Supporting Statement A

Attachment 3

OS Participant Questionnaire

Instructions

OBSERVATIONAL STUDY

PARTICIPANT QUESTIONNAIRE INSTRUCTIONS

Medical History Update

Activities of Daily Life

Health Follow-Up by Proxy

Medication and Supplement Inventory

Breast Cancer Prevention and Treatment Medications

FORM: **33 - MEDICAL HISTORY UPDATE**

Version: 8 – April 1, 2005

Description: Self-administered or interviewer-administered; 4-page booklet; scanned and imaged at Clinical Coordinating Center (CCC) or key-entered at the Field Center (FC).

When used: At annual contacts for Clinical Trial (CT) and Observational Study (OS) participants enrolled in the WHI Extension Study. Completed at a non-routine contact when a participant death is reported.

Purpose: To provide initial notice of outcomes that may need further documentation on *Form 33D - Medical History Update (Detail)* and to collect information on self-reported outcomes.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 33*) and Spanish (*Form 33S*) versions. Both English and Spanish versions are in marksense format. Use the appropriate form for the participant.

2. The CCC labels and mails the annual *Form 33* for WHI Extension Study participants directly to the participant.

   - The mailing asks the participant to mail back the completed form in a return envelope by a specified date. If the participant does not return the *Form 33* within 3 months of the first mailing, the CCC will send it again. If the form is not returned within 2 months of the second mailing, the form will be sent a third time. If the form is still not returned, the FC becomes responsible for collecting the missing *Form 33*. The CCC will scan and image forms returned, and make the image available to the FC in WHIX.

3. Follow your FC's procedures for administering this form, either by mail or phone contact.

   - For FC phone contacts, administer the form as an interview. Record the finish date of the last WHI or WHI Extension Study *Form 33* in the "health problems since" date on page 1.

4. Forms returned to the FC:

   FC staff key-enter forms that the FC mails, receives, or collects. Review the form for completeness. Note that responses to questions 2-8 must be answered for appropriate reporting of the form. If these questions are not complete, contact the participant for the necessary information. Routinely run *WHIX 0621 – Outcome Screening Action Required* for a list of participant *Form 33, Ver. 8*, whose *Form 33* contains incomplete or inconsistent information. The report will list those forms collected at the FC and forms scanned at the CCC. Edit the *Form 33* and key-enter the correct form responses.

   - Complete the *Office Use Only* section on the first page. (See item instructions.)
   - Key-Entry: Key-enter the form in its entirety and initial the first page of the form after entry.
   - Use *Table 1 - Form 33 Algorithm to Initiate Administration of Form 33D* below to identify specific items that trigger a need for a *Form 33D*. Alternatively, run *WHIX 0622 – Members with Potential Outcomes* to identify those participants who need to complete *Form 33D - Medical History Update (Detail).*
   - File the form in the participant's file.

Table 1

Form 33-Medical History Update* (Ver. 8) - Algorithm to Initiate Administration of *Form 33D - Medical History Update (Detail) (Ver. 8)

Item	Criterion	Form Responses that require *Form 33D*
2	Have you been admitted to a hospital for a stay of 2 nights or more?	Code 1 - "Yes"
3.1	For which of the following heart or circulation problems were you diagnosed or treated?	Code 5 - Procedure to unblock narrowed vessels to your heart (opening the arteries of the heart with a balloon or other device, sometimes called a PTCA, coronary angioplasty, coronary stent, or laser) Code 6 - Stroke Code 9 - Blood clots in your legs (deep vein thrombosis or DVT) **[HT only]**
3.1	For which of the following heart or circulation problems were you diagnosed or treated?	Code 1 - MI Code 4 - Heart bypass operation (coronary bypass surgery or CABG) Code 8 - Procedure or operation to unblock narrowed blood vessels in your neck (carotid endarterectomy, carotid angioplasty, or carotid stent) Code 10 - Blood clots in your lungs (pulmonary embolism or PE) **[HT only]** Code 11 - Poor blood circulation or blocked or narrowed blood vessels to your legs or feet (claudication, peripheral arterial disease, gangrene, or Buerger's disease) **AND**
3.2	For any of the selected items marked in 3.1 were you admitted to a hospital for at least one night?	Code 1 - "Yes"
4.1	What type of cancer?	Code 8 - Other cancer or malignant tumor
5.1	Which bone(s) did you break, fracture, or crush?	Code 1 - Hip
8	Which exams, tests, or procedures were done by a doctor or a nurse?	Code 10 - Removal of the uterus or womb (hysterectomy) **[HT only]**

Item Instructions

	Date received	Date received at FC or date completed by phone interview. Located in *Official Use Only* on page 1. When the CCC mails the form to and receives it back from the participant, this item is left blank and instead the scan date is inserted into WHIX.
	Reviewed by	5-digit WHI Extension study employee ID. For forms scanned at the CCC, this item is left blank and instead WHIX inserts the ID of the CCC staff person scanning the form.
	Contact type	Mark appropriate box. For forms scanned at the CCC, this item is left blank, and WHIX inserts "2 – Mail" into WHIX.
	Visit type	Mark appropriate box. For forms scanned at the CCC, this item is left blank, and WHIX inserts "3 – Annual" into WHIX. Mark Non-Routine only for a WHI Extension study participant death. Note: Visit Type non-routine is accepted by the WHIX data base only after entry of *Form 120 – Initial Notification of Death.*
	Language	Indication of English (E) or Spanish (S) version of the form. The response to this item is printed on the form.
	Field Center Alert (FCA) bubble	Used by CCC to alert the FC that a form has participant comments and the image should be reviewed.
	OU1 bubble	Reserved for future use.
	OU2 bubble	Reserved for future use.
	Health problems and health care since date	Refers to item #9 - "date form finished" the participant recorded on the last page of the most recent, routine *Form 33 – Medical History Update.* For CCC mailings, the CCC prints the *Form 33* Label Set and affixes the date label to the front of the form. For subsequent FC contacts (e.g., because of non-response to CCC mailings) the FC can print a *Form 33* Label Set that includes a label to affix within the appropriate box on the front of the form. Use of this label is strongly recommended to ensure accurate collection of outcomes within the specified date range. If the participant is unsure if the outcome occurred since the date on the front of the form, she should report the information on the current form.
1.	Identify person providing responses for this form	Mark the corresponding box identifying who provided the responses for the form.
2.	Admitted to a hospital for 2 nights or more	No/Yes. This question refers to all overnight hospital admissions of 2 nights or more where the participant occupied a hospital bed. **Do not include** visits to hospital outpatient departments or emergency departments, unless the participant stayed 2 nights or more. Marking "1 – Yes" to this question requires completion of *Form 33D.*

3.	Diagnosed or treated for heart problems, blood vessels, stroke or other circulation problems	No/Yes. Includes hospitalized and outpatient diagnosis or treatment for the heart problems, blocked or narrowed blood vessels, stroke or circulation problems.
3.1	Type of heart or circulation problem	Mark all that apply. Select appropriate heart and or circulation problems from the list provided. The purpose of this questions is to identify WHI outcomes/events. Marking any of the following diagnoses or procedures requires completion of a *Form 33D*: Code 5 - Procedure to unblock narrowed vessels to your heart (opening the arteries of the heart with a balloon or other device, sometimes called a PTCA, coronary angioplasty, coronary stent, or laser) Code 6 - Stroke Code 9 - Blood clots in your legs (deep vein thrombosis or DVT) **[HT only]**
3.2	Admited to a hospital for at least one night	No/Yes. If Q3.2 is checked "Yes" AND any of the following heart or circulation problems are checked in Q3.1, requires completion of a *Form 33D:* Code 1 - MI Code 4 - Heart bypass operation (coronary bypass surgery or CABG) Code 8 - Procedure or operation to unblock narrowed blood vessels in your neck (carotid endarterectomy, carotid angioplasty, or carotid stent) Code 10 - Blood clots in your lungs (pulmonary embolism or PE) **[HT only]** Code 11 - Poor blood circulation or blocked or narrowed blood vessels to your legs or feet (claudication, peripheral arterial disease, gangrene, or Buerger's disease)
4.	New cancer or a malignant tumor	No/Yes
4.1	Type of cancer	Mark all that apply. This question refers to any new diagnosis of cancer. The purpose of this question is to distinguish between non-melanoma skin cancer that does not require investigation verses a report of cancer that requires investigation. Marking "code 8 - other cancer or malignant tumor" requires completion of a *Form 33D.*
5	New broken, crushed or fractured bone	No/Yes.
5.1	Bone broken	Mark all that apply. This question refers to any new diagnosis of fracture. All other fractures (non-hip) are collected as a self-report. Marking "code 1 - hip fracture" requires completion of a *Form 33D.*

6. New medications

Mark all of the medications that have been prescribed since the last Form 33 was completed. Medication is defined as a pharmacologic preparation prescribed by a physician, nurse practitioner, or physician assistant. It does not include non-pharmacologic remedies such as herbal preparations.

Boxes 1-3 – Diabetes. Medication for treatment of diabetes that is used to lower the blood sugar level. This medication can be in the form of pills or shots. For "2 - insulin shots for diabetes," mark only if the participant requires insulin shots on an ongoing basis, not if the participant usually requires pills alone but was given an insulin shot for a brief period when her diabetes was poorly controlled. Mark "3-Diet and/or physical activity for diabetes if it was prescribed by the healthcare professional. It does not include a participant initiated diet and/or exercise plan.

Box 4 – High blood pressure/hypertension. Medication used to treat high blood pressure or hypertension that is used to lower a participant's blood pressure. Mark "4 - pills for high blood pressure or hypertension" even if the participant has not been taking this blood pressure medication as prescribed.

Box 5-6 – Depression; anxiety, panic, phobia. Medication and/or therapy used to treat depression, anxiety, panic, or phobia. Therapy includes conventional therapy such as structured counseling, psychotherapy. It does not include alternative forms of therapy a participant may engage in such as yoga, acupuncture, or aromatherapy.

Box 7-8 – Osteoporosis. Medication used to treat osteoporosis, a disease that causes a decrease of the bone mass that results in bone thinning and possible fracture. Box 8 is asking specifically about calcium supplements.

Box 10 – Estrogen. Medication often used to treat relief of menopausal symptoms and/or protect against diseases such as osteoporosis.

Mark "99 - None of the above" if no new medication has been prescribed since the last *Form 33* was completed. Check to make sure the participant marked this box and did not accidentally skip this question.

7. Diagnosis of new conditions

Mark all new conditions diagnosed since the last *Form 33* was completed. Mark only conditions that have been identified by a doctor for the first time. Mark "99 - None of the above" if none of the specific conditions apply. Check to make sure the participant marked this box and did not accidentally skip this question.

8. Exams, tests, or procedures by doctor or nurse

Mark all exams, tests, and procedures that have been done or prescribed by a doctor, nurse practitioner, or physician assistant since the last *Form 33* was completed. The participant should report all tests and procedures she had of those listed. If the participant has not had any of the procedures or tests listed, mark "99 - None of the above." Check to make sure the participant marked this box and did not accidentally skip this question.

Marking "code 10 - hysterectomy (HT only)" requires completion of a *Form 33D.*

9. Date finished form

Date the participant answered the questions on the form. This date may need to be edited if the FC staff review the form with the participant after she completes it.

FORM: **33D - MEDICAL HISTORY UPDATE (Detail)**

Version: 9 – March 30, 2007

Description: Self-administered or interviewer-administered; 12-page booklet; key-entered at Field Center (FC).

When used: To be completed after a *Form 33 – Medical History Update (Ver. 8)* has identified a medical problem, event, or procedure that indicates a possible WHI Extension Study outcome has occurred and needs to be further investigated. Completed at annual follow-up contacts for Clinical Trial (CT) participants and Observational Study (OS) participants enrolled in the WHI Extension Study, as appropriate.

Completed at a non-routine contact when a participant death is reported and the *Form 33* completed by the proxy indicates a *Form 33D* is required.

Purpose: To identify possible WHI Extension Study outcomes needing further documentation.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 33D*), and Spanish (*Form 33DS*) versions. Use the appropriate form for the participant. The WHIX report, *WHIX 0622 – Form 33s with Potential WHI Extension Study Outcomes*, identifies the WHI Extension Study participant who needs to complete *Form 33D.*

2. Place the participant barcode label on the front page of the questionnaire.

3. Use the WHIX-generated label to record the date of the participant's last WHI *Form 33* in the indicated box. This "health problems since" date (also known as the "start date" on *WHIX 0621 - Outcome Screening Actions Required for Form 33 Version 8* and WHIX*0622 - Form 33s with Potential WHI Extension Study Outcomes*) is the same as the matching *Form 33 - Medical History Update* that triggered this *Form 33D.*

4. Follow your FC's procedures for administering this form, either by mail or phone contact. The WHIX database report *WHIX 0622* lists names and phone numbers of participants requiring a *Form 33D* and can serve as a phone log for completing this form by interview.

   To facilitate accurate completion of *Form 33D*, encourage the participant to have her personal calendar, medical records (discharge instructions, Explanation of Benefits (EOBs), or medical bills with dates of service) available to reference when completing this detailed form.

   - For phone contacts, administer the form as an interview.
   - For mail contacts, the FC mails to the participant and asks her to mail back in a return envelope by a specified date.

5. Returned *Form 33D*s:

   - Review the form for completeness. If a question is not complete, e.g., incomplete or missing, contact the participant for the necessary information.
   - Key-Entry: Key-enter the form and initial the first page of the form after entry.
   - File the form in the participant's outcomes file.

Item Instructions

	Date received	Date received at FC or date completed by phone interview. Located in *Official Use Only* box on page 1.
	Reviewed by	5-digit WHI Extension study employee ID.
	Contact type	Mark appropriate box.
	Visit type	Annual Contact. If received between visits, use visit for which you intended the form. Non-Routine: For a WHI Extension study participant death only. Completed only when the proxy's *Form 33* indicates completion of *Form 33D* is required.
	Health problems and health care since date	Refers to the "date form finished" the participant recorded on the last page of the previous, routine *Form 33 - Medical History Update.* The FC can print the *Form 33D* label set and affix the start date label to the front of the form. Use of this label is strongly recommended to ensure accurate collection of outcomes within the date range specified on the *Form 33* (i.e., the date on the front of the *Form 33* and corresponding *Form 33D* match). *WHIX 0622 – Members with Potential Outcomes* provides the "date form finished" if a label is not available. Data Entry: Key-enter the "health problem since" date. The WHIX database will generate warning notice if the key-entered start date differs form the matching *Form 33* "health problems since" date.
1.	Identify person providing responses for this form	Mark the corresponding box identifying who provided the responses on the form.
2.	New broken, fractured, or crushed hip or upper leg bone	Yes/No. To identify any new diagnosis of hip fracture, including that which was self reported as upper leg.
2.1	Where was the fracture?	Mark appropriate box(es).
2.2.	Hip fracture diagnosed or treated during hospital stay?	Yes/No.
2.3.	Location of hip fracture treatment	Write in the name, address, and phone number (FAX optional) of the place where the fracture was treated. Enter the provider identification number assigned by the WHIX database in the provider ID box. If more than one hip fracture is reported for this time period, write the provider information for treatment for the first hip fracture. Record the information for the second hip fracture on the last page of this form. Key-Entry: Key-enter the provider identification number only. Do not key-enter the facility name and address.

2.4.	Date Entered	Record the date of hospital admission. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the *Form 33D* that the date recorded is an estimate.
2.5.	Date Left	The date of discharge (or date of death if the participant died in the hospital).
2.6.	X-ray/MRI completed	Yes/No. To identify if an X-ray or imaging scan (MRI) was taken to diagnose the fracture.
2.7.	Location of X-ray or imaging scan (MRI) records	Write in the name, address, and phone number (FAX optional) of the place where the X-ray or imaging scan (MRI) was completed. Enter the provider identification number assigned by the WHIX database in the provider ID box. Data Entry: Do not key-enter the provider identification number if it is the same as the one data entered in 2.3. Do not key-enter the facility name and address.
2.8	Date of X-ray or imaging scan (MRI)	Write in the date the X-ray or imaging scan (MRI) was completed. If there was more than one visit, record the date for the first visit.
3.	New cancer or malignant tumor	Yes/No. To identify information regarding a new (incident) cancer, malignant growth or tumor. Do not include benign tumors or cancers first diagnosed before the "health problems since" date on the front of the form.
3.1.	Type of cancer	Mark all that apply. Mark the primary site(s) of the cancer. Do not include a secondary or metastatic site unless the primary site is unknown. If the kind of cancer is not listed, mark "88 - Other cancer" and write in the cancer type. Data Entry: Do not key enter "code 88 - other cancer" text.
3.2.	Cancer diagnosed or treated during hospital stay?	Yes/No. To identify if the cancer or tumor was diagnosed or treated during a hospital stay of one or more nights.
3.3.	Address where cancer medical records kept	Write in the name, address, and phone number (FAX optional) of the place where the most complete record or tests, surgeries, and examinations used to diagnose the cancer can be obtained. Enter the provider identification number assigned by the WHIX database in the provider ID box. If more than one cancer is reported for this time period, write the location where the medical records are kept for the <u>first</u> cancer. Record the information for each additional cancer on the last page of this form. Key-Entry: Key-enter the provider identification number only. Do not key-enter the facility name and address.
3.4.	Date Entered	Record the date of hospital admission. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the *Form 33D* that the date recorded is an estimate.
3.5.	Date Left	The date of discharge (or date of death if the participant died in the hospital).
3.6.	Date of cancer diagnosis	Write in the date the cancer or tumor was first diagnosed.

3.7.	Name and address where the cancer was first diagnosed.	Write in the name, address, and phone number of the place where the cancer or tumor was first diagnosed. This information is needed so that further information can be requested if needed. Enter the provider identification number assigned by the WHIX database in the provider ID box. If more than one cancer is reported for this time period, write the name of the physician who diagnosed the first cancer. Record the information for each additional cancer on the last page of this form. Data Entry: Do not key-enter name and address. Do not enter the provider ID if it is the same as the one recorded in 3.3.
3.8.	Name and address where other tests/procedures were done.	Write in the name, address, and phone number of the place where other tests or procedures for the cancer or tumor were done. This would include any further diagnostic tests or procedures conducted following the initial diagnosis of the cancer. Enter the provider identification number assigned by the WHIX database in the provider ID box. If more than one cancer is reported for this time period, write the name of the physician who diagnosed the first cancer. Record the information for each additional cancer on the last page of *Form 33D*. Data Entry: Do not key-enter name and address. Do not enter the provider ID if it is the same as the one recorded in 3.3 or 3.7.
4.	Hysterectomy	Yes/No. Hysterectomy: an operation to remove the uterus or womb. Include a hysterectomy done as a day surgery procedure or an overnight hospital stay.
4.1.	Date of operation	Write in the date the hysterectomy was done.
4.2.	Name and address where operation was done.	Write in the name, address, and phone number of the place where the hysterectomy operation was done. This may be a hospital, surgi-center, or ambulatory care center. Enter the provider identification number assigned by the WHIX database in the provider ID box. Key-Entry: Key-enter the provider identification number only. Do not key-enter name and address.
4.3.	Doctor's name	Write in the name, address, and phone number of the physician who did the hysterectomy operation. This information is needed so that further information can be requested if needed. Data Entry: Do not key-enter name and address. Do not key enter the provider ID if it is the same as the one recorded in 4.2.
5.	Treatment for heart or circulation problems	No/Yes. Refers to treatment because of heart problems, blocked or narrowed blood vessels, stroke or other problems with circulation problem (e.g., DVT and/or PE).
5.1.	Hospital stay of 1 night or more for heart or circulation problem.	Yes/No. Overnight hospitalization (where the participant occupied a hospital bed), for any heart problems such as blocked or narrowed blood vessels, stroke, or problems with blood circulation (e.g., DVT and/or PE). Do not include outpatient visits, emergency room visits, day surgery.

5.2.	Heart and circulation conditions	Mark all that apply. Select from the list all heart and circulation problems that apply. Included in the list are medical diagnoses as well as clinical procedures and operations. If an "other" heart condition was reported and treated during an overnight hospitalization, mark "88 - Other heart problem".
5.3	Details of **First** hospitalization admission for heart or circulation problems	Write in the first hospital name address and phone number (FAX optional). Provide sufficient information to identify the specific hospital as many hospitals have the same name and differ only by geographic location. If the hospital is outside the FC area, the participant should give as complete an address as possible.
5.4.	Date Entered	Record the first date of hospital admission. If unsure of the exact day, use the 15th of the month as the default date and indicate on the *Form 33D* that the date recorded is an estimate.
5.5.	Date Left	The date of discharge (or date of death if the participant died in the hospital). Note: **A discharge date is required.**
5.6.	**Second** hospitalization	These questions refer to the second overnight hospitalization for diagnosis or treatment of a heart or circulation problem. See instructions under 5.3-5.5 above.
6.	Outpatient DVT	Yes/No. Outpatient shots received at home or as an outpatient for blood clots in the legs, called deep vein thrombosis or DVT?
6.1.	Date shots started	Write the date the shots for the DVT were started.
6.2.	Name, address of doctor	Write in the name, address, and phone number of the physician who treated the participant for the blood clots in the legs (DVT). Enter the provider identification number assigned by the WHIX database in the provider ID box. Data Entry: Key-enter the provider ID number. Do not key-enter name and address.
6.3.	Outpatient tests performed to diagnose DVT	Yes/No. Outpatient test to diagnose for blood clots in the legs (DVT).
6.4.	Date of procedure	Write in the date the outpatient DVT test was done.
6.5.	Address for outpatient DVT medical records	The name, address, and phone number of where the diagnostic testing was done. This may be an outpatient facility, surgi-center, or ambulatory care center. Enter the provider identification number assigned by the WHIX database in the provider ID box. Key-Entry: Do not key-enter name and address. Do not key-enter the provider ID if it is the same as the one recorded in 6.2.
7.	Outpatient Stroke	Yes/No. Diagnosed or treated for an outpatient stoke. Do not include diagnosis or treatment for TIA.
7.1.	Date of diagnosis or treatment for stroke	Write in the first date the participant was diagnosed or treated for the stroke.

7.2.	Address for outpatient stroke medical records	The name, address, and phone number of location where the diagnosis or treatment for the stroke was completed. This may be an outpatient facility, surgi-center or ambulatory care center. Enter the provider identification number assigned by the WHIX database in the provider ID box. Data Entry: Key-enter the provider ID number only. Do not key-enter name and address.
8.	Outpatient PTCA	Yes/No. Outpatient or day surgery procedure to unblock blocked or narrowed vessels of the heart. PTCA, coronary angioplasty, stent, or atherectomy.
8.1.	Date of procedure	Write in the date the PTCA or other coronary revascularization procedure was performed.
8.2.	Address for outpatient PTCA medical records	The name, address, and phone number of where the revascular procedure was done. This may be an outpatient facility, surgi-center or ambulatory care center. Enter the provider identification number assigned by the WHIX database in the provider ID box. Data Entry: Key-enter the provider ID number. Do not key-enter name and address.
9.	Hospital stay of 2 or more nights	Yes/No. This question refers to all overnight hospital admissions of 2 nights or more where the participant occupied a hospital bed. Do not include visits to hospital outpatient departments or emergency departments, unless the participant was ultimately admitted to the hospital and the stay in the hospital was 2 nights or more.
9.1.	Details of **First** hospital admission of 2 nights or more	Write in the hospital name address and phone number (FAX optional). Provide sufficient information to identify the specific hospital as many hospitals have the same name and differ only by geographic location. If the hospital is outside the FC area, the participant should give as complete an address as possible. Enter the provider identification number assigned by the WHIX database in the provider ID box. Note: Include a 2-night or more hospitalization for a hysterectomy reported in Item 4 (for HT and non-HT participants). Data Entry: Key-enter the provider ID number. Do not key-enter name and address.
9.2.	Date Entered	Record the first date of hospital admission. If unsure of the exact day, use the 15th of the month as the default date and indicate on the *Form 33D* that the date recorded is an estimate.
9.3.	Date Left	The date of discharge (or date of death if the participant died in the hospital). This hospital discharge date is optional.
9.4.	Reason for hospital stay	Select all appropriate reasons for the hospital stay of 2 nights or more from the list provided. If the reason for the hospital admission is not listed, mark "88 – Other" and write in the reason for the admission.
9.5.	**Office use only**	FC Outcomes staff mark this box if in Q.9.4, "88 – Other" is marked and written text indicates the reason for the hospital stay(s) is excluded from investigation because it is listed on *Selected hospitalized procedures requiring no follow-up* (i.e., the Bunionectomy list). (See *Vol. 8, Table 2.1 – WHI Outcomes and Required Outcomes Forms* for a complete list of diagnoses and procedures that do not require investigation.)
9.6.	**Second** hospitalization	These questions refer to the **Second** hospital stay of 2 nights or more. See instructions under 9.1. above.

9.11. **Third** hospitalization — These questions refer to the **third** hospital stay of 2 nights or more. See instructions under 9.1. above.

10. Date form finished — Date the participant finished answering the form. Edit this data appropriately if the form is reviewed with the participant after she completed it. The date the *Form 33D* was finished must be between the "health problems since" date and the "encounter" date of the form.

Table 1

***Form 33D--Medical History Update* (Detail) – Analyzer interpretation of a correctly completed Form**

Form Response "Yes"	Sub-question responses	Analyzer Result: Condition and provider visit created and linked *
Q. 2 – Fracture	2.2 is marked *yes*	Hip fracture condition, inpatient provider visit
	2.2 and 2.6 are marked *yes*, and 2.7 provider ID is not a duplicate	Second inpatient provider visit
	2.2 is marked *no* and 2.6 is marked *yes*	Hip fracture condition, outpatient provider visit
Q.3 – Cancer	3.1-Box 1, 2, 3, and/or 5 checked	Breast, ovary, endometrial, and/or colon/rectum cancer condition created
	3.1-Box 4, 7, 8, 9, 10, 11, 12, 13, and/or 88 checked	Other cancer condition created
	3.1-Only Box 6 is checked	Skin cancer only, no condition or provider visit created (in past versions, the analyzer created an inpatient visit for this)
	3.2 is marked *yes*	Inpatient visit with provider ID in 3.3, 3.7, and 3.8
	3 is marked *yes* and 3.2 is marked *no*	Outpatient visit with provider ID in 3.7 and 3.8
Q. 4 – Hysterectomy	4 is marked *yes* (HT only)	Hysterectomy condition, inpatient visit with provider ID in 4.2
	Provider ID 4.3 is not a duplicate of 4.2 (HT only)	Hysterectomy condition and second inpatient visit with provider ID in 4.3
Q. 5 – Heart/circulation	5.1 is marked *yes* and 5.2, Box 1, 2, 3, 4, 5, and/or 8 checked	MI, CABG, PTCA, carotid artery disease (CAD), stroke, and/or peripheral artery disease (PAD) condition, inpatient provider ID in 5.3 and/or 5.6
	5.1 is marked *yes* and 5.2, Box 6 and/or 7 checked (HT only)	DVT and/or PE condition, inpatient provider ID in 5.3 and/or 5.6
	5.1 is marked *yes* and 5.2, Box 6 and/or 7 checked (Non-HT) and hospitalized 2 nights or more	Unknown event condition, inpatient provider ID in 5.3 and/or 5.6
	5.1 is marked *yes* and 5.2, Box 88 checked and hospitalized for 2 nights or more	Unknown event condition, inpatient provider ID in 5.3 and/or 5.6

Table 1 (continued)

***Form 33D--Medical History Update* (Detail) – Analyzer interpretation of a correctly completed Form**

Form Response "Yes"	Sub-question responses	Analyzer Result: Condition and provider visit created and linked *
Q.6 – DVT	6 is marked yes (HT only)	DVT condition, outpatient provider ID in 6.2 (if one is not already reported in Q.5)
	6.3 is marked *yes* and 6.4 and 6.5 are not duplicate of 6.1 and 6.2	Second outpatient provider visit
Q. 7 – Stroke	7 is marked *yes*	Stroke condition, outpatient provider ID in 7.2 (if one is not already reported in Q.5)
Q. 8 – PTCA	8 is marked *yes*	PTCA condition, outpatient provider ID in 8.2 (if one is not already reported in Q.5)
Q. 9 – Hospital stay of 2 nights or more	9 is marked yes and 9.4, Box 88 is checked and 9.5 is blank	Unknown event condition, inpatient visit, provider ID is in 9.1
	9 is marked *yes* and 9.9, Box 88 is checked and 9.10 is blank	Unknown event condition, inpatient visit, provider ID is in 9.6
	9 is marked *yes* and 9.14, Box 88 is checked and 9.15 is blank	Unknown event condition, inpatient visit, provider ID is in 9.11

*Excludes non-melanoma skin cancer

FORM: **151 – ACTIVITIES OF DAILY LIFE**

Version: 9 – March 30, 2007

Description: 1-page, 2-sided form; scanned at CCC.

When used: Mailed annually to Extension Study participants; mailed routinely with the *Form 33 – Medical History Update.*

Purpose: To record information about the impact of disease events on daily functioning and quality of life in aging participants. There is no expectation that the FCs follow-up on information that a participant marks on this form.

GENERAL INSTRUCTIONS

The form is printed in both English (*Form 151*) and Spanish (*Form 151s*) and both are in mark-sense format. For both forms, follow the instructions on the front of the form for marking the answers.

The CCC places the participant barcode label on the front page of the form and mails it with the annual *Form 33 – Medical History Update* and one-time *Form 134 – Addendum to the Medical History Update* to HT participants two months before the randomization anniversary month.

Participants are asked to mail the completed form back to the CCC together with the *Form 33 – Medical History Update* and the *Form 134 – Addendum to the Medical History Update* in the return envelope provided.

Data entry at the CCC. Review the form for comments and mark the FCA box in the Office Use Only box as needed. Scan the form.

Item Instructions

Date received	Date received at FC or date completed by phone interview. Located in *Official Use Only* on page 1. When the CCC mails the form to and receives it back from the participant, this item is left blank and instead the scan date is inserted into WHIX.
Reviewed by	5-digit WHI Extension study employee ID. For forms scanned at the CCC, this item is left blank and instead WHIX inserts the ID of the CCC staff person scanning the form.
Contact type	Mark appropriate box. For forms scanned at the CCC, this item is left blank, and WHIX inserts "2 – Mail" into WHIX.
Visit type	Mark appropriate box. For forms scanned at the CCC, this item is left blank, and WHIX inserts "3 – Annual" into WHIX.
Language	Indication of English (E) or Spanish (S) version of the form. The response to this item is printed on the form.
Field Center Alert (FCA) bubble	Used by CCC to alert the FC that a form has participant comments and the image should be reviewed.
OU1 bubble	Reserved for future use.
OU2 bubble	Reserved for future use.

1.	In general, how is your health?	Mark one box
2.	Overall, rate your quality of life	Mark one box, 0 (worse than being dead) to 10 (best quality of life)
3.	Does your place have special services for older people?	No/Yes
3.1	Currently receiving any of these services?	No/Yes
4.	Stayed in nursing home in past year?	No/Yes
5.	Do you use aids to walk on level surface?	Mark one box (1 – 5)
6.	Taking a calcium supplement such as Oscal, Viactiv, or Tums?	No/Yes
7.	Does your health limit moderate activities?	Mark one box: No (not limite)d/Yes (limited a little)/Yes (limited a lot)
8.	Does your health limit lifting or carrying groceries?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)

9.	Does your health limit climbing flights of stairs?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
10.	Does your health limit climbing one flight of stairs?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
11.	Does your health limit bending, kneeling, stooping?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
12.	Does your health limit walking more than a mile?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
13.	Does your health limit walking several blocks?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
14.	Does your health limit walking one block?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
15.	Does your health limit bathing or dressing?	Mark one box: No (not limited)/Yes (limited a little)/Yes (limited a lot)
16.	Can you feed yourself?	Mark one box: By myself/With some help/Completely unable to do by myself
17.	Can you dress and undress yourself?	Mark one box: By myself/With some help/Completely unable to do by myself
18.	Can you get in/out of bed by yourself?	Mark one box: By myself/With some help/Completely unable to do by myself
19.	Can you bathe or shower by yourself?	Mark one box: By myself/With some help/Completely unable to do by myself
20.	Can you do your own grocery shopping?	Mark one box: By myself/With some help/Completely unable to do by myself
21.	Can you keep track and take your medication?	Mark one box: By myself/With some help/Completely unable to do by myself

FORM: **152 – HEALTH FOLLOW-UP BY PROXY**

Version: 1

Description: Self-administered or interviewer-administered; optional for the Field Center (FC) to either file in the participant's chart or key-enter in WHIX.

When used: A one-time mailing sent by the Clinical Coordinating Center (CCC) to a participant in an annual Extension mailing packet.

Purpose: For the participant to designate a proxy who is able to provide information about her when she cannot because of serious illness or death.

GENERAL INSTRUCTIONS

1. The *Form 152* can be printed locally and is available on the WHIOPs study operations website. The form is available in both English (*Form 152*) and Spanish (*Form 152S*) versions. The appropriate form will be used for the participant.

2. The one-time mailing of the *Form 152* for a WHI Extension Study participant will be labeled and mailed directly from the CCC to the participant in an annual Extension mailing.

   - If at least one of the forms in the mailing packet is returned to the CCC, without the *Form 152*, it will be assumed that the participant received the *Form 152* but decided not to complete and return the form to the CCC. In this instance, the *Form 152* will not be mailed again.

   - If the participant does not return to the CCC any of the forms in the mailing packet, the *Form 152* will be included in subsequent mailings until at least one of the forms in the mailing packet is returned to the CCC.

3. The CCC will distribute the returned proxy forms to the FCs via U.S. mail each week.

4. At the FC's option, the form will either be filed in the participant's chart or the information will be data entered in WHIX. A tracking system for the *Form 152* is discretionary for the FC.

Item Instructions

Name of Proxy:	Full legal name of proxy
Street Address:	Street address for proxy
City:	City of residence for proxy
State:	State of residence for proxy
Zip:	Zip code of residence for proxy
Phone #:	Phone number for proxy
Other Phone #:	Another phone number where proxy can be reached
Relationship to me:	Relationship of the proxy to the participant, e.g., spouse, daughter, son.
Signature of Participant/Date:	Signature and date of signature of the participant

FORM: **153 – MEDICATION AND SUPPLEMENT INVENTORY**

Version: 1 – November, 2008

Description: Self-administered or interviewer-administered; 9-page booklet; key-entered at the Clinical Coordinating Center (CCC).

When used: Collected one time as part of the annual contacts for Clinical Trial (CT) and Observational Study (OS) participants enrolled in the WHI Extension Study. Completed at a non-routine contact when a participant death is reported.

Purpose: To collect updated information on the prescription and over-the-counter medications and nutritional supplements currently being used by participants.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 153*) and Spanish (*Form 153S*) versions.

2. The *Form 153* for WHI Extension Study participants will be labeled and mailed from the CCC directly to the participant.

    - The CCC mails the form to the participant and asks her to mail it back in a return envelope by a specified date. Following the CCC mailing, if the participant does not return the *Form 153* within 3 months of the first mailing, it will be sent again. If the form is not returned within 2 months of the second mailing, the form will be sent a third time. If the form is still not returned, CCC staff will contact the participants by telephone to collect the information from willing participants. The CCC will data enter the forms, and will use the Medispan database to code medications during the data entry process.

3. In the event that this form is collected by FC staff, the form should be sent to the CCC for data entry.

Item Instructions

Cover page

1.	Date Received	Fill in date received at the CCC.
2.	Reviewed By	Fill in standard 3-digit WHI employee ID of staff member reviewing the form for data entry.
3.	Contact Type	Mark appropriate box (phone, mail, other).

Prescription Medications

1.	Currently Taking Prescription Medications	No/Yes. Participants indicating "No" skip to Q 4 in Section B.
2a.	Prescription Medication Name	For each prescription medication listed, participant records the name of the medication.
2b.	Prescription Medication Strength	For each prescription medication listed, participant records the strength of the medication.
2c.	Prescription Medication Type	For each prescription medication listed, participant records the medication type, e.g., capsule, tablet, cream, liquid, suppository, inhaler, injection.
2d.	Prescription Medication Duration	For each prescription listed, participant indicates length of time taking medication. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 provide the actual number of years.

Repeat 2a-d for each prescription medication, up to 10 medications.

3.	Other Prescription Medications	Participant records name of any other prescription medications they are taking, if there was not enough room to list them in item 2 above.
4.	Barriers to Prescription Medications	Participant checks all barriers that apply.

Non-Prescription Medications

Participant indicates the following information for each of these non-prescription medications: aspirin, anti-inflammatories, antacid or heartburn medicines, and natural female hormones. Participants can list up to 2 types of anti-flammatories, antacids, and natural hormones.

5.	Taken the Non-Prescription Medication in Past Two Weeks	Yes/No. Participants indicating "No" skip to the next non-prescription medication.
5.	Name of the Non-Prescription Medication	For each medication they are taking, participant provides the name of the product.
5.	Strength of the Non-Prescription Medication	For each medication they are taking, participant provides the strength of the product.
5.	Non-Prescription Medication – Frequency	For each medication they are taking, participant indicates how often they take it. The options are: 1. Once a day or more; 2. 4-6 days a week; 3. 2-3 days a week; 4. Once a week; 5. 1-3 days a month.
5.	Prescription Medication Duration	For each medication they are taking, participant indicates how long they have been taking it. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 also indicate the actual number of years.

6.	Over-the-Counter Insulin	Participants are asked if they are taking over-the-counter insulin Yes/No. Those who indicate yes, are asked to provide the name of the product, the strength, how often it is taken (1. Once a day or more; 2. Less than once a day) and how long it has been taken (1. Less than a month; 2. 1-12 months; 3. More than 1 year. How many years?)

Dietary Supplements

7 M/V.	Daily Multi-Vitamin Supplement – Taken in Past 2 Weeks	Yes/No. Participants indicating "No" skip to the next supplement.
	Daily Multi-Vitamin Supplement – Product Name	Participant provides the name of the product.
	Daily Multi-Vitamin Supplement – Frequency	Participant indicates how often they take it. The options are: 1. Once a day or more; 2. 4-6 days a week; 3. 2-3 days a week; 4. Once a week.
	Daily Multi-Vitamin Supplement – Duration	Participant indicates how long they have been taking it. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 also indicate the actual number of years.
7 Cal/ VitD.	Calcium/Vitamin D Supplementation Mixture – Taken in Past 2 Weeks	Yes/No. Participants indicating "No" skip to the next supplement.
	Calcium/Vitamin D Supplementation Mixture – Product Name	Participant provides the name of the product.
	Calcium/Vitamin D Supplementation Mixture – Strength	Participant provides strength of calcium and strength of vitamin D.
	Calcium/Vitamin D Supplementation Mixture – Frequency	Participant indicates how often they take it. The options are: 1. Once a day or more; 2. 4-6 days a week; 3. 2-3 days a week; 4. Once a week.
	Calcium/Vitamin D Supplementation Mixture – Duration	Participant indicates how long they have been taking it. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 also indicate the actual number of years.
7 Cal.	Calcium Single Supplement – Taken in Past 2 Weeks	Yes/No. Participants indicating "No" skip to the next supplement.
	Calcium Single Supplement – Product Name	Participant provides the name of the product.
	Calcium Single Supplment - Strength	Participant provides strength of calcium.
	Calcium Single Supplement – Frequency	Participant indicates how often they take it. The options are: 1. Once a day or more; 2. 4-6 days a week; 3. 2-3 days a week; 4. Once a week.
	Calcium Single Supplement – Duration	Participant indicates how long they have been taking it. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 also indicate the actual number of years.

7 VitD.	Vitamin D Single Supplement – Taken in Past 2 Weeks	Yes/No. Participants indicating "No" skip to the next supplement.
	Vitamin D Single Supplement – Product Name	Participant provides the name of the product.
	Vitamin D Single Supplment - Strength	Participant indicates strength of the vitamin D.
	Vitamin D Single Supplement – Frequency	Participant indicates how often they take it. The options are: 1. Once a day or more; 2. 4-6 days a week; 3. 2-3 days a week; 4. Once a week.
	Vitamin D Single Supplement – Duration	Participant indicates how long they have been taking it. Response choices are: 1. Less than a month; 2. 1-12 months; 3. More than 1 year. Those indicating response 3 also indicate the actual number of years.
8.	Date	Month/Day/Year the form was completed.

FORM: **154 – BREAST CANCER PREVENTION AND TREATMENT MEDICATIONS**

Version: 1 – November, 2008

Description: Self-administered or interviewer-administered; 3-page booklet; key-entered at the Clinical Coordinating Center (CCC).

When used: Collected one time as part of the annual contacts for Clinical Trial (CT) and Observational Study (OS) participants enrolled in the WHI Extension Study who have indicated a previous breast biopsy or diagnosis of breast cancer on WHI Form 33/33D.

Purpose: To collect updated information on specific types of medications (SERMS and aromatase inhibitors) currently being prescribed for the prevention and treatment of breast cancer.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 154*) and Spanish (*Form 154S*) versions.

2. The *Form 154* for WHI Extension Study participants will be labeled and mailed from the CCC directly to the participant. Form is only mailed to participants with a previous breast biopsy or diagnosis of breast cancer.

    - The CCC mails the form to the participant and asks her to mail it back in a return envelope by a specified date. Following the CCC mailing, if the participant does not return the *Form 153* within 3 months of the first mailing, it will be sent again. If the form is not returned within 2 months of the second mailing, the form will be sent a third time. If the form is still not returned, CCC staff will contact the participants by telephone to collect the information from willing participants. The CCC will data enter the forms.

3. In the event that this form is collected by FC staff, the form should be sent to the CCC for data entry.

Item Instructions

1.	Tamoxifen (Nolvadex) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q2.
1.1.	Tamoxifen – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
2.	Raloxifene (Evista) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q3.
2.1.	Raloxifene – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
3.	Toremifene (Fareston) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q4.
3.1.	Toremifene – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
4.	Anastrozole (Arimidex) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q5.
4.1.	Anastrozole – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
5.	Exemestane (Aromasin) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q6.
5.1.	Exemestane – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
6.	Letrozole (Femara) – Ever Taken	No/Yes/DK. Participants indicating "No" or "DK" skip to Q7.
6.1.	Letrozole – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
7.	Ever Taken Any Other SERM or Aromatase Inhibitor	No/Yes/DK. Participants indicating "No" or "DK" skip to Q8.
7.1.	Other SERM or Aromatase Inhibitor – Duration	Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years.
8.	Barriers to Breast Cancer Medications	Check all that apply.