FORM: **25 – PARTICIPANT TREATMENT ASSIGNMENT: ESTROGEN-ALONE**

Version: 1.1 – Mar. 1, 2004

Description: Completed by Clinical Center (CC) staff as interview or by participant as a self-administered form; 2-page form (plus 1-page reason code sheet for staff); key-entered at CC.

When used: At the contact during which you discuss the 2004 NHLBI letter and give the Estrogen only (E-alone) participant her E-alone treatment assignment.

Purpose: To document information about stopping study pills, completing *Form 33 – Medical History Update*, and participant's perceived treatment assignment before providing the E-Alone participant with her treatment assignment information

GENERAL INSTRUCTIONS

1. Provide this form to the participant or administer as an interview after the participant has received the 2004 NHLBI letter, and before she has received her treatment assignment information. However, if the participant insists on getting her treatment assignment information before completing this form, you should provide her with the appropriate information.

2. Once the form has been completed, run *WHIP9755 – Estrogen Alone Study Treatment Assignment.* Provide one copy to the participant and file a second copy in the participant's chart. Provide a copy of the report for her health care provider, if she requests one.

3. Ask the participant if she has any questions and refer to the 2004 E-Alone Staff Questions and Answers for suggestions on how to respond to participant questions.

4. Let the participant know that the information she is providing is important because, even after she stops taking study pills, there is still much more to learn from the E-alone study about women's health.

5. Review the form for completeness and forward to Data Entry.

6. Data Entry: Key-enter the form into WHILMA. See *Vol. 5 - Data System, Section 7.1 - Key-Entry* for specific instructions on how to key-enter this form. Initial the first page after key-entry.

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

Item Instructions

	Date Received contact	Record the date that the interview is conducted with the participant or the date on which the form is received from the participant (if self-administered).
	Reviewed by	Standard 3-digit WHI employee ID of staff person completing the form.
	Contact Type	Mark appropriate oval or box. (See common data items.)
	Visit Type	Contact for which the participant completed the form. Mark appropriate oval or box for visit type and number. (See common data items.)
	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 entire form as an interview. 4 - Assistance: Participant needed partial assistance from CC staff or others to complete the form.
1	Stopped study pills	No/Yes 0 – No If the participant says "No", counsel the participant to stop her HT study pills and discuss the importance of stopping study pills now that the intervention phase of the trial is over. 1 – Yes Respond to the additional items about when study pills were stopped and what symptoms has the participant had since stopping.
1.1	Stopped before or after update	1 – Before: Mark if the participant says she stopped study pills at any time before she received the 2004 NHLBI letter (either through the mail or in person). 2 – After: Mark if the participant was taking study pills and then stopped them after receiving the 2004 NHLBI letter.
1.2	Date stopped	Date the participant says she stopped her HT study pills. This date should be on or after Mar. 1, 2004. Note that this date may be different than the date on which you do the participant's final adherence collection.
1.3	Symptoms	No/Yes. Record whether or not the participant says she had any symptoms since stopping her study pills (after received the 2004 NHLBI letter).
1.4	Symptom information	Mark the boxes corresponding to symptoms the participant reports having since stopping her study pills (*mark all that apply*): 1 – Hot flashes (or flushes) 2 – Night sweats 3 – Vaginal spotting or bleeding 4 – Mood swings 5 – Other (specific other information is not data-entered)
2.	Filled out *Form 33*	No/Yes. Record whether or not the participant says she has filled out the *Form 33 – Medical History Update* after receipt of the NHLBI letter. 0 – No. If the participant says she has not completed *Form 33*, ask her to fill out a *Form 33* now by saying, "Why don't you fill out the form now, while I get your treatment assignment information?" Hand the participant a *Form 33* with the appropriate "health problems and health care since" date filled in. 1 – Yes.

3	Perceived treatment assignment	Record which treatment arm the participant perceived she was assigned to before she stopped her study pills. If she names a treatment arm, ask her why she thought that (see below). 1 – Active hormones 2 – Inactive placebo pills 9 – Don't know
	Reason for perception	Write in the reason the participant gives for thinking she was in the treatment arm she named. Text is not data entered. Refer to the *Reason Codes for Form 25* sheet and record the corresponding 2-digit reason codes for up to three reasons in the Office Use Box.
	Experienced Worsening Symptoms	Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced worsening (or new) symptoms before she stopped study pills. 1 – Vaginal bleeding or spotting 2 – Breast tenderness or other breast changes 3 – Hot flashes (flushes) or night sweats 4 – Mood swings or depression 5 – Tiredness or difficulty sleeping 6 – Skin/hair changes 7 – Vaginal or genital changes 8 – Forgetfulness or problem concentrating 9 – Headaches 10 – Weight or appetite changes 11 – Cholesterol changes 18 – Other symptoms

Experienced Improvement in (or absence of) Symptoms	Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced an improvement in (or absence of) symptoms before she stopped study pills. 21 – Vaginal bleeding or spotting 22 – Breast tenderness or other breast changes 23 – Hot flashes (flushes) or night sweats 24 – Mood swings or depression 25 – Tiredness or difficulty sleeping 26 – Skin/hair changes 27 – Vaginal or genital changes 28 – Forgetfulness or problem concentrating 29 – Headaches 30 – Weight or appetite changes 31 – Cholesterol changes 37 – No symptoms 38 – Other symptoms
Other	Record appropriate reason codes under this section if the participant says that she thought she was in a particular treatment arm because she had experienced other symptoms before stopping her study pills. 41 – Told by family member or friend 42 – Told by personal health care provider 43 – Told by WHI staff 44 – Read it on a report 45 – Pill appearance, taste, or smell 46 – Diagnosed with a medical condition 88 – Other 99 – Don’t know