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 <u>first</u> 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 <u>first</u> 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 <u>first</u> 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