

**FORM:** 4 - HRT WASHOUT

**Version:** 1 - February 16, 1994

**Description:** Completed by Clinical Center (CC) staff; 1-page form; key-entered at CC.

**When used:** After woman has completed *Form 2/3 - Eligibility Screen* and agreed to complete Hormone Replacement Therapy (HRT) washout.

**Purpose:** To determine questions relating to symptoms after completing HRT washout.

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### GENERAL INSTRUCTIONS

1. This form is printed in both English (*Form 4*) and Spanish (*Form 4S*) versions. Use the appropriate form for the participant.
2. Initiate the form if a participant is eligible for HRT based on responses on *Form 2/3* and needs to go through the HRT washout (i.e., has taken hormone replacement in the last three months).
3. Affix a participant barcode label to the form.
4. Complete Items 1 - 4, identifying the date, staff person completing the form, contact type, and visit type and number.
5. Read the scripts to the participant and complete the items.
6. Follow the instructions on the form.

If the instructions say "Schedule SV1," the participant is eligible to continue screening for HRT. Schedule a Screening Visit 1 (SV1) and continue screening.

If the question answer shows "HRT ineligible" in a shaded box, the participant is not eligible for HRT. Do not schedule an SV1 if she is only interested in HRT. If the participant is interested in the Dietary Modification (DM) and is eligible based on responses to *Form 2/3*, schedule an SV1 and continue screening (participants also interested in the the Observational Study [OS] may be scheduled for SV1 at CC discretion).

7. Review the form for completeness and forward to Data Entry.
8. Process and key-enter the form in the manner that best fits the flow of your CC. Options include:
  - Key-enter Items 1 - 4 to initiate the form in the database and key-enter the remainder of the form after you complete Items 5 - 8.1. To do this:
    - Send the form to Data Entry after completing Items 1 - 4. Store the form in the participant file until it is time to complete the remainder of the form.
    - Complete the remainder of the form as needed, and send the complete form to Data Entry for key-entry of the remainder of the form.
  - Key-enter Items 1 - 4 to initiate the form in the database and key-enter the remainder of the form after you complete Items 5 - 8.1. To do this:
    - Store the form in the participant's file until it is ready to complete the remainder of the form.

- Complete the remainder of the forms as needed, and send the complete form to Data Entry for key-entry.
9. Data Entry: Regardless of which processing option is chosen, review the form for completeness and consistency and return to the responsible staff person with any problems noted. Key-enter after you resolve any questions. Initial the form after key-entry.

*Note:* If a washout was required for eligibility, you must key-enter this form before you can randomize the participant into HRT.

10. File the key-entered form in the participant's file.

**Item Instructions**

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|------|---|---|
| 1.   | Date of contact                         | Date you <u>initiated</u> the form.<br><br>Record the date you speak to the woman about starting her washout. This may frequently be the same date as the date of the <i>Form 2/3</i> . It is not necessarily the date she starts the washout or the date you review the results of the washout.  |
| 2.   | Completed by                            | Standard 3-digit WHI employee ID. (See common data items.)  |
| 3.   | Contact type                            | Mark appropriate box. (See common data items.)  |
| 4.   | Visit type                              | The contact at which the form was initiated or the most recent past contact if the form was initiated between contacts. In most cases, this will be Screening Visit 0 (SV0). Mark the appropriate box and write in the screening visit number.  |
| 5.   | Date washout started                    | Date the woman says she stopped taking her hormones.  |
| 6.   | Date washout reviewed                   | Date you review the results of the washout with the woman and ask her the remaining questions on the form.  |
| 7.   | Washout start at least three months ago | No/Yes. Indicate if the time between the Date Washout Started and Date Washout Reviewed is three calendar months. Count one calendar month as starting and stopping on the same date of the month. For example, starting on the 21st of January and ending on the 21st of February would be one calendar month.<br><br>Mark "No, participant willing to continue" if the time between the start and review dates is less than three calendar months but the woman is willing to stay off hormones for three months. Do not continue with the form. Wait until three calendar months have passed before completing the rest of the form. If three months pass, and the participant is willing to continue, cross out the old Date Washout Reviewed, write in the new date, and initial the change. Complete the remainder of the form.<br><br>Mark "0 - No, participant not willing to continue" if the time between the dates is less than three calendar months and the woman is <u>not</u> willing to stay off hormones for three months. The woman is not eligible for HRT. Do not ask the remainder of the questions.<br><br>Mark "1 - Yes" if the time between the dates is three calendar months or more. |
| 8.   | Have symptoms                           | No/Yes. If the participant answers "0 - No," she is eligible for HRT; schedule an SV1. Do not ask the remaining questions on the form.  |
| 8.1. | Still having symptoms                   | No/Yes. If the participant answers "0 - No," she is eligible for HRT; schedule an SV1. Do not ask the remaining questions on the form. If the participant responds "Yes," go on to Question 8.2.  |
| 8.2. | How severe are symptoms                 | If the woman answers "1 - Mild" or "2 - Moderate," ask Question 8.3. If the woman answers "3 - Severe," she is not eligible for HRT.  |
| 8.3. | Interest in participating               | No/Yes. If the participant answers "0 - No," she is not eligible for HRT. If she answers "1 - Yes," she is eligible; schedule an SV1. Make it clear to the participant that randomization to a placebo is a possibility and her symptoms could continue.  |
|      | Language                                | Data Entry: English or Spanish version of the form. (See common data items.)  |