
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 <i>Form 33D - Medical History Update (Detail)</i> 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 <i>Form 33D</i>
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 <i>Official Use Only</i> 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	<p>Mark appropriate box. For forms scanned at the CCC, this item is left blank, and WHIX inserts “3 – Annual” into WHIX.</p> <p>Mark Non-Routine only for a WHI Extension study participant death. Note: Visit Type non-routine is accepted by the WHIX data base <u>only</u> after entry of <i>Form 120 – Initial Notification of Death</i>.</p>
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	<p>Refers to item #9 - “date form finished” the participant recorded on the last page of the most recent, 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 FC contacts (e.g., because of non-response to CCC mailings) the FC 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>
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	<p>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.</p> <p>Marking “1 – Yes” to this question requires completion of <i>Form 33D</i>.</p>

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 Admitted 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.