact(s) by proxy should be a careful decision based on the participant's situation and the individual proposed to serve as her proxy. Obtain approval to conduct contacts by proxy from the participant or her legal next-of-kin, if possible. Proxy contacts must be approved by the FC Principal Investigator (PI) and other FC investigators, consultants, and/or staff, as determined at your FC.

When the proxy is first identified, establish contact with that person(s) and discuss how he/she was identified as the proxy (e.g., listed as a close contact or her personal physician). Determine if s/he has any questions about the study and/or the proxy role. If necessary, initial contact with the proxy can be by mail. When contacting a proxy by mail, include the *Cover Letter for Proxy Contact (Figure 7.6)* to explain the purpose and role of the proxy.

Local IRB approval of the materials and procedures is required before collection of proxy contact information can begin. If the local IRB requires changes to the materials or procedures, FCs may modify them as requested. Revised participant materials should be submitted to the CCC for review before use.

7.2.1.1 For Participants Who Do Not Have a Designated Proxy

If a participant has not designated a proxy, or if the proxy is deceased, cannot be located, refuses contact, or is unable to participate, FCs may (subject to local IRB approval) contact one of the participant's other personal contacts to serve as the proxy.

When using other personal contacts to collect proxy information, in order of data collection preference, contact:

- Spouse or partner
- Other close family member
- Close friend
- Health care provider

7.2.2 Proxy Follow-Up by Mail by CCC (Required)

The CCC will mail the annual data collection forms directly to the designated proxy when a participant is on "proxy follow-up". These forms will be mailed according to the same procedures as those used for non-proxy participants (i.e., three mailed contacts) with a cover letter specifically designed for proxies (see *Figures 7.6 – Cover Letter for Proxy Contact* and *7.7 – Cover Letter for Proxy Contact 2/3)*. A field on the PIU screen allows a proxy's address to be flagged as undeliverable.

If the participant is on proxy follow-up but a proxy has not been identified, the participant will appear on *MAIL003* and FC staff will need to identify a proxy and collect follow-up data for that year. Once contact information has been entered in WHIX, data will be collected from the proxy by mail in subsequent years.

7.2.3 Proxy Follow-Up by Phone by FC

If a proxy fails to reply to the mailed attempts, he/she will appear on *MAIL003 – Members Needing FC Follow-up* to collect *Form 33* (and *Form 134*, if not collected previously). (See *Figure 7.5 – Suggested Script for Proxy Telephone Contact*). Phone contact with the proxy may also be necessary if repeated attempts to reach the participant have failed, or if the participant is recently deceased. When the proxy is first contacted by the FC, discuss how that person was identified as the proxy (e.g., designated by the participant, listed as a personal contact). Determine if s/he has any questions about the study and/or the proxy role. Provide the proxy with relevant information about the study (e.g., Proxy Update, consent forms, study information sheets), as needed. Any ongoing efforts used to promote rapport and retention with the participant should also extend to your contacts with the proxy.

If the participant is alive, each proxy contact should be preceded by a discussion of the participant's ability to resume her own follow-up contacts, depending on her particular situation. If it has not been done, complete a *Form 9 – Participation Status*, to reflect that she is on "Proxy follow-up" and complete the proxy's contact information.

If the participant is deceased, details on proxy follow-up outcomes information are described in *Section 8 – Outcomes*.

For participants on "proxy follow-up", all relevant forms will be collected by mail annually. These may include:

- *Form 33 – Medical History Update* and, if appropriate, *Form 33D – Medical History Update (Detail).*
- *Form 134 – Addendum to Medical History Update* (collected during first annual data collection only).
- *Form 151 – Activities of Daily Life*
- *Form 150 – Hormone Use Update* (for HT participants only)
- *WHIX0441 – Personal Information Update.*

For participants whose proxies do not respond to the mailed forms, collect only *Form 33 – Medical History Update, Form 134 – Addendum to Medical History Update,* and *Form 33D – Medical History Update (Detail)* by phone. The other forms should not be collected by phone from the proxy.

For women who are deceased (see *Section 8 – Outcomes*), collect the following from the proxy:

- *Form 120 – Initial Notification of Death*
- *Form 33 – Medical History Update* and, if appropriate, *Form 33D – Medical History Update (Detail).*

7.2.4 Using Proxies to Obtain Medical Records

The role of the proxy in obtaining medical records is determined by local state and institutional laws and policies. The designated proxy, especially if she/he is a family member or has medical power of attorney, may be able to sign medical releases. FCs will need to contact their local IRB and medical institutions for information and policies on this issue.

7.3 Follow-up of Participants with Less than Full Participation Status (Required)

For women with less than full participation status, collect annual forms to the extent possible, given her status. Specific situations are given below as examples.

7.3.1 Participants on No Mail Follow-Up

Annual follow-up mailings will not be sent to participants who have requested "partial follow-up with no mail". For a woman who refuses mail contact but allows phone contact, the FC will collect the forms by telephone annually. These women will appear on *MAIL003 – Members Needing FC Follow-up*, along with non-responders.

7.3.2 Participants Who Are Lost-to-Follow-Up

Continue to search periodically for participants who are lost to follow-up. For procedures, see *Section 9.4 – Locating "Hard to Find" Participants*. Annual mailings will continue to be sent to women who are "lost-to-follow-up", in the hopes that they will complete a *Form 33* and no longer be "lost", as long as they have a deliverable address in WHIX. Mailings are not sent to "lost to follow-up" women who have an undeliverable address.

7.3.3 Participants on No Follow-Up

A letter or postcard (see model in *Figure 7.8 – Postcard for Participants on No Follow-Up*) should be sent or phone call made yearly to inquire if the participant would be willing to "rejoin" the WHI Extension Study or if she would, at a minimum, complete *Form 33 – Medical History Update*. See *Section 9.5.3 – Reactivation of Participants with Changes in Participation Status*.

7.3.4 Participants on Absolutely No Contact (Required)

Do not mail, phone, or attempt to collect data from participants who have requested absolutely no contact.

7.4 Non-Routine Contacts

Non-routine contacts may occur for any WHI Extension Study participant. These contacts give the FC the opportunity to continue efforts to build rapport and promote retention. Reasons why a participant may contact the FC non-routinely in person or by phone are detailed below along with brief information and references on how to manage such contacts:

- **Questions about the WHI study (perhaps in response to a recent news item):** The nature of the participant questions will determine the approach you take. Refer the participant to a FC staff person or investigator who has understanding of the issues involved with the news item or specific skill in responding to concerned participants (see *Section 9 – Retention*).
- **Report an outcome or other major event:** If the participant reports an outcome at a **non-routine** contact, remind her to record this information on her next routine medical history update. Interim reports of outcomes are not processed.
- **Provide new address or phone information:** Update the most recent *WHIX0441 – Personal Information Update* report in the participant's file and provide this information to the appropriate data entry staff person to update the information in WHIX.

Each of these non-routine contacts should be documented in contact notes contained in the participant's file along with any referrals or actions taken.

7.5 Mammography

All HT participants in the WHI Extension Study are required to have an annual mammogram during the first two years of the study. The two mammograms are counted as Extension Study mammograms if done between January 1, 2005 – March 31, 2007 and they are more than nine months (270 days) apart. FCs do not actively pursue mammograms after March 31, 2007. It is not required that FCs data enter a *Form 85 – Mammogram* for a mammogram that is done after March 31, 2007 but FCs may do so at their own discretion.

The mammogram is to be performed by a standard low dose radiation technique. It is recommended, but not required, that the mammogram occurs at an American College of Radiology (ACR) or Food and Drug Administration (FDA)-accredited facility and read by a qualified radiologist.

FCs will collect mammogram reports that are ordered by the participant's usual Primary Care Provider (PCP). Unlike the WHI, FCs in the WHI Extension Study will not be responsible for following up with participants for incomplete or abnormal mammogram findings. FCs are responsible for the following tasks:

- obtaining the mammogram report
- reviewing the results of the mammogram
- recording the results of the mammogram report onto the *Form 85 – Mammogram*
- data entering the *Form 85 – Mammogram*

FCs will classify and code mammograms on the *Form 85 – Mammogram* using the ACR classification system as negative, benign, probably benign, suspicious, or highly suggestive of malignancy. Breast ultrasounds, MRIs, or other newer medical procedures are not acceptable substitutes for mammograms.

The participant's PCP should order the mammogram and provide any follow-up or direction following the mammogram.

Participants are reimbursed by the FC for any screening mammogram not covered by Medicare, Medicaid, or other third party insurance, as well as partial payments, and/or co pays. The Extension Study does not cover the cost of any follow-up mammogram or diagnostic test the participant's PCP orders as the result of an abnormal mammogram. FCs should have a list of resources available for referring participants who are uninsured or have no PCP.

7.5.1 Timing of Mammogram

The majority of HT participants will have been on a regular schedule of annual mammograms as part of WHI. Anniversary dates for the mammograms may coincide with the annual mammograms that were done before close-out of WHI. Even though the WHI anniversary date of the participant may not coincide with the date of the Extension Study annual mammogram, the mammogram report is still collected. The due date for the first mammogram for the Extension Study is one year after the participant's last mammogram (if the last mammogram occurred on or after January 1, 2004) otherwise the due date for the first mammogram is January 1, 2005. It is well understood, however, that some participants have been less diligent, for a variety of reasons, and schedule mammograms less frequently. Other participants may be on a more frequent schedule for closer medical observation.

7.5.2 Requesting and Receiving Mammogram Results

FCs will determine individually how to best obtain the mammogram results in a timely manner based on their staffing, organization, requirements of their local IRB and HIPAA, and their contractual budgets.

The most efficient procedure to collect mammogram reports is to request the participant to mail the mammogram report directly to the FC. If this can not happen, a Release of Information (ROI) is obtained from the participant to collect mammogram results from the participant's PCP or the facility where the mammogram was done.

Recommendations for receiving timely follow-up mammograms include:

- Develop a plan with the participant and/or her PCP for obtaining a mammogram report.
- Send reminder letters and make reminder phone contacts to participants and/or the participant's PCP. However, some caution is advised so that the participant and/or the PCP are not over burdened with reminders. Send a stamped, self-addressed envelope to the participant for mailing her mammogram report back to the FC.
- Emphasize to the participant why she needs to have a mammogram rather than telling a participant that "we need a mammogram report,"
- You may use a lay report in lieu of the original report. To use a lay report, the following criteria must be included as part of the lay report:
  - date
  - participant's name
  - institutional letterhead
  - normal or benign findings are documented
  - recommended mammogram follow up is 12 months or more
- Have the participant sign several releases, if permitted by your IRB, to use for requesting future mammogram requests.
- Establish a contact person at the PCP's office.
- Establish a contact person at the mammogram facility.
- Be proactive and persistent.
- Use the WHIX reports to identify and track the participants who are due for a mammogram.
- Refer to Question #9 on the *Form 150 – Hormone Use Update* if you need to know the date and the location of the participant's mammogram in the last year,
- Check with the participant or the PCP one week after the date of the participant's scheduled mammogram to see if a mammogram report has been received.

7.5.3 Recording Results of Mammogram Reports

Mammogram coding is based on the ACR's classification system. Most radiology facilities use this system in their reporting of the mammogram results. The results of the mammogram report should be reviewed and recorded on the *Form 85 – Mammogram* and data entered. If the report does not use the ACR's classification system, the descriptions in the form instructions should help find the appropriate category to complete the form accordingly.

There will be instances when the BI-RADS code will not correspond to the narrative text and best judgment is needed to assign a code that most accurately reflects the results of the mammogram report. Refer to the *Form 85* instructions for guidelines on coding the summary results into the appropriate BI-RADS category.

7.5.4 Actions Based on Mammogram Results

FCs should not take any action based on the results of the mammogram report. All actions or future interventions are the responsibility of the participant and the participant's PCP.

7.5.5. Mammogram Tracking

WHIX reports are available to help track mammogram collection. The FC can track mammograms that are due and mammograms that have been completed by using *MAMM001 – Mammograms Due*. The *MAMM002 – Mammograms Not Completed* will assist the FC to monitor the success of collecting the *Form 85 – Mammogram*.

7.6 WHI-Extension Study Dietary Modification (WHI-ES DM) Program Description

The WHI-ES DM program is the low intensity dietary maintenance and assessment program for WHI-ES participants previously randomized to the WHI Dietary Modification (DM) Trial.

This program has three components: (1) general letter, (2) continuation of the *WHIse Choices* newsletters, and (3) dietary assessment.

7.6.1 General Letter

Women who joined the WHI-ES and who were previously randomized in the WHI DM Trial (intervention and comparison) will receive a letter thanking them for their participation in the WHI-ES, underscoring the importance of following up the dietary intervention effects in light of the uncertain results of the WHI DM Trial, especially for breast cancer (see *Figure 7.9 – WHI-ES DM General Letter*). The letter will direct women to the WHI Extension Study newsletter, *WHI Matters*, for study updates and periodic nutrition news and dietary tips. The letter will also introduce the optional dietary maintenance and assessment components of follow-up. The letter will be provided in Spanish for Spanish-speaking participants.

7.6.2 Continuation of the *WHIse Choices* Newsletter

Following the letter, WHI-ES women who were in the Dietary Change (intervention) arm of the DM Trial (n~1,510) will receive quarterly mailings, a continuation of the *WHIse Choices* newsletter received during the WHI DM Trial, with strategies for maintaining the low-fat dietary pattern should they wish to do so. Because self-monitoring of food intake was found to be a strong correlate of adherence, the mailings will include encouragement for women to continue self-monitoring. The strategies in the newsletters will be behaviorally and nutritionally based, include recipes, and be written in a style following the motivational interviewing principles of self-efficacy, empowerment, and exploration and resolution of ambiguity that began being implemented in the WHI DM intervention program in 1999.

Each *WHIse Choices* newsletter will include a toll-free telephone number that women can call if they have questions or no longer wish to receive the newsletters. The toll-free telephone number will route to the WHI CCC in Seattle, Washington.

The newsletters will be mailed centrally from the WHI Extension Study CCC in Seattle, Washington. Mailings will be provided in Spanish for Spanish speaking participants.

7.6.3 Dietary Assessment

Dietary assessment will be continued among a consenting subset of WHI-ES DM participants. The purpose of the dietary assessment is to estimate mean intake of the intervention and comparison groups during WHI-ES, which will assist in the interpretation of diet-disease effects during WHI-ES. Diet will be assessed by one 24-hour recall conducted by telephone interview. A single 24-hour recall per person is adequate for estimating group means. The subsample will be composed of WHI-ES-consented women who were part of the WHI DM Trial 4.6% subsample cohort. Women in this cohort provided additional data at WHI years 3, 6, and 9, including 24-hour recalls, and thus are familiar with the 24-hour recall format. Approximately half of the women will receive the 24-hour recall during 2007 and half during 2009/2010. In this way we will be able to estimate intake throughout the WHI-ES while minimizing participant burden and dietary assessment costs.

Consenting for this additional recall will be done by approach letter and telephone call. About two weeks before the 24-hour recall, participants will be mailed an approach letter describing the 24-hour recall process and specifying that when called, they may choose not to be interviewed (see *Figure 7.10 – WHI-ES DM Approach Letter* and *Figure 7.11 – 24-Hour Recall Interview Script*). If consent is not granted, the interviewer will thank the participant for her time and end the call. During the WHI DM Trial, 3% of participants declined the 24-hour recall. If consent is granted, the interviewer will proceed with the recall, which takes about 20 minutes.

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The Fred Hutchinson Cancer Research Center (FHCRC) Nutrition Assessment Shared Resource (NASR) will conduct the 24-hour recalls using the 5-step multiple-pass method as they used during the WHI DM Trial. In this method, participants first list all foods and beverages consumed followed by interviewers asking about typically forgotten foods, eating occasions, details, and final questions about anything else consumed. To facilitate the interview, participants will receive a serving size booklet with the approach letter. Thirty percent of recalls will be taken for weekend days and 70% for weekdays. Per standard WHI procedure, interviewers will make 12 call attempts per participant and after every fourth attempt they will leave a voice-mail message with contact information. After making contact, receiving consent, and completing the recall, the interviewer will thank the participant for her time. Quality assurance monitoring of the calls will be done on 10% of the recalls with participant's permission. The CCC will mail a thank you letter to participants who complete the 24-hour recall (see *Figure 7.12 – WHI-ES DM Thank You Letter*). Calls and letters will be provided in Spanish for Spanish-speaking participants. The FHCRC NASR uses the Minnesota Nutrient Data System for coding and nutrient analysis of the 24-hour recalls.

7.6.4 WHI-ES DM Timeline

WHI-ES DM maintenance program and dietary assessment timeline				
	WHI-ES Year 1-2 (2006-2007)	WHI-ES Year 2-3 (2007-2008)	WHI-ES Year 3-4 (2008-2009)	WHI-ES Year 4-5 (2009-2010)
Mail general letter	1 mailing to WHI-ES intervention and comparison participants			
Mail *WHIse Choices* newsletter	2 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants	4 mailings to all WHI-ES DM intervention participants
Implement 24-hour recall	Half of the 4.6% subsample of WHI-ES DM participants			Half of the 4.6% subsample of WHI-ES DM participants

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Figure 7.1
Cover Letter for Contact 1

Thank you for being part of the Women's Health Initiative Extension Study! The purpose of the WHI Extension Study is to learn more about women's health and about the causes of disease in women. As a participant in the WHI Extension Study you are asked to fill out forms each year so we can update information on your health. This information will be used to learn more about the relationship between lifestyle habits and women's health. We want the results of this study to represent all women, so your continued participation is very important to us.

The enclosed forms ask several questions about your health, including your recent medical history. Please use the enclosed pencil to complete the forms so our machines can read your answers. When you have completed the forms, return them right away in the postage-paid envelope to the Extension Study Clinical Coordinating Center in Seattle, Washington.

If you have any questions about the forms or need help filling them out, you may call your Clinical Center at the telephone number listed on the attached page. For the next several years, we will need to know where to send your newsletter and health forms. Please notify your Clinical Center if you move to a different address or if your phone number changes.

All information you provide will be kept confidential and your name will not be linked with data given to anyone other than WHI research staff. Participation in this study is voluntary and you may refuse to answer any questions on the forms. However, we do appreciate having complete follow-up information on all participants to make sure the results of the WHI Extension Study are accurate and scientific.

We appreciate your continued participation in the WHI Extension Study. This is an important study that may help us to improve the health of women for generations to come. Every woman counts, so please keep in touch.

You are part of the answer!

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Figure 7.2
Cover Letter for Contact 2 / 3

A few months ago we sent you a packet of health forms to complete for the Women's Health Initiative Extension Study. We have not yet received all of your completed forms. New forms and a postage-paid envelope are enclosed, in case your copies were misplaced or not received. **If you have already completed and mailed your forms, you do not need to fill them out again and can ignore this request.**

The purpose of the WHI Extension Study is to learn more about women's health and about the causes of disease in women. As a participant in the WHI Extension Study you are asked to fill out forms each year so we can update information on your health. This information will be used to learn more about the relationship between lifestyle habits and women's health. We want the results of this study to represent all women, so your continued participation is very important to us.

The enclosed forms ask several questions about your health, including recent medical history. Please use the enclosed pencil to complete the forms so our machines can read your answers. When you have completed the forms, return them right away in the postage-paid envelope to the Extension Study Clinical Coordinating Center in Seattle, Washington.

If you have any questions about the forms or need help filling them out, you may call your Clinical Center at the telephone number listed on the attached page. For the next several years, we will need to know where to send your newsletter and health forms. Please call your Clinical Center if you move to a different address or if your phone number changes.

All information you provide will be kept confidential and your name will not be linked with data given to anyone other than WHI research staff. Participation in this study is voluntary and you may refuse to answer any questions on the forms. However, we appreciate having complete follow-up information on all participants to make sure that the results of the WHI Extension Study are accurate and scientific.

We appreciate your continued participation in the WHI Extension Study. This is an important study that may help us to improve the health of women for generations to come. Every woman counts, so please keep in touch.

You are very important to the WHI, so we hope to hear from you. You are part of the answer!

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Figure 7.3
Personal Information Update Cover Letter

Thank you for being part of the Women's Health Initiative (WHI) Extension Study! The purpose of the WHI is to learn more about women's health and the risk for disease in postmenopausal women. One of our most important goals is to keep track of any major changes in your health through the end of the study. In order to do that, we need to make sure we can contact you throughout the course of the study. We ask that you check and, if necessary, update the contact information we have for you, the other contacts you listed, your doctor or primary care clinic, and your proxy.

To help us continue to collect the study information we need, we are asking you to:

1. Review the enclosed ***Personal Information Sheet***. This sheet has information you have given us about your personal contacts and your doctor or clinic. If you notice that any information is wrong, please cross it out and write in the correction. Also, if any information is blank, we ask that you fill in the missing information.

2. Mail the updated ***Personal Information Sheet*** back to the WHI Clinical Coordinating Center using the postage-paid envelope provided. If you do not have any corrections, we would still like you to mail the sheet back to us. Simply write "no corrections" on the top. That way we will know that you received our request and were able to review the information.

Thank you for taking the time to complete this important task. Remember that all information you provide to us will always be kept confidential. We appreciate your continued participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Every woman counts, so please keep in touch!

Figure 7.4
Suggested Script for Contact 4 Telephone Contact

The caller should telephone until she/he is able to reach the woman or other personal contact. Actual contact is required to confirm that the FC has the right address and phone number.

"Hello Mrs./Miss/Ms._____, this is _____ from the Women's Health Initiative Extension Study **(name of field center)**."

"Several weeks ago a form packet was mailed to you from the Women's Health Initiative Extension Study. Did you receive the packet?"

If not received:

"I'm sorry to hear that. Maybe it was sent to the wrong address. Let me check your mailing address so that we can update our files."

(Record correct address, then continue.)

"Because your participation is very important to us and we would like to include your responses in the study results, I would like to go over one of the forms with you over the telephone. Is this a good time for us to complete the form over the phone?"

If no:

"When would you like me to call back?"

(Confirm time, thank participant, terminate call, call back later to conduct interview.)

If yes:

"Great. I will read you the questions over the telephone and record your answers."

Conduct interview: complete Form 33.

"Thank you very much for spending the time to answer these questions over the telephone. We're very glad to have you as part of the Women's Health Initiative Extension Study.

(Terminate call.)

Figure 7.4 (continued)

If yes:

"Good. Because your participation is very important to us and we would like to include your responses in the study results, I would like to go over one of the forms with you over the telephone. Is this a good time for us to complete the form over the phone?"

If no:

"When would you like me to call back?"

(Confirm time, thank participant, terminate call, call back later to conduct interview.)

If yes:

"Great. I'll read you the questions over the telephone and record your answers."

Conduct interview: complete Form 33.

"Thank you very much for spending the time to answer these questions over the telephone. We're very glad to have you as part of the Women's Health Initiative Extension Study.

(Terminate call.)

If during a contact you learn that the participant is deceased, is unable to communicate, or has poor cognitive functioning, end call appropriately (e.g., if she is deceased): *"I am so sorry to hear that Mrs./Miss/Ms._____ has passed away. She was an important member of our study."*

If deceased - complete Form 120 – Initial Notification of Death

If poor cognitive function, communication abilities, explore possibility of changing to proxy follow-up.

If at any point during the contact her participation status changes (e.g., she requests no further telephone contact):

Update Form 9 – Participation Status.

Initiate Form 24 – Retention Worksheet (optional).

Figure 7.5
Suggested Script for Proxy Telephone Contact

Ask to speak to (in order of priority for contact):

Proxy (if one has been identified)

If none identified:

spouse or partner

nearest relative

friend

Once contact is established, start at beginning of script.

If none of the above are available, contact the woman's physician.

"Hello, this is _____ from the Women's Health Initiative Extension Study **(name of field center)**. May I speak to ***[proxy name]***?"

If proxy is available, continue.

If proxy is not currently available:

"Can you suggest a time when I may be able to call back and speak with him [her]?"

Confirm time, thank person on phone, call back later to talk with proxy.

If identified proxy continues to be unavailable after several calls, try to contact another proxy.

If participant is deceased:

"We were very sorry to hear that Mrs./Miss/Ms._____ has passed away. As you may be aware, she was an important member of our study, the Women's Health Initiative."

(Continue below.)

If participant is unable to communicate or has poor cognitive functioning:

"We were very sorry to hear that Mrs./Miss/Ms._____ has had a recent decline in her health. As you may be aware, she is an important member of our study, the Women's Health Initiative."

(Continue.)

"Because we want the study to represent **all** women, we would still like to include her in the results. In order to do this, I would like to ask you some questions about her health during the past year. Would this be a good time for me to ask the questions?"

If yes:

Complete Form 33 – Medical History Update.

"Thank you very much for your help in the Women's Health Initiative Extension Study. The information you have provided is very important to the results of the study."

If no:

"When would you like me to call back?"

(Confirm time, call back later to conduct interview.)

If husband/partner refuses to participate, thank him/her, terminate the call, and try to contact another proxy.

In order of priority for contact:

spouse or partner

nearest relative

friend

Once contact is established with new proxy, start at beginning of script.

If none of the above are available, contact the woman's physician.

For all participants, Update Form 9 – Participation Status, if it has not already been updated (e.g., regarding the participant's death or poor cognitive functioning).

Figure 7.6
Cover Letter for Proxy Contact

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in the Women's Health Initiative Extension Study. The purpose of the Women's Health Initiative is to learn more about women's health and the risk for disease in postmenopausal women. This important health study includes over 110,000 women across the U.S. One of our most important goals is to keep track of any major changes in the health of our participants through the end of the study. When a participant in the Women's Health Initiative becomes unable to answer questions about her health, we ask for her proxy's help in providing this information.

Enclosed in this packet are the health update questionnaires that we are asking you to complete, to the best of your ability. They include questions about any hospitalizations or serious illnesses the participant may have had in the previous year. This information is collected to help WHI find answers to important questions about women's health. Depending upon your responses, you might be contacted for additional details. If there is something that you do not know, it is okay to leave the answer blank.

Thank you for taking the time to complete these important questionnaires. It is very important for WHI to have complete follow-up information on all participants to ensure that WHI results are accurate and trusted by scientists and physicians. With your generous help, the Women's Health Initiative will have the information that is vital for the study to succeed. If you have any questions or need any help, please call your Clinical Center at the phone number listed on the following pages. Remember that all information you provide to us will always be kept confidential. We appreciate your participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Thank you for your contribution to the Women's Health Initiative!

Figure 7.7
Cover Letter for Proxy Contact 2 / 3

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in the Women's Health Initiative Extension Study. A few months ago we sent you a packet of health forms to complete for the Extension Study. We have not yet received your completed forms. New forms and a postage-paid envelope are enclosed, in case your copies were misplaced or not received. **If you have already completed and mailed the forms, you do not need to fill them out again and can ignore this request.**

The purpose of the Women's Health Initiative is to learn more about women's health and the risk for disease in postmenopausal women. This important health study includes over 110,000 women across the U.S. One of our most important goals is to keep track of any major changes in the health of our participants through the end of the study. When a participant in the Women's Health Initiative becomes unable to answer questions about her health, we ask for her proxy's help in providing this information.

Enclosed in this packet are the health update questionnaires that we are asking you to complete, to the best of your ability. They include questions about any hospitalizations or serious illnesses the participant may have had in the previous year. This information is collected to help WHI find answers to important questions about women's health. Depending upon your responses, you might be contacted for additional details. If there is something that you do not know, it is okay to leave the answer blank.

Thank you for taking the time to complete these important questionnaires. It is very important for WHI to have complete follow-up information on all participants to ensure that WHI results are accurate and trusted by scientists and physicians. With your generous help, the Women's Health Initiative will have the information that is vital for the study to succeed. If you have any questions or need any help, please call your Clinical Center at the phone number listed on the following pages. Remember that all information you provide to us will always be kept confidential. We appreciate your participation in the Women's Health Initiative. This study is important for the health of women for generations to come.

Thank you for your contribution to the Women's Health Initiative!

Figure 7.8
Postcard for Participants on No Follow-Up

WOMEN'S HEALTH INITIATIVE EXTENSION STUDY

1. Have you had any major health problems since we last saw you?
   ☐ No ☐ Yes → Please describe:_____
   _____
2. Is this address label correct?
   ☐ Yes ☐ No → Change to:_____
   _____
3. May we contact you about joining the Women's Health Initiative Extension Study?
   ☐ No ☐ Yes

   I have questions, please call me at:_____
   Best times to call:_____

   Please call [FC phone number] or return this postcard to [FC address].

Figure 7.9
WHI-ES DM General Letter

To our valued WHI Extension Study participants who were in the Dietary Study

Thank you for continuing your commitment to the Women's Health Initiative by joining the WHI Extension Study. Recently, we sent you an important issue of the *WHI Matters* newsletter summarizing the results to date about the WHI Dietary Study that had been published in the *Journal of the American Medical Association*. These results showed that breast cancer rates may turn out to be lower in the low-fat Dietary Change (intervention) group compared to the Comparison (usual diet) group. However, the observed 9% difference was not statistically *significant* (a measure used to evaluate study results), meaning that the results remain uncertain.

As a participant in the WHI Extension Study, the health information you provide every year will help scientists determine if the WHI low-fat dietary pattern will eventually result in statistically significant changes over time of breast cancer, colorectal cancer, and heart disease. This is because the effect of diet change may take a long time to develop. To learn more about dietary effects over time, there is a small chance that you will be called and asked about the foods you eat. If you are called, you may choose whether or not to participate in the interview.

We will continue providing you with up-to-date news about the Women's Health Initiative, plus general health and nutrition news, in upcoming issues of *WHI Matters*. If you were in the Dietary Change group of the Dietary Study, we are pleased to let you know that the National Institutes of Health will continue providing quarterly issues of the *WHIse Choices* newsletter. We hope the newsletters will be helpful to those of you who wish to maintain the low-fat eating pattern adopted during the WHI Dietary Study. The first *WHIse Choices* for the Extension Study period, planned for later this year, will give you the option of not receiving future issues, if you prefer.

Thank you for being in the WHI! The Women's Health Initiative is one of the largest and most comprehensive studies ever conducted. Because of your continued cooperation, we will continue to find the answers to important questions concerning women's health. In addition to the updates we send, ongoing news about WHI may be found at www.whi.org, www.nhlbi.nih.gov/whi, and http://orwh.od.nih.gov/WHIConference.htm.

You are part of the answer!

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Figure 7.10
WHI-ES DM Approach Letter

FRED HUTCHINSON
CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center

DATE

«Title» «FirstName» «LastName»
«Address1»
«City», «State» «PostalCode»

Dear «Title» «LastName»,

In the next few weeks, staff from the Coordinating Center for the Women's Health Initiative Extension Study in Seattle will call you for a short interview. The interviewer will ask about foods you ate on the previous day. The enclosed booklet will help you estimate your serving sizes. Please have it available for the telephone interview. You do not need to do anything special to prepare for the call. The interview will take about 20 minutes.

You were specially selected for this interview, and we hope that you will participate. This information will help us learn more about how diet affects women's health.

If you would like to participate but are busy when we call, we will ask if we can call you at another time. If you would rather not participate, you are welcome to decline when called.

If you have any questions, please ask the interviewer when he or she calls.

Sincerely,

Garnet L Anderson

Garnet Anderson, Ph.D.
Women's Health Initiative
Co-Project Director, Clinical Coordinating Center
206/667-2834

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Figure 7.11
24-Hour Recall Interview Script

Women's Health Initiative Extension Study (WHI-ES)
Dietary Modification (DM) Trial Cohort

24-HOUR RECALL INTERVIEW SCRIPT

MAKE THE PHONE CALL. PRESS THE PRIVACY RELEASE BUTTON AFTER THE PHONE IS ANSWERED.

Hello, my name is <your name> and I'm calling from the Coordinating Center for the Women's Health Initiative Extension Study in Seattle. May I please speak with_____?

Q1. Is this_____? VERIFY NAME OF PARTICIPANT ON CALL RECORD SHEET.

- IF YES, GO TO Q2.
- IF NO, AND PARTICIPANT IS NOT AVAILABLE,

  When would be a good time for me to call again? Thank you very much. Good-bye.

  WRITE DOWN TIME ON THE CALL RECORD SHEET. DELETE PARTICIPANT INFORMATION FROM THE RECORD HEADER SCREEN.
- IF YOU REACH VOICE MAIL OR AN ANSWERING MACHINE, AND

  This is the fourth, eighth, or 12th call attempt:

  This is <your name> calling from the Coordinating Center of the Women's Health Initiative Extension Study in Seattle. I am calling for _____ to complete a telephone interview about foods you eat. Please call 1-800-704-2804 and leave your name, phone number, and generally the best times to reach you. Also tell us you are calling about the WHI study. Thank you.

Q2. This is <your name> calling for the Coordinating Center of the Women's Health Initiative Extension Study in Seattle. I am calling to complete an interview about what you eat. Is this a good time for you to talk?

- IF YES, GO TO Q3
- IF NO,

  Is there a more convenient time for me to call you today? Thank you. I will call you again at _____.

  NOTE TIME ON CALL RECORD SHEET.
- IF NO CONVENIENT TIME LATER THAT DAY CAN BE ARRANGED,

  Thank you very much, I will call again another day. Good bye.

  NOTE ON THE CALL RECORD SHEET.
- IF FIRM REFUSAL,

  I understand that you don't want to be called again for this part of the study. Thank you.

  NOTE REFUSAL ON THE CALL RECORD SHEET.

Q3. There is a legal requirement that you consent to participate in this interview. So I would like to read you a brief description of the interview process before we begin.

This interview requires answering detailed questions about the foods you ate and the beverages you drank the previous day. The interview will take about 20 minutes.

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By taking part in this study, you will help increase scientific knowledge about how diet affects women's health. There are no risks of participating in this interview.

Everything you tell me will be kept strictly confidential as required by law. Your personal identity will not be revealed in any publication or release of results.

Your decision to participate in this interview is voluntary. You may stop at any time and for any reason.

Do you have any questions?

- IF NO, GO TO Q4.
- IF YES, AND YOU DO NOT KNOW THE ANSWER TO A PARTICIPANT'S QUESTION, WRITE DOWN THE QUESTION CAREFULLY.

  I am going to refer your question to one of the scientists on this study. We will call you with an answer very soon. GO TO Q5.

Q4. Do you agree to participate in this interview? NOTE ANSWER ON CALL RECORD.

- IF YES, GO TO QUESTION 5.
- IF NO,

  Thank you very much for your time. Have a good day.

Q5. The interview will take about 20 minutes. Is this a convenient time?

- IF A CONVENIENT TIME, GO TO QUESTION 6.
- IF NOT A CONVENIENT TIME,

  What are more convenient times for me to call you today and on other days? (IF APPROPRIATE**, If it is better for me to call you at home, may I have your home phone number?) Thank you, I will call you again.**

  NOTE TIMES ON THE CALL RECORD SHEET.

Q6. There is a 10% chance my supervisor will listen to this interview to monitor my performance.

- IF PARTICIPANT SAYS SHE DOES NOT WANT THE SUPERVISOR TO LISTEN TO THE INTERVIEW, **I will call you back on an unmonitored line**. CALL THE PARTICIPANT BACK ON ANOTHER LINE.

GO TO QUESTION 7.

Q7. This interview has 3 parts. The first part is called the Quick List. You will just list the foods and beverages you ate and drank yesterday. Next, we will describe the foods and beverages in more detail. Then, I will review your intake for any final revisions.

I need just a moment to enter some information into the computer. Please use this time to get your Serving Size booklet and think about what you ate and drank yesterday.

- IF THE SERVING SIZE BOOKLET IS NOT AVAILABLE, **A ruler, measuring cups, and measuring spoons work just as well. I can wait a minute while you get them.**

Complete the NDS-R Record Header Tab:

- The participant's ID number which is listed on the Call Record Sheet.
- The date of intake (previous day, which is the date the food was consumed).
- The participant's name and gender.
- Your interviewer ID.
- Visit number.

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Q 8. **For the Quick List, tell me the time and place you ate and then briefly list everything you had to eat or drink starting from midnight, <day of week>, until midnight last night. Okay? What time was it when you had your first item to eat or drink after midnight <day of the week>?**

ENTER EACH FOOD AND BEVERAGE ITEM ON THE NDS-R QUICK LIST WINDOW.

ENTER ENOUGH INFORMATION SO YOU WILL BE ABLE TO RECOGNIZE IT WHEN YOU GET TO THE FOOD SEARCH WINDOW. ITEMS WILL BE GROUPED BY MEALS AS THEY ARE ENTERED: BREAKFAST, LUNCH, DINNER, SNACKS. THIS WILL HELP YOU AND THE PARTICIPANT SPOT OMISSIONS. THINK ABOUT THE FOODS, BEVERAGES AND MEALS THE PARTICIPANT HAS RECALLED. ASK ABOUT POSSIBLE OMITTED FOODS AND BEVERAGES AT EACH MEAL/SNACK AND BETWEEN MEALS AND SNACKS. THE FOLLOWING ARE EXAMPLES OF PROBES:

Did you have:

- **anything to eat or drink in the car?**
- **any snacks in the morning while you were at work?**
- **fruit, chips, or a dessert with your lunch?**
- **anything to eat or drink when you got home from work, for example, while dinner was being prepared or before you ate dinner?**
- **something to drink with dinner?**
- **anything to eat or drink before you went to bed?**

WHEN FINISHED PROBING AFTER THE QUICK LIST, GO TO Q9.

Q 9. **Now we'll go over the foods we just listed and you can describe them in more detail. When I ask you about amounts, please use the Serving Size Booklet (AND/OR measuring cups and spoons OR ruler), to help you estimate portion sizes. The first thing you said you had yesterday was <name of food/beverage> at <time of day>.**

PROBE FOR ADDITIONS AT THE ADD FOOD WINDOW.

PROCEED WITH THE 'FOOD SEARCH', AND 'ITEM DETAIL' WINDOWS TO FURTHER DESCRIBE EACH ITEM. FOLLOW PROBES ON THE SCREEN TO COMPLETE THE DETAILS REQUIRED.

AFTER GETTING THE DETAILS, GO TO Q10.

Q 10. **Now we will review your day's intake. Feel free to stop me at any time if you recall having any other foods or beverages or if I have stated an incorrect amount or type of food.**

USE THE 'FOOD REVIEW' WINDOW TO THOROUGHLY VERBALLY REVIEW THE DAY'S INTAKE WITH THE PARTICIPANT. READ EACH FOOD, PREPARATION METHOD (WHEN NECESSARY) AND SERVING SIZE TO THE PARTICIPANT TO CONFIRM FOOD INTAKE. MAKE CHANGES, IF NECESSARY. WHEN YOU ARE FINISHED REVIEWING THE INTAKE, ASK ONE FINAL TIME IF THE PARTICIPANT RECALLS EATING OR DRINKING ANYTHING ELSE.

AFTER REVIEWING, GO TO END.

END. **This concludes the interview. Thank you, <participant's name> , for giving us such detailed information. This information is very important to this research project.**

COMPLETE THE RECORD TRAILER TAB:

The INTAKE was USUAL (*default).*

The RELIABILITY OF THE INFORMATION is the subjective opinion of you, the interviewer.

If the participant seemed confident in recalling his or her intake, record RELIABLE.

If the participant was unable to remember meals or snacks, record UNABLE TO RECALL ONE OR MORE MEALS. Make a note to alert the RN.

If the interview seemed unreliable for other reasons, record UNRELIABLE FOR OTHER REASONS. Note why on the Call Record Sheet. Make a note to alert the RN.

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AFTER THE INTERVIEW:

1. EDIT THE RECORD.
2. COMPLETE THE CALL RECORD SHEET.
3. PRINT OUT ALL RECORD REPORTS AND ATTACH TO THE CALL RECORD SHEET.
4. IF YOU HAVE A RN QUESTION PRINT OUT A RECORD REPORT, ATTACH IT TO THE CALL RECORD SHEET, NOTE 'RN' ON THE CALL RECORD SHEET.
5. PLACE THE CALL RECORD SHEET IN THE '*COMPLETE RECALL TRAY*'.

Figure 7.12
WHI-ES DM Thank You Letter

WOMEN'S HEALTH INITIATIVE

FRED HUTCHINSON CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center

DATE

«Title» «FirstName» «LastName»
«Address1»
«City», «State» «PostalCode»

Dear «Title» «LastName»,

A few weeks ago, staff from the Coordinating Center for the Women's Health Initiative in Seattle called to talk with you about the foods you ate on the previous day. Thank you for taking the time for this activity. This is an important part of the Women's Health Initiative study that will help us learn more about how diet affects women's health.

We appreciate your continued participation in the Women's Health Initiative. Together we can do a lot to improve the health of women for generations to come.

Sincerely,

Garnet L Anderson

Garnet Anderson, Ph.D.
Women's Health Initiative
Co-Project Director, Clinical Coordinating Center
206/667-2834

7.7 Standard Operating Procedures (SOP) for Ancillary Studies of Self-Reported Outcomes in the Women's Health Initiative

This section describes the procedures for obtaining consent for the study of self-reported outcomes (SRO) by ancillary studies (ASs) in the Women's Health Initiative (WHI). These procedures refer specifically to studies using self-reported outcomes where participants from multiple WHI Field Centers (FCs) are needed to obtain a large enough sample.

These procedures are intended to be used to obtain validation data (e.g., medical records) on conditions previously reported to WHI either to confirm all eligible cases or, in the case of more common conditions, to estimate the reliability of self-reported events in a representative sample of eligible cases. The ancillary study (AS) may be a stand-alone validation study to test whether self-report is good enough to allow analyses based on the self-reported outcome.

7.7.1 Background

The overall mission of the WHI is to examine the risks and benefits of three specific prevention interventions and to determine risk factors for the major causes of morbidity and mortality in postmenopausal women. In support of this, WHI has already collected self-reports of a diverse list of medical events from participants, but has had the resources to collect medical records confirming only the event types of highest priority to the primary study objectives. Many of the other conditions represent important health concerns of older women for which WHI participants have already contributed considerable information. Because some of these conditions are very rare, the WHI may constitute a unique resource for information on these health outcomes. The specific self-reported outcomes are listed in *Tables 7.1-7.3 – Self-Reported Outcomes in WHI.*

The purpose of these procedures is to provide an efficient mechanism for obtaining the supporting medical records for the self-reported health outcomes already known to us when an AS designed to study one of these outcomes is funded. Because subcontracting with 40 Field Centers is logistically burdensome and cost prohibitive for each AS to repeat, the proposed process is centralized at the WHI Clinical Coordinating Center (CCC) for institutional review, approval, and implementation, contingent upon approval of their Standard Operating Procedures (SOP) is obtained at participating sites.

For this type of AS (referred to below as a Self-Reported Outcomes AS, or SRO-AS), WHI participants who had previously reported a diagnosis of the outcome of interest would be identified in the WHI database, contacted, and asked to consent to having WHI staff obtain the medical records associated with that outcome. As proposed, CCC staff would contact participants who have reported that outcome, obtain the signed authorization to release their medical records, and collect the pertinent records of consenting participants. This new stage in the CCC WHI contract is a natural progression of its federally designated role into outcomes collection for data repository collaboration.

7.7.2. Overview of Process (Proposed)

The process for consenting and collecting medical information from participants who have reported one of the self-reported outcomes listed in *Tables 7.1-7.3* is described below.

Following review and approval of these procedures by the CCC (Fred Hutchinson Cancer Research Center) Internal Review Board (IRB), each FC will seek local IRB approval for this SRO protocol. Under the original WHI consent, participants have provided data on their health outcomes with the expectation that it will advance scientific knowledge; that expectation applies to the study of SRO, just as it does to the primary outcomes in WHI.

Participants from FCs that obtain local IRB approval of the SRO protocol will be eligible for approach for all future SRO-ASs. Participants from FCs who do not have IRB approval for the SRO protocol will not be included in the centrally supported activities of these types of AS, although individual SRO-ASs may choose on a case-by-case basis to negotiate directly with the local institutions to participate.

Once this SRO-protocol is approved, the process to be followed for each specific SRO-AS is summarized here, with details provided below:

1. The proposal for the SRO-AS is reviewed and approved via the existing standard WHI AS review structure (detailed in *Section 7.7.3* below).
2. Funding is secured for the SRO-AS.
3. The WHI CCC receives IRB approval for each SRO-AS. The Principal Investigator (PI) of the SRO-AS also obtains IRB approval from his/her institution.
4. The CCC IRB approval for the study is sent to all FC IRBs who have approved the SRO protocol as an FYI.
5. The CCC identifies eligible participants with the outcomes of interest for that SRO-AS.
6. The CCC sends a packet to participants with that outcome. The packet includes a cover letter explaining the study, a short questionnaire requesting information on the diagnosis and treatment, and a request to obtain medical records.
7. Consenting participants return the questionnaire, and medical records release to the CCC. The CCC re-contacts non-responders for possible participation.
8. The CCC collects and processes medical records according to the specified protocol described below, including removal of personal identifiers if records need to be reviewed and/or adjudicated by another party.
9. Participants' medical records are stored at the CCC.
10. Data analysis is conducted at the CCC or by the SRO-AS investigators. Any data provided to SRO-ASs investigators will be de-identified by the CCC before release.

7.7.3. Details on Existing Approval Process for WHI Ancillary Studies

To be considered as a potential WHI AS, all AS proposals follow a standard set of requirements and procedures. A WHI AS is any study that requires the collection of additional data from participants enrolled in any WHI component, including data obtained from existing specimens. An AS is conducted with non-WHI funds, with some basic CCC support covered by the WHI contract. The WHI accepts AS proposals from investigators within and outside of the WHI organization. Studies conducted by non-WHI investigators must be sponsored by a WHI PI.

Ancillary Study proposals fall into two general categories: those requesting biospecimen and those without biospecimen requests. The procedures and review process are slightly different for each. For biospecimen proposals, an additional level of review is conducted by the Laboratory Working Group (LWG), the CCC, and the Executive Committee (EC). All proposals are reviewed according to the AS review criteria listed in *Table 7.4 – WHI AS Review Criteria*

Once a proposal has been approved by the ASC, it is sent to the NHLBI Project Office (PO) and the WHI EC for review and approval. The Observational Study Monitoring Board (OSMB) review is also required if the study requires additional consent from participants, and/or will involve additional participant burden. When the PO and OSMB have reviewed and approved the proposal, the PO sends an approval letter to the AS PI and the PI is free to submit an application for funding the AS.

The AS application may include a subcontract to the CCC. Before submission for funding, AS proposals are given a brief review by the AS PI's local institution and by the CCC's IRB (at the Fred Hutchinson Cancer Research Center); an IRB application is then submitted once the AS receives a fundable score.

7.7.4 Details on Approval Process for Self-Reported Outcomes Ancillary Studies (SRO-AS) *(Proposed)*

When an SRO-AS involving one of the outcomes listed in *Tables 7.1-7.3* has been funded, the CCC will notify all PIs at FCs with participants reporting that particular outcome. The purpose of this notification is to let PIs know that some of their participants will be contacted by the CCC regarding possible participation in the SRO-AS. The PI notification will include a cover letter and abstract and brief description of the approved SRO-AS.

Upon receipt of the notification letter, the FC PI will follow the local procedures for notifying his/her IRB regarding the SRO-AS, which may involve the PI sending the CCC IRB approval and study description to their local IRB as an FYI. This process will vary depending on the agreement that has been established at the local level.

7.7.5 Details on Obtaining Consent for participation in SRO-ASs and Medical Records Collection *(Proposed)*

The following process will be followed for each SRO-AS. Consent and medical outcomes reports for participants in these studies are collected centrally by the CCC.

A. Eligibility. The CCC will create a list of participants who have reported the self-reported outcome of interest for each participating FC. This list will be used to create cover letters and mailing labels for eligible participants. Women are eligible for approach if they reported the outcome of interest during the original WHI, with the exception of those who were classified as "absolutely no contact" at the end of WHI, or who became "absolutely no contact" during the Extension Study. For participants on proxy follow-up, the consent packet will be sent to the proxy, with a different cover letter. The next of kin for women who are deceased may also be approached, depending on the type of data needed for that specific AS. This process will be established for each AS separately, as needed.

B. Recruitment. The CCC will mail an initial consent packet to participants who have previously reported the outcome in the study. The packet will include:

- Cover letter (see *Figure 7.13 – Model of Consent Cover Letter*). This letter explains why we are contacting the participant, outlines the contents of the packet, and explains what their participation will entail. A contact person and phone number for both the CCC and the SRO-AS PI are included in the letter.
- Brief questionnaire to confirm the data we have from the participant pertaining to the outcome and to ask for information on the health care provider(s) providing diagnosis and treatment (see *Figure 7.14 – Model of Health History Questionnaire*). This questionnaire would be modified to include questions that meet the specific needs of each SRO-AS.
- Consent Form to participate in the SRO-AS, if required. For those studies that need a signed Authorization to Release Medical Records only, a consent form will not be included. If participation in the SRO-AS requires additional questionnaire or lab data from the participant, a consent form and additional information outlining the study's requirements will be included.
- Authorization to Release Medical Records form (see *Figure 7.15 – Model of Authorization to Release Medical Records*). This form asks the participant to give the CCC permission to obtain medical records that may be related to the outcome of interest. She will be asked to complete and sign this form before mailing it back to the CCC. The medical records release form sent to each participant will be specific to that participant's FC institution, and, because different diseases might require different kinds of documents, possibly by the disease outcome. Release forms will need to meet the Federal HIPAA regulations. The model in *Figure 7.16 – Model Request for Medical Records Information Sent to Healthcare Providers and Institutions* provides a sample of what a typical medical release form looks like.
- Business Reply Envelope for returning the signed consent form and medical release form(s) to the CCC.

C. Follow-up with non-respondents. The CCC will track returned packets in the WHI database. A second packet with letter and medical release will be sent to non-respondents two months after the initial mailing. One month later, a CCC staff member will call non-respondents to answer questions and prompt return of the forms. If participants are not interested in participating at that point, or cannot be reached or found, they will no longer be contacted for participation.

D. Requesting records from medical care providers. The documents to be requested depend on the diagnosis and needs of the SRO-AS. The SRO-AS investigator will provide a list of specific documents needed to the WHI CCC Outcomes Unit. This document set will be listed on the *Request for Medical Records Information* (see *Figure 16*) sent to the health care provider(s) listed on the questionnaire. In most cases the generic release may be sufficient documentation, but in some cases the hospital/doctor may have their own medical release specific to their organization, institution, or state that needs to be signed. In those cases, the CCC will send the provider-specific release to the participant for a signature. Healthcare providers will be asked to send the requested documents to the CCC in the return envelope provided.

E. Review and adjudication of health outcomes. Upon receipt at the CCC, all medical records will be reviewed for completeness and fact of receipt data entered in the WHI database. All records will then be assembled in a packet, copied, and the copies sent out to the adjudicators identified for that SRO-AS. All patient and next-of-kin identifiers will be removed from documents before distribution to adjudicators. Following adjudication, all records and completed forms will be returned to the CCC for data entry or, destroyed if they are duplicates. If during the process, adjudicators determine that additional medical records are needed, the CCC would conduct the steps necessary to obtain those documents and provide them to the adjudicator(s). Following adjudication and data entry, all documents are archived at the CCC.

F. Data Entry and Analysis. The CCC database staff will be responsible for data entry and storage of all data received through this process. CCC statisticians will work with the SRO-AS investigators to analyze data and prepare manuscripts on study results. Any data released to SRO-AS investigators will be de-identified.

Table 7.1
Self-Reported Outcomes in WHI - General

- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Asthma
- Benign breast disease
- Cataracts
- Dementia
- Diabetes (treated)
- Dialysis for kidney disease
- Diverticulitis
- DVT
- Emphysema/COPD
- Gall bladder disease
- Glaucoma
- Heart failure
- Hypertension
- Hysterectomy
- Intestinal polyps
- Inflammatory bowel disease
- Joint replacement
- Kidney stones
- Liver disease
- Macular degeneration
- Multiple sclerosis
- Osteoarthritis
- Osteoporosis
- Parkinson's disease
- Pancreatitis
- Peptic ulcer disease
- Pulmonary embolism
- Rheumatoid arthritis
- Systemic lupus erythematosus
- Thyroid disease
- Venous thromboembolism
- ICD-9 CM codes
- Diagnostic procedures, such as sigmoidoscopy, colonoscopy, biopsy of benign breast lesions

Table 7.2
Self-Reported Outcomes in WHI – Non-Primary Cancers

- Accessory sinus
- Adrenal gland
- Anus
- Appendix
- Biliary tract
- Bladder
- Bones/joints/articular cartilage
- Brain
- Cervix
- Central nervous system (excludes brain)
- Connective/subcutaneous/soft tissues
- Endocrine glands, related structures
- Esophagus
- Eye and adnexa
- Genital organs
- Kidney
- Larynx
- Leukemia
- Liver
- Lung
- Lymph nodes
- Lymphoma, Hodgkins
- Lymphoma, Non-Hodgkins
- Melanoma of the skin
- Multiple myeloma
- Oral (mouth)
- Palate
- Pancreas
- Parotid gland (Stensen's duct)
- Peripheral nerves and autonomic nervous system
- Pyriform sinus
- Respiratory system, intrathoracic, other
- Salivary glands, major
- Stomach
- Thyroid
- Tongue, part of
- Urinary organs
- Uterus, not otherwise specified
- Other, not specified above (from the International Classification of Diseases for Oncology ICD-02 Reference Manual)

Table 7.3
Self-Reported Outcomes in WHI – Non-Primary Fractures

<u>Those that may already have been locally verified</u>

- Ankle
- Carpal bone(s) in wrist
- Clavicle or collarbone
- Elbow, not otherwise specified
- Humerus
- Metacarpal bone(s)
- Patella
- Pelvis
- Radius or ulna
- Sacrum and Coccyx
- Scapula
- Shaft of femur
- Tarsal/metatarsal bones
- Tibia and fibula
- Tibial plateau
- Upper radius/ulna
- Vertebral

<u>Self-reports only</u>

- Elbow
- Foot
- Hand
- Hip
- Knee
- Lower arm or wrist
- Lower leg
- Pelvis
- Tailbone
- Upper arm or shoulder
- Upper leg
- Spine

Table 7.4
WHI AS Review Criteria

I. Scientific Review

A. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of this study on the concepts or methods that drive this field?

B. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

C. Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

D. Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

E. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

F. (CT Studies) Relevance to CT: Does the project draw on the randomized nature of the CT design? Is the proposed study optimally addressed in the CT; does it require an experimental, randomized design to address the study question?

II. WHI Priorities and Policy

A. Potential for contributing to the health of post-menopausal women
B. Draws on unique characteristics of the WHI
C. Complement the current portfolio of studies
D. Value of scientific resource contributed to the WHI
E. Years of service to the WHI of the AS principal investigator
F. (CT studies) Draws on unique characteristics of the WHI CT

III. Operational Criteria

A. Acceptable Informed Consent: Accurate, clear and complete; appropriately distinguishes AS participation from WHI participation
B. Acceptable burden to WHI study participants
C. None/minimal burden to WHI collaborating centers
D. Meets approval from partner WHI institutions (e.g., CCC)
E. Appropriate plan for disposition of AS data (e.g., confidentiality, submission of results data to CCC)

Figure 7.13
Model of Participant Consent Cover Letter for SRO-Ancillary Studies

This letter is sent to the participant to explain why we are contacting her, outlines the contents of the packet, and reviews what is needed from her if she chooses to participate in the SRO-AS. The letter is signed by a Co-Investigator of the WHI CCC and includes contact telephone numbers for both the CCC and the SRO-AS PI.

(date)

<<participant name>>
<<address>>
<<city,state,zipcode>>

Dear <<name>>,

Thank you for being a part of the Women's Health Initiative! The WHI was created to learn more about women's health and the causes of disease in women. As an important member of the Women's Health Initiative over the years, you and the other WHI participants have provided valuable health information that has changed medical practice and will continue to help women for generations to come.

The WHI database indicates that during your participation in the WHI, you reported that you had been diagnosed with, or received medical treatment for <<*medical condition*>>. Dr. <<*Principal Investigator*>>, a researcher at the <<*institution*>>, is conducting further research on WHI participants nationwide who have experienced this particular health condition, and is very interested in obtaining additional details about your experience. To do so, we need to review your medical records to obtain more information about your diagnosis and treatment. In WHI, health tracking has generally been done by your local clinical center. For this special WHI study, the WHI Clinical Coordinating Center (CCC) at the Fred Hutchinson Cancer Research Center in Seattle will assist with this work.

We are asking your permission to obtain medical records about this health condition from the health care providers, clinics, and hospitals that may have been involved in your care for this condition.

If you are willing to participate in this effort, we ask that you:

- ☐ Complete and return the enclosed "Health History Questionnaire" to provide some of the details we need for this research and to find out more about the type of health care you received.
- ☐ Sign and return the enclosed "Authorization to Release Medical Records". This will authorize us to access and review the medical records associated with the health condition described above.
- ☐ Return both documents to us using the enclosed postage-paid envelope.

Please be assured that all information we receive is used for research purposes only. Records are kept strictly confidential, and no names or other identifying information will be released except as required by law. Participation in this study will have no impact on your enrollment in the Women's Health Initiative, regardless of whether or not you are currently an active participant.

We greatly appreciate the contributions you have made as a volunteer in the Women's Health Initiative. If you have any questions about this letter or about the study, please call either the WHI Clinical Coordinating Center staff toll-free at 1-800-514-0325, or Dr. <<*Principal Investigator*>> at <<*phone number*>>.

Sincerely,

Andrea Z. LaCroix

Andrea LaCroix, RN, MPH, PhD
Co-Investigator, Women's Health Initiative Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Figure 7.14
Model of Health History Questionnaire for SRO-Ancillary Studies

The *Health History Questionnaire* would include questions designed specifically for each SRO-AS, depending on the needs of the study and the condition being investigated.

Women's Health Initiative
Health History Questionnaire

In a previous health update questionnaire that you completed for the Women's Health Initiative, you indicated that you had the medical condition listed below. We are currently studying that condition and need some additional information about your diagnosis. Please answer the following questions to the best of your ability, even if they are asking about events that occurred several years ago.

On a previous WHI questionnaire, you indicated that you had been diagnosed with the following condition:

Place label listing condition here

1. Please confirm that you were diagnosed with this condition:

   Yes – continue
   No – Please return this form in the envelope provided and thank you for your time

2. To the best of your knowledge, when were you first told by a doctor or other health care provider that you had this condition?

   Month / Year

3. Who is your current doctor / health care provider? If you have more than one that you visit on a regular basis, please list them below.

   Health care provider 1:
   Name
   Address
   Phone

   Health care provider 2 (3, 4):
   Name
   Address
   Phone

The next set of questions ask about visits to your doctor(s), hospital admissions, medical problems, procedures, and tests that you may have had **related to the condition listed above**. In the following questions, do not report visits that are related to other health conditions. We are specifically interested in the medical condition listed above.

4. Was the condition listed above diagnosed or treated during a visit to your doctor's office?

   Yes
   No

   a. Please provide the contact information for doctor who first diagnosed or treated this condition. If the doctor is already listed above, please provide the name only.

      Name:
      Address:
      Phone:

5. Was the condition diagnosed or treated during a hospital stay?

   a. What is the name, address, and phone number of the medical facility where you were diagnosed or treated for this condition?

      Name of hospital:
      Address:
      Phone:

   b. What was the date you entered the hospital? If you do not know the exact date, please provide the month and year.

6. Are you still receiving treatment for this condition?

   Yes
   No

7. If yes, where are you receiving the treatment? If the doctor is already listed above, please provide the name only.

   Name of provider:
   Address:
   Phone:

Thank you for your participation!

Please return all documents in the postage-paid envelope provided.

Figure 7.15
Model of Authorization to Release Medical Records Form for SRO-Ancillary Studies

The *Authorization to Release Medical Records* form sent to each participant will be tailored to meet the specific requirements of each participant's clinical center institution and state. The model below provides a sample of what a typical medical release form will include.

FRED HUTCHINSON CANCER RESEARCH CENTER
A LIFE OF SCIENCE

WHI Clinical Coordinating Center
1100 Fairview Ave. N.
PO Box 19024
Seattle, WA 98109-1024
(800) 514-0325 FAX: (206) 667-5826

AUTHORIZATION TO RELEASE MEDICAL RECORDS

The Women's Health Initiative (WHI) is a 40-center national study sponsored by the National Institutes of Health to follow for cardiovascular disease, cancer, and fractures in post-menopausal women. By signing this document, I give permission to the Principal Investigator and the WHI Clinical Coordinating Center at the Fred Hutchison Cancer Research Center – Seattle, Washington, Andrea LaCroix, RN, MPH, PhD and her staff, to request my medical records.

I hereby authorize any and all medical facilities including:

_____
Name of Physician and/or medical institutions

To disclose medical records relating to the following conditions:

Hospitalizations (overnight admission)	*Procedures and Operations*
Fractures	*X-rays, Radiology reports, Procedure report*
Cardiovascular conditions	*Medical documents including and pertaining to Myocardial Infarction, CABGs, PTCAs, CHF, Strokes, EKGs, and other Cardiovascular disease*
Mammograms	*Reports only- NO FILMS*
Cancers	*Including screenings, Breast exams, Pelvic exams, Pap smears, Ultrasounds, Endometrial biopsies and Pathology reports*

By signing, I, acknowledge that I have read and understood the following:

Duration The authorization will remain in effect until its expiration on October 1, 2010.

Revocation This authorization may be revoked at any time by calling (800) 514-0325. Revocation will be in effect immediately upon notification.

Re-disclosure Information in the above medical records may be shared with researchers at the Fred Hutchinson Cancer Research Center (the coordinating center for the study), the staff at the National Institutes of Health, and regulatory bodies such as the US Food and Drug Administration, and the Fred Hutchinson Cancer Research Center Institutional Review Board. Once disclosed this information may no longer be protected.
The WHI **may not** further use or disclose the information in my medical records unless I sign another authorization giving them permission to do so or unless such use or disclosure is required and permitted by law. Any information that is re-disclosed by the WHI Clinical Coordinating Center will have my personal information blocked on all record

After completion of the study, I will have the right to inspect or copy the information in my study file.

The records requested are required for data collection in the WHI. My compliance, or refusal, to sign this authorization has no affect whatsoever on my enrollment in WHI, nor my status as a participant.

INITIAL HERE IF YOU DESIRE A COPY OF THIS AUTHORIZATION _____
The following information is needed to assure accurate identification and is **ONLY for identification purposes**.

Patient Legal Name (Please Print)	Social Security Number (Optional)
Date of birth	Place of birth (Optional)
If another party is signing for participant, please list relationship:	Mother's Maiden Name (Optional)
Patient's Signature (or signature of party authorized to sign)	Date

Figure 7.16
Model Request for Medical Records Information Sent to Healthcare Providers and Institutions

This is a model of the form that will be sent to the health care provider to request medical records. The specific set of documents to be requested is determined by the condition and the SRO-AS investigator.

Women's Health Initiative (WHI)
Request for Medical Record Information

Date Requested: 05-09-07

To: Medical Records Department
Grossmont Hospital (Sharp)
5555 Grossmont Center Drive
La Mesa, CA 91942
Phone: (619) 740-4029 Fax: (619) 740-4466

RE Patient:	Patient ID:	Date of Service (on or about):	DOB:	SSN: xxx-xx-

Patient Address:

Phone:

WHI Use Only:
WHI Ref:
Visit ID: 9
Ext Date: 12/06/05

Enclosed is a copy of the above patient's authorization to release her medical records to the Women's Health Initiative (WHI) at UNIVERSITY OF CALIFORNIA AT SAN DIEGO. We understand that the patient was treated/admitted at your facility in connection with the following condition(s):

- **Claudication, ischemic ulcers, gangrene**
- **Pulmonary embolism (blood clot in lungs)**

Please send copies of the following documentation:

Hospital Face Sheet
ICD9-CM Codes
History & Physical/Physical Exam
Discharge Summary (if unavailable, please send Progress Notes)
Percutaneous Transluminal Coronary Angioplasty;Stent/Artherectomy
Stress Test by ECG, echo or perfusion scintigraphy report
Thallium or Technetium Studies Report
Operative or Procedure Report
Cardiac Catheterization/Angiogram/Arteriogram/Contrast Ventriculogram
Venogram Report
Impedence Plethysmography
Doppler flow study report
Isotope Scan Report

Please return a copy of this request along with the available documentation to:

UNIVERSITY OF CALIFORNIA AT SAN DIEGO
WHI CCC OUTCOMES UNIT
1100 FAIRVIEW AVENUE NORTH M3-A410
P.O. BOX 19024
SEATTLE WA 98109
Phone: (800) 514-0325 Fax: (206) 667-5829

Section 7
Follow-Up Contacts

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