Section 7
Follow-Up Contacts

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Section 7

Follow-Up Contacts

Introduction

This section describes the required and recommended procedures for carrying out routine and non-routine follow-up contacts for all WHI participants. Follow-up contacts with Women's Health Initiative (WHI) Extension Study 2010-2015 (ES2) participants include mail and/or phone contacts to collect follow-up data, maintain current contact information, follow participants for study outcomes, and promote retention. These contacts provide an opportunity for Regional Center sites to continue a professional, caring relationship with the participant throughout the duration of the study.

See *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, suicidal ideation).

7.1 Annual Mail Contact

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 contacts (by the CCC) and telephone contacts (by the RC sites) during the follow-up period.

The timing of the annual mailings is determined by the participant's original randomization/enrollment date in WHI. For the first year of the ES 2, Oct 2011 – Sept 2012, the mailing schedule is slightly different, with the mailings starting in January 2011 rather than in August 2010, due to the time needed to close-out the Extension Study 2005-2010. By August 2012, all participant mailings follow the regular mailing schedule as described below.

Table 7.1 below shows the routine forms to be collected during each annual cycle of ES 2.

Table 7.1
Data Collection Schedule

Form #	Data collection	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
--	Re-consent and Personal Information Update	X				
33	Medical History Update	X	X	X	X	X
151	Activities of Daily Life (ADL)	X		X	X	X
155	Lifestyle Questionnaire (includes ADL)		X			
153	Medication and Supplement Inventory			MRC		

X = all Extension participants
MRC = Medical Records Cohort only

7.1.1 CCC Responsibilities for Annual Follow-Up

The CCC conducts at least two annual mailings (Contacts 1-2) to collect the forms listed in Table 1 on an annual basis. The CCC is responsible for all printing (through the Government Printing Office [GPO]), assembly, and outgoing postage costs for the mail contacts.

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 mail Personal Information Updates (PIU) to participants when the CCC staff 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)

An initial mailing of the entire questionnaire packet (Contact 1) is mailed 2 months before the participant's randomization/enrollment date. Participants with an invalid address or those with a WHIX participant status of 'no CCC mail', 'no follow-up', 'absolutely no contact', or 'deceased' are excluded from the mailing.

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 RC is responsible for attempting to collect the forms that would have been sent in the packet.

If a participant enrolls in the ES 2 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 RC site telephone numbers listed (see *Figure 7.1 – Cover Letter for Annual Contact 1)*;
- A postage-paid, CCC-addressed return envelope with business reply information;
- Data collection forms. All participants receive a *Form 33 – Medical History Update* and a *Form 151 – Activities of Daily Life* annually, except during Year 2. In Year 2 (2011-2012) participants will receive *Form 155 – Lifestyle Questionnaire* instead of the *Form 151* in their mailing; *Form 151* questions have been incorporated into *Form 155*. (See *Table 7.1 – Data Collection Schedule.*)

The *Form 33* has two labels:

1) **Date Label**: a Date Label with the finished date of the last WHI Medical History Update (from the last *Form 33*), contact number (C1 or C2), and participant ID.
2) **Participant ID label:** a Participant Identification Label with participant name, participant ID and barcode, contact number (C1 or C2), 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 (non-profit) 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 mailing of the entire questionnaire packet is mailed to those who do not respond to Contact 1 (Contact 2) within 2 months of 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 Annual Contacts 2*) with a RC site telephone numbers list attached;
- 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 (non-profit) 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 Processing Returned Packets (Contacts 1-2)

CCC staff is responsible for indicating in WHIX that the mailed packets have been returned. The CCC attempts to scan all the received forms within two weeks of receipt, 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 RC 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 RC staff are responsible for contacting participants by telephone to resolve problems (e.g., missing data) on *Form 33*.

Participant Comments on Forms:

CCC staff will also review the form for any handwritten comments, post-it notes, or letters. If a note refers to any health or study-related issue or any personal note that is a request for RCs attention, the CCC will bubble in the RCA (Regional Center Alert) bubble on the form. The form is then scanned. The RCs can check for comments on the form by looking at the RCA field on the encounters screen. Forms with the RCA bubbled in will appear on *RCA001 – Forms with Comments to Review*. The CCC does not take action if a participant requests to be taken off the study; in these cases, the RCs 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 RCs should be sure to review the entire form for comments. Post-its, letters, or other communication enclosed with the forms are sent to the RCs 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.

Instead the CCC will send the originals to the RCs.

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 packets.

Following the two 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 RC Follow-Up* (see *Section 7.1.2.2 – RC Data Collection for Non-Respondents to Mailings*).

7.1.1.4 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 7.1.1.5 – Completing Form 120 – Initial Notification of Death 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 as soon as possible. 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 RCs should run *WHIX0611 – Address Problems* monthly and obtain correct addresses for participants who are listed on the report.

Note: 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 RCs for RC 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).

7.1.1.5 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 RCs by e-mail and send the *Form 120* and any notes, comments, or letters from family members or the USPO to the RCs, RCs will process these participants according to procedures in *Section 8 – Outcomes*.

7.1.2 RC Responsibilities during Annual Follow-Up Mailings (Required)

The RC'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.
- 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 RC learns of the address change.
- Conduct participant searches as needed.
- Making address and other contact information corrections as soon as they become available.

7.1.2.1 Running Monthly Follow-up Reports from WHIX

Several reports are available to help RCs 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 RC should run the following reports:

1. *WHIX0611 – Address Problems.* This provides a list of all participants (or their proxies) with undeliverable addresses in the RC'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 RC staff (see *Section 7.1.2.2 – RC 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 RC 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], following the two CCC mailings. A participant appears on this form two months after the mailing of Contact 2 if no *Form 33* has been data entered since Contact 1 was initiated and if her follow-up status is not: 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 the participant is on "no mail" follow-up or if she has an undeliverable address). RCs should not attempt to contact participants to collect annual form data until they appear on the report or after they drop off.

   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 – RC Data Collection for Non-Respondents to Mailings*, RCs 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. *RCA001 – Forms with Comments to Review*. This report lists the participants with handwritten comments on their forms requiring RC review.

4. *WHIX0983 – Analysis Encounters with Info. Conditions.* 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 (*Form 33)*. This contact may be necessary in the case of missing data, multiple marks on an item, or incorrect skip patterns.

5. *WHIX1519 – Participants Who are Lost to Follow-up.* Lists all participants who have a status of "Lost to Follow-up".

7.1.2.2 RC Data Collection for Non-Respondents to Mailings

RCs are required to attempt to collect *Form 33 – Medical History Update* for participants who have not responded to that year's mailings. If a participant has not responded to annual mail Contacts 1-2, RC 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 RC Follow-Up*.

RC 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 3), and, if needed, mail or phone contacts with the personal contacts to trace participants.

RC attempts to collect *Form 151 – Activities of Daily Life* and *Form 155 – Lifestyle Questionnaire* from non-respondents are optional.

RCs need to data enter forms collected by RC staff .

7.1.2.3 Telephone Contact to Ascertain Correct Address and to Collect Medical History Update (Contact 3) (Required)

If *Form 33* has not been returned by two months after the third mailing of the follow-up packet (CCC Contact 2), the RC 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*. Use *MAIL003 – Members Needing RC 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 3 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 – RC 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".

RCs 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 RC 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

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 RC.

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*). RC 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 RC learns of any change to personal information that comes from a source other than the CCC (e.g., the participant calls the RC directly or they learn of the change during a data collection phone call), the RC 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 RC learns that a participant is deceased (either from the CCC or a family member), RC 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. RCs 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 RCs/OCS of the participant's location during that time. RCs 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, RCs can set the flag to indicate that the alternative should be used for mailings. RCs 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 RCs 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 2 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

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 RC Principal Investigator (PI) and other RC investigators, consultants, and/or staff, as determined at your RC.

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 he/she 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.

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, RCs may 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., two mailed contacts) with a cover letter specifically designed for proxies (see *Figures 7.6 – Cover Letter for Proxy Contact 1* and *7.7 – Cover Letter for Proxy Contact 2)*. 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 RC 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 RC

If a proxy fails to reply to the mailed attempts, he/she will appear on *MAIL003 – Members Needing RC Follow-up* to collect *Form 33*. (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 RC, discuss how that person was identified as the proxy (e.g., designated by the participant, listed as a personal contact). Determine if he/she 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 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*
- *Form 151 – Activities of Daily Life* (collected at all but Year 2*)*
- *Form 153 – Medication and Supplement Inventory* (collected during Year 3 only for MRC)
- *Form 155 – Lifestyle Questionnaire* (collected during Year 2 only)
- *WHIX0441 – Personal Information Update.*

For participants whose proxies do not respond to the mailed forms, collect only *Form 33 – Medical History Update*. 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.*

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. RCs 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 RC will collect the forms by telephone annually. These women will appear on *MAIL003 – Members Needing RC 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 RC the opportunity to continue efforts to build rapport and promote retention. Reasons why a participant may contact the RC 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 RC 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 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.

7.5.1 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 7.2 and 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 former 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) was 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.

Following review and approval of these procedures by the CCC (Fred Hutchinson Cancer Research Center) Internal Review Board (IRB), each Field Center (FC) attempted to get 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.

7.5.2. 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 7.2 and 7.3*.

Participants formerly followed by FCs that obtained local IRB approval of the SRO protocol are eligible for approach for all future SRO-ASs. Participants formerly followed by 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 7.5.3* 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.

7.5.3. 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 (see http://www.whiscience.org/ancillary/new_studies.php for details). For biospecimen proposals, an additional level of review is conducted by the Laboratory Working Group (LWG), the CCC, and the Steering

Committee (SC). 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 SC 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.

7.5.4 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 7.2 and 7.3* has been funded, the CCC will notify all PIs at RCs 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 RC 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.

7.5.5 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 RC. 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 7.9 – Model Consent Cover Letter for SRO – Ancillary Studies*). 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 7.10 – Model Health History Questionnaire for SRO – Ancillary Studies*). 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 7.11 – Model Authorization to Release Medical Records for SRO – Ancillary Studies*). 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 RC 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 7.12 – 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 7.12*) 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 7.2
Self-Reported Outcomes in WHI Extension Study (2010-2015)

Alzheimer's disease
Angina or chest pain
Blood in stool
Bone density scan (DEXA)
Breast exam
Dementia
Diabetes (treated)
Emphysema/COPD
Endometrial biopsy
Falls
Hypertension
Hysterectomy
Intestinal polyps
Macular degeneration
Mammogram
Osteoarthritis
Parkinson's disease
Systemic lupus erythematosus
Transient ischemic attack
Diagnostic procedures, such as sigmoidoscopy, colonoscopy, biopsy breast

Table 7.3
Self-Reported Outcomes in WHI Extension Study – Non-Primary Fractures (non-hip)

Self-reports only

Elbow
Foot (not toe)
Hand (not finger)
Knee
Lower arm or wrist
Lower leg
Pelvis
Tailbone
Upper arm or shoulder
Spine
Finger or toe
Jaw, Nose, face and/or skull
Ribs and/or chest or breast bone

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. Efficient use of biologic specimens (volume of specimen; number of genotypes/phenotypes tested; use of high throughput facilities; need for ad hoc thawing)

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 7.1
Cover Letter for Annual Contact 1

Thank you for being a part of the Women's Health Initiative Extension Study! This important study continues to work toward improving the health and quality of life of women for generations to come.

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.

- You may recall that the Medical History Update form changed last year. The questions that all women need to complete appear in the first section of the form. Women who have experienced certain health events will be asked to complete the second part of the form.
- In this packet we have included a new *Lifestyle Questionnaire*, replacing the two-page *Activities of Daily Living* form sent to you previously. This new form asks more questions about your activities, thoughts, and feelings.
- When you have completed the forms, return them as soon as possible in the postage-paid envelope to the WHI Clinical Coordinating Center.

If you have any questions about the forms or need help filling them out, you may call your WHI Regional Center site at the phone number listed on the attached sheet or call the WHI Clinical Coordinating Center toll-free message line at 1-800-218-8415.

Please notify your WHI Regional Center if you move to a different address or if your phone number changes, so that we know where to send your study newsletters and health forms.

Your continued participation is very important to us. Thank you again for your ongoing commitment to the study!

You are part of the answer!

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CvrLtr1v3.doc 8-1-11.doc

Figure 7.2
Cover Letter for Annual Contact 2

Thank you for continuing to be part of the Women's Health Initiative Extension Study! 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.**

This important study will continue to work toward improving the health and quality of life of women for generations to come. 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.

- You may recall that the Medical History Update form changed last year. The questions that all women need to complete appear in the first section of the form. Women who have experienced certain health events will be asked to complete the second part of the form.
- In this packet we have included a new *Lifestyle Questionnaire*, replacing the two-page *Activities of Daily Living* form sent to you previously. This new form asks more questions about your activities, thoughts, and feelings.
- When you have completed the forms, return them as soon as possible in the postage-paid envelope to the WHI Clinical Coordinating Center.

If you have any questions about the forms or need help filling them out, you may call your WHI Regional Center site at the phone number listed on the attached sheet or call the WHI Clinical Coordinating Center toll-free message line at 1-800-218-8415.

Please notify your WHI Regional Center if you move to a different address or if your phone number changes, so that we know where to send your study newsletters and health forms.

Your continued participation is very important to us. Thank you again for your ongoing commitment to the study!

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 3 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 RC has the right address and phone number.

"Hello Mrs./Miss/Ms._____, this is _____ from the Women's Health Initiative Extension Study **(name of Regional Center or Outcomes Collection Satellite)** ."

"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.)

If Received:

“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 Regional Center or Outcomes Collection Satellite)**. 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 1

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in 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. This is important for the health of future generations of women!

Important goals of the study are to keep complete information on our participants and track any major changes in their health through the end of the study. When a participant in the WHI 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. Depending upon your responses, you may 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. If you have any questions or need any help, please call the _____at _____. Remember that all information you provide to us will always be kept confidential.

Thank you for your contribution to

the Women's Health Initiative!

Figure 7.7
Cover Letter for Proxy Contact 2

Thank you for your willingness to serve as a proxy (personal health contact) for a participant in the Women's Health Initiative (WHI) Extension Study. A few months ago we sent you a packet of health forms to complete. 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 yet received. **If you recently completed and mailed the forms, you do not need to fill them out again and can ignore this request.**

Important goals of the study are to keep complete information on our participants and track any major changes in their health 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.

Please complete the enclosed questionnaires to the best of your ability. They include questions about any hospitalizations or serious illnesses the participant may have had in the previous year. Depending upon your responses, you may 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. If you have any questions about the forms or need help filling them out, you may call your WHI Regional Center site at the phone number listed on the attached sheet or call the WHI Clinical Coordinating Center toll-free message line at 1-800-218-8415. Remember that all information you provide to us will always be kept confidential.

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

Figure 7.10
Model 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 7.11
Model 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 7.12
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