

- FORM:** 40 – ADDENDUM TO MEDICAL HISTORY UPDATE
- Version:** 1 – April 15, 2002
- Description:** Self-administered or interviewer-administered; 2-page form; scanned at Clinical Center (CC).
- When used:** Administered one-time only at a semi-annual or annual follow-up contact for Clinical Trial (CT) participants and at an annual contact for Observational Study (OS) participants.
- Purpose:** To collect family history of deep vein thrombosis and pulmonary embolus.

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#### GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 40*) and Spanish (*Form 40S*) 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 mailing of *Form 40* to OS participants will be labeled and sent out from the CCC directly to the participant.
3. 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.
4. Review the form for completeness, looking for missed page. Do not review the questions with the participant.
5. Complete the *Office Use Only* section on the first page.
6. Data Entry: Scan the form and initial the first page of the form after entry.
7. File the form in the participant's file.

**Item Instructions**

Date received	Date received at CC.
Reviewed by	Standard 3-digit WHI employee ID. (See common data items.)
Contact type	Mark appropriate box. (See common data items.)
Visit type	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.)  Mark appropriate box.
Form administration	Method used to administer form to participant:  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.
Language	Indication of English (E) or Spanish (S) version of the form. The response to this item is printed on the form.
1. Any relatives ever have DVT	No/Yes. Include full-blooded relatives only. If the participant is not sure about all relatives listed, have her indicate the number she knows of.
1.1 Number of relatives with DVT	Mark the box corresponding to the number of full-blooded relatives who have ever had DVT. Staff may be asked to clarify the difference between DVT and other types of bloodclots in the leg. Review the description on the form with the participant. Staff may also want to consult a medical dictionary or other resources for their own clarification.
2. Any relatives ever have a PE	No/Yes. Include full-blooded relatives only. If the participant is not sure about all relatives listed, have her indicate the number she knows of. Note that a PE is usually a catastrophic event/medical emergency and that the relative will likely have been hospitalized or died due to the event.
2.1. Number of relatives with PE	Mark the box corresponding to the number of full-blooded relatives who have ever had PE.