

- FORM:** 33 - MEDICAL HISTORY UPDATE
- Version:** 5 – January 15, 2001
- Description:** Self-administered or interviewer-administered; 4-page booklet; scanned at Clinical Center (CC).
- When used:** At semi-annual and annual follow-up contacts for Clinical Trial (CT) participants and annual contacts for Observational Study (OS) participants. Completed at a non-routine contact following a WHI participant death or when participants amend completed outcomes information.
- 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. Place the participant barcode label on the front page of the questionnaire. The annual mailings of *Form 33s* for OS participants (except for year 3 where they come for a CC visit) will be labeled and sent out from the CCC directly to the participant. (See *Vol. 2 - Procedures, Section 16 - Follow-Up.*)
3. Record the date of the last WHI medical update in the indicated box on page 1. See *Item Instructions* for further details.
4. Follow your CC's procedures for administering this form, either by mail, phone, or CC visit. See the description of contact options in *Vol. 2 - Procedures, Section 16 - Follow-Up.*
 - For visits, mail form to the participant before her scheduled visit and ask her to bring the completed form to the visit. In the appointment reminder (letter or phone call), remind the participant to bring the completed questionnaire to the follow-up visit. You may also ask her to complete the form during the visit.
 - For phone contacts, administer the form as an interview.
 - For mail contacts, mail to the participant before her scheduled contact date and ask her to mail back in a return envelope by a specified date. Phone or mail appropriate reminders to the participant to check whether she has received the questionnaire and/or remind her to mail it to the CC as soon as possible.
5. Review the form for completeness. Note that responses to questions 4-10 must be included for appropriate outcomes analysis of the form. If these questions are not complete, contact the participant for the information. *Table 1 - Form 33 Algorithm to Initiate Administration* below identifies specific items that trigger a need for a *Form 33D*. If the participant is present (e.g., for a follow-up visit), clarify missing and unclear responses. If the questionnaire is mailed in, follow-up missing responses by phone. *WHIP 0621 – Outcome Screening Action Required* lists *Form 33, Ver. 3* and greater, whose *Form 33* contains incomplete or inconsistent information. Forward the form to Data Entry.
6. Complete the *Office Use Only* section on the first page.
7. Data Entry: Scan the form and initial the first page of the form after entry. *WHIP 0622 – Members with Potential Outcomes* lists those participants who need to complete *Form 33D - Medical History Update (Detail)*.
8. File the form in the participant's file.

Table 1
Form 33 (Ver. 4) - Algorithm to Initiate Administration of Form 33D - Medical History Update (Detail)

ITEM	CRITERION	ANSWER THAT TRIGGERS FORM 33D
4.1	Overnight hospitalization for any reason	If selected ANY response code 1 through 8
6.1	Has a doctor told you for the first time that you have a <u>New</u> broken, crushed or fractured bone?	6.2 - Code 8 - Other broken bone
6.3	Has a doctor told you for the first time that you have a <u>New</u> cancer or a malignant tumor?	6.4 - Code 8 - Other cancer or malignant tumor
9.0	Had exams, tests, or procedures done by a doctor or a nurse at a place other than WHI clinic	Code 6 - Procedure to unblock narrowed blood vessels to your heart muscle (opening the arteries of the heart with a balloon or other device sometimes called a PTCA, coronary angioplasty, coronary stent) Code 10 - Removal of the uterus or womb (hysterectomy)

Form 33 (Ver. 5) - Algorithm to Initiate Administration of Form 33D - Medical History Update (Detail)

ITEM	CRITERION	ANSWER THAT TRIGGERS FORM 33D
4.1	Overnight hospitalization for any reason	If selected ANY response code 1 through 8
6.0	Has a doctor told you for the first time that you have a <u>New</u> broken, crushed or fractured bone?	6.1 - Other broken bone
7.0	Has a doctor told you for the first time that you have a <u>New</u> cancer or a malignant tumor?	7.1 - Other cancer or malignant tumor
10.0	Had exams, tests, or procedures done by a doctor or a nurse at a place other than WHI clinic	Code 6 - Procedure to unblock narrowed blood vessels to your heart muscle (opening the arteries of the heart with a balloon or other device sometimes called a PTCA, coronary angioplasty, coronary stent) Code 10 - Removal of the uterus or womb (hysterectomy) Code 18 - Shots at home for blood clots in legs followed by blood thinning medications (such as Coumadin, Warfarin)

Item Instructions

Date received	Date received at CC. Located in the top left corner of page 1.
Reviewed by	Standard 3-digit WHI employee ID. (See common data items.)
Contact type	Mark appropriate box. (See common data items.)
Visit type	<p>Contact at which the CC received the form. If received between visits, use visit for which you distributed the form. For routine contacts select semi-annual or annual as appropriate for CT/OS participant. (See common data items.) In addition, for this form, there are two other visit types:</p> <p>Non-Routine For a WHI participant death only. A proxy (family, friend, or health care provider) contacts the CC to report a participant death, or the CC identifies a participant death. A close-out <i>Form 33</i> and, if appropriate, a <i>Form 33D</i> should be completed.</p> <p>Mark appropriate box.</p>
Form administration	<p>Method used to administer form to participant:</p> <p>1 - Self: Participant completed the form by herself. 2 - Group: Participant completed the form with a group of other participants. 3 - Interview: CC staff completed <u>entire</u> form as an interview. 4 - Assistance: Participant needed partial assistance from CC staff or others to complete the form.</p>
Language	Indication of English (E) or Spanish (S) version of the form. The response to this item is printed on the form.
Date of last WHI medical update	<p>CT participants (semi-annual/annual contacts): For the initial contact, the date refers to the date of randomization. For all subsequent follow-up contacts, this date is the "date form finished" the participant recorded on the last page of the most recent, routine <i>Form 33 - Medical History Update</i>. At the CC, you 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>OS participants (annual contacts): For the initial contact, the date refers to the date of enrollment. For all subsequent follow-up contacts this date it is the "date form finished" the participant recorded on the last page of the most recent, routine <i>Form 33 - Medical History Update</i>. For CCC mailings to OS participants, the CCC prints the <i>Form 33</i> Label Set and affixes the date label to the front of the form. For subsequent CC contacts (because of non-response to CCC mailings or for 3rd year OS visits) the CC 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>Data Entry: Do not key-enter date.</p>
1. Identify person completing this form	Mark the corresponding box identifying who completed the form.
2. Fainting episodes	No/Yes. This refers to all black-out episodes, any loss of consciousness and/or fainting events.

3. Number of falls 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.
4. Overnight hospitalizations No/Yes. This question refers to all overnight hospital admissions where the participant occupied a hospital bed. **Do not include** visits to hospital outpatient departments or emergency departments, unless the participant stayed overnight.
- 4.1. Reason(s) for overnight hospitalization Select appropriate reason(s) for hospitalization and mark all that apply. The purpose of this questions is to identify WHI outcomes/events. If hospitalization occurred for another reason, mark “8 - Other reasons” and write in the response.
Data Entry: Do not key-enter the “Specify” text.
5. Emergency Room, day surgery, or outpatient visit No/Yes.
- 5.1 Reason for ER, day surgery, or outpatient visit Select appropriate reason(s) for the ER or day surgery visit and mark all that apply. If the visit occurred for another reason, select “8 - Other” and write in the response.
Data Entry: Do not key-enter the “Specify” text.
6. New broken, crushed or fractured bone No/Yes.
- 6.1 Bone broken Mark all that apply. This question refers to any new fracture. The purpose of this question is to distinguish between non-WHI fractures that do not require investigation verses a report of a fracture that requires *Form 33D* follow-up
7. New cancer or a malignant tumor No/Yes
- 7.1 Type of cancer Mark all that apply. This question refers to any new diagnoses 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 *Form 33D* follow-up.
8. Diagnosis of new conditions From the list provided, mark all new conditions diagnosed since the last medical update. Mark only conditions that have been identified by a doctor for the first time. Select “9 - 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.

9. New medications From the list provided, mark all of the medications that have been prescribed since the last medical update.
- Medication for treatment of diabetes is used to lower the blood sugar level. This medication can be in the form of pills or shots. Regarding “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.
- Medication used to treat high blood pressure or hypertension would be used to lower a participant's blood pressure. Mark “3 - pills for high blood pressure or hypertension” even if the participant has not been taking this blood pressure medication as prescribed. These medications could have been prescribed by a doctor, nurse practitioner, or physician assistant.
- Mark “9 - None of the above” if no new medication has been prescribed since the last medical update. Check to make sure the participant marked this box and did not accidentally skip this question.
10. Exams, tests, or Mark all exams, tests and procedures that have been done or prescribed by a doctor or a nurse since the last documented medical update. 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.
11. Date finished form Date the participant completed the form. This date may need to be edited if the form is reviewed with the participant after she completes it.