

- FORM:** 33 - MEDICAL HISTORY UPDATE
- Version:** 11 – October 1, 2010
- Description:** Self-administered or interviewer-administered; 16-page booklet; scanned and imaged at Clinical Coordinating Center (CCC) or key-entered at the Regional Center (RC).
- When used:** At annual contacts for all Extension Study participants. Completed at a non-routine contact when an MRC participant death is reported.
- Purpose:** To identify possible WHI Extension Study outcomes needing further documentation.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 33*), and Spanish (*Form 33S*) versions. Use the appropriate form for the participant.
2. The annual mailings of *Form 33* for WHI Extension Study participants will be labeled and mailed from the CCC directly to the participant.
 - The CCC mails to the participant and asks her to mail back in a return envelope by a specified date. Following the CCC mailing, if the participant does not return the *Form 33* 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, it becomes the RC's responsibility to collect the missing *Form 33*. The CCC will scan and image forms returned to the CCC, and make the image available to the RC in WHIX.
3. RC staff key-enter forms that the RC mails, receives, or collects. Follow your RC's procedures for administering this form, either by mail or phone contact.
 - For RC phone contacts, administer the form as an interview. Record the finish date of the last WHI Extension Study *Form 33* in the "health problems since" date on page 1.
4. Forms returned to the RC:

Review the form for completeness. Note that responses to questions 2-16 must be answered for appropriate reporting of the form. If these questions are not complete, contact the participant for the necessary information. Routinely view WHIX and/or the corresponding report X2-0983 for a list of participant *Form 33* whose form contains incomplete or inconsistent information. The report will list those forms collected at the RC 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.
- File the form in the participant's file.

Item Instructions

Health problems and health care since date	<p>Refers to the “date form finished” the participant recorded on the last page of the previous, routine <i>Form 33 - Medical History Update</i>.</p> <p>For CCC mailings, the CCC prints the <i>Form 33</i> Label Set and affixes the date label to the front of the form. For subsequent RC contacts (e.g., because of non-response to CCC mailings) the RC can print a <i>Form 33</i> Label Set that includes a label to affix within the appropriate box on the front of the form.</p> <p>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.</p> <p>Data Entry: Key-enter the “health problems since” date. The WHIX database will generate a warning notice if the key-entered start date differs from the previous <i>Form 33</i> “health problems since” date.</p>
Date Received	Date received at the CCC or RC.
Reviewed by	5-digit WHI Extension study employee ID.
Contact type	Mark appropriate box.
Visit type	<p>Annual Contact. If received between visits, use visit for which you intended the form.</p> <p>Non-Routine: For a WHI Extension study MRC participant death only. Note: WHIX accepts a Visit Type of non-routine only after data entry of <i>Form 120 – Initial Notification of Death</i>.</p>
Field Center Alert (RCA) bubble	Used by CCC to alert the RC that a form has participant comments and the image should be reviewed.
Language	Data Entry: English or Spanish version of the form.
1. Today’s date	Date <i>Form 33</i> is completed.
2. Identify person providing responses for this form	Mark the corresponding box identifying who provided the responses on the form.
3. Exams, tests, or procedures by doctor or other health care provider	Mark the bubble if the exam, test, or procedure was done or prescribed by a doctor, nurse practitioner, or physician assistant since the last <i>Form 33</i> was completed. The participant should report <u>all</u> tests and procedures she had of those listed.
4. Diagnosis of new conditions	Mark the bubble for all new conditions diagnosed since the last <i>Form 33</i> was completed. Mark only conditions that have been identified by a doctor for the first time.

5. New treatments for diabetes Mark response for each of the three treatments for diabetes to lower blood sugar 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.
- For “Insulin,” mark Yes 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.
- For “Diet and/or physical activity,” mark Yes only if it was prescribed by the health-care professional. It does not include a participant initiated diet and/or exercise plan.
6. New high blood pressure or hypertension pills Yes/No. Mark Yes if the pills used to treat high blood pressure or hypertension were used to lower a participant's blood pressure. Mark Yes even if the participant has not been taking this blood pressure medication as prescribed.
7. Number of times fallen on ground Mark appropriate box. Number of falls where participant landed on the ground. If participant is unsure of the number of falls, give best estimate. The purpose of this question is to distinguish participants with frequent falls from other participants. If the participant is unsure whether she had two or three falls, but falls infrequently, answer “two times.” This question does not refer to falls due to participation in “high risk activities” such as skiing or falls from inadvertently slipping on ice due to inclement weather.
8. New broken, fractured, or crushed bone Yes/No. To identify any new broken, fractured, or crushed bone.
- 8.1 Broken bone Mark all that apply. This question refers to any new diagnosis of fracture. All non-hip and non-upper leg fractures are collected as a self-report only.
- 9-16. New diagnosis, treatment, or hospital stay of 1 or more nights for any reason. Yes/No. Mark Yes if the participant has been newly diagnosed for any of the listed conditions in Qxs 9-16 or been hospitalized for one or more nights (where the participant occupied a hospital bed) in Qx 16. Do not include outpatient visits, emergency room visits, day surgery. The intent of these questions is to screen out those participants who have not had the listed conditions and do not have to take time to complete the rest of the form.
- 17-29. Diagnosed/treated for stroke, heart and, circulation conditions Mark Yes or No for each condition in 17-29.
- 17-29 Sub-questions Hospitalized one night or more. Yes/No.
30. Name and address of first Provider for stroke, heart, and circulation conditions Write in the name and address of the first Provider who diagnosed or treated the stroke, heart, or circulation conditions for health conditions or procedures marked in Qxs 17-29. This information is needed so that further information can be requested if needed.
31. Date diagnosed, treated or admitted to hospital Write in the date diagnosed, treated or admitted to hospital. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the form that the day is an estimate.
32. Number of nights Write in the number of nights in the hospital.

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| 33-35 | Name and address of <u>second</u> Provider. | See description for Qxs 30-32. |
| 36-38 | Name and address of <u>third</u> Provider. | See description for Qxs 30-32. |
| 39-41 | Name and address of <u>fourth</u> Provider. | See description for Qxs 30-32. |
| 42. | Other hospital stays for stroke, heart, or circulation conditions | Yes/No. To identify other hospital stays for health conditions for stroke, heart or circulation problems. |
| 42.1 | Number of other hospital stays | Mark appropriate box. |
| 43. | New broken, fractured, or crushed hip or upper leg bone | Yes/No. To identify the new broken, fractured, or crushed hip or upper leg bone. |
| 43.1 | Which one(s) | Hip/Upper leg. Mark all that apply. |
| 43.2 | Diagnosed or treated in hospital | Yes/No. |
| 43.3 | Name and address where diagnosed or treated | Write in the name and address of the place where diagnosis and treatment for the broken, fractured, or crushed hip or upper leg bone was done. This information is needed so that further information can be requested if needed.

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. |
| 43.4 | Date admitted to hospital | Write in the date admitted to hospital. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the form that the day is an estimate. |
| 43.5 | Stay overnight? | Yes/No. |
| 43.6 | X-ray/MRI completed | Yes/No. To identify if an X-ray or imaging scan (CT or MRI) was taken to diagnose the fracture. |
| 43.7 | Name and address where diagnosed or treated | Write in the name and address of the place where diagnosis and treatment for the broken, fractured, or crushed hip or upper leg bone was done. This information is needed so that further information can be requested if needed. |
| 43.8 | Date of X-ray or imaging scan | Write in the date of X-ray or imaging scan (CT or MRI) was taken. If there was more than one visit, record the date for the X-ray or other imaging scan during the first visit. |
| 44. | New cancer, malignant growth or 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. |
| 44.1 | 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 the circle "other cancer" and write in the cancer type. |

- 44.2 Date cancer diagnosed Write in the date the participant was told she had cancer.
- 44.3 Doctor's name Write in the name and address of the physician or other health care provider who diagnosed the cancer. This information is needed so that further information can be requested if needed.
- 44.4 Name and address where the cancer was first diagnosed. Write in the name and address of the place where the cancer was first diagnosed. This information is needed so that further information can be requested if needed.
- 44.5 Diagnosed in hospital Yes/No.
- 44.6 Date admitted to hospital Write in the date admitted to hospital. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the form that the day is an estimate.
- 44.7 X-ray or imaging Yes/No.
- 44.8 Name and address of X-ray/imaging center Write in the name and address of the place where the cancer imaging was. This information is needed so that further information can be requested if needed.
- 44.9 Date of X-ray or scan Write in date of X-ray or imaging scan.
45. Cancer-related surgeries Yes/No. To identify any cancer-related surgeries after the cancer was first diagnosed.
- 45.1 Planned cancer surgeries Yes/No. To identify if any cancer-related surgeries are planned.
- 45.2 Number of cancer surgeries To identify the number of cancer-related surgeries.
- 45.3 Type(s) of cancer surgery To identify types of cancer-related surgery, specify.
- 45.4 Name and address where cancer surgery was done. Write in the name and address of the place where the cancer-related surgery was done. This information is needed so that further information can be requested if needed.
- 45.5 Date of first cancer surgery Write in date of first cancer-related surgery.
- 45.6 Treated during overnight stay Yes/No.
- 45.7 Number of nights Write in the number of nights in the hospital.
46. Admitted overnight for listed conditions Yes/No.
47. Hospital stay of one or more nights Yes/No. One or more nights of hospitalization (where the participant occupied a hospital bed) not already reported on this form.
- 47.1 Name and address of first hospital stay Write in the name and address of the first two hospital stays. This information is needed so that further information can be requested if needed.

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| 47.2 | Date admitted to hospital | Write in the date admitted to hospital. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the form that the day is an estimate. |
| 47.3 | Number of nights | Mark appropriate box. |
| 47.4 | Reason for hospital admission | Write in reason for the hospital stay. |
| 47.4.1 | First hospital reason bunionectomy | Yes/No. On the <i>Form 33</i> data entry screen, but not on form (paper) itself. |
| 47.5 | Name and address of <u>second</u> hospital admission of one or more nights | Write in the name and address of the second hospital admission of one or more nights. This information is needed so that further information can be requested if needed. |
| 47.6 | Date admitted to hospital | Write in the date admitted to hospital. If unsure of the exact day, use the 15th of the month as the default date. Indicate on the form that the day is an estimate. |
| 47.7 | Number of nights | Mark appropriate box. |
| 47.8 | Reason for hospital admission | Write in reason for the hospital stay. |
| 47.8.1 | Second hospital reason bunionectomy | Yes/No. On the <i>Form 33</i> data entry screen, but not on form (paper) itself. |
| 48. | Other hospital stays | Yes/No. |
| 48.1 | Number of other hospital stays | Mark appropriate box. |