FORM: **10 - HRT MANAGEMENT AND SAFETY INTERVIEW**

Version: 7 – November 15, 2001

Description: Interviewer-administered; 3-page form; key-entered at Clinical Center (CC).

When used: For Hormone Replacement Therapy (HRT) participants at SV3, six-week phone call, semi-annual and annual phone or visit contacts, and non-routine contacts with HRT participants, as needed to document HRT safety or adherence concern. Complete this form at the next two routinely scheduled visits or contacts after stopping HRT intervention. (See *Form 10A* for mail contacts.)

Purpose: To assess symptoms of HRT participants for safety issues and to identify needs and strategies to improve adherence.

GENERAL INSTRUCTIONS

1. This form is printed in both English (*Form 10*) and Spanish (*Form 10S*) versions. Use the appropriate form for the participant. The form is also printed in a self-administered version for use at semi-annual contacts – see *Form 10A*.

2. For the semi-annual and annual visits, include the form in the packet of forms to be completed at the visit.

3. Affix the participant barcode label to the front of the form.

4. The interview may be conducted on the phone or in person during CC visits.

5. Complete the contact information in Questions 1-4.

6. Assess the participant's adherence to taking her HRT medications.

7. Determine the participant's hysterectomy status before asking Question 6. To check the participant's hysterectomy status in WHILMA, refer to the a recent print-out of the participant's visit plan for this contact (see *WHIP 0144*). Refer to the guidelines on the form when completing Question 6. If the participant's hysterectomy status has changed, contact the CCC before dispensing study pills.

8. Complete the remainder of the form as the interview/discussion proceeds.

   - Review the possible symptoms and conditions in Questions 7-11. If the participant marked "yes" to any questions in 7-11, refer to CP. Indicate a summary of the discussion in Question 13 – Resulting Action. At a minimum reassure the participant about her continuation on the study pills.
   - Review the participant's responses to taking pills. If she reports missing any pills, discuss ways to help remember pills each day. Indicate a summary of the discussion on Question 14.5 – Strategies.
   - Answer Questions 15-16 to indicate follow-up plans.

   Note: If participant is off HRT intervention and you are completing the form for the 2 contacts after stopping, you do not need to complete Items 14-16.

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

10. Data Entry: Review the form for completeness and return to responsible clinical personnel with any problems or questions. Key-enter when complete or questions have been resolved.

    Initial the first page after key-entry.

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

Item Instructions

1.	Contact date	Date you conducted the interview.
2.	Staff person	Standard 3-digit WHI employee ID of staff person performing the interview. (See common data items.)
3.	Contact type	Mark appropriate box. (See common data items.)
4.	Visit type	The contact at which you conducted the interview. Mark the appropriate box and enter the number. (See common data items.)
5.	Dosage/adherence	Review the participant's current dosage status on the latest *Form 54 - Change of Medications* to determine if the participant is on the standard WHI dosage. If she is, mark "Yes" to Item 5.1 and "No" to Item 5.2. If she is taking an altered dosage based as indicated on *Form 54*, mark "No" to Item 5.1 and "Yes" to Item 5.2. Determine adherence using the procedures in *Vol. 2, Section 15.6 - Study Pill Adherence Monitoring.* Write the adherence rate in the appropriate space provided. Data Entry: Adherence data not key-entered from Question 5. Pill adherence is key-entered in Task 951 – Adherence Collection.
6.	Hysterectomy	Yes/No (based on WHILMA hysterectomy status or participant report). Mark "Yes" if participant has had a hysterectomy and go to Item 6.1. - Any Vaginal Bleeding. Mark "No" if participant has not had a hysterectomy and go to Item 6.2. - Any Vaginal Bleeding.
6.1.	Any bleeding (hysterectomy)	No/Yes. Continue to Item 7, but refer participant to CP.
6.2.	Any bleeding (no hysterectomy)	No/Yes. If “No”, continue to Item 7. If “Yes”, continue to 6.3 to quantify the amount of bleeding. The “Comments” section (Item 14) may be used for documentation. Refer any reported heavy bleeding or any bleeding after the first six months of HRT study pill usage to the Clinic Practitioner (CP) or Gynecologist for evaluation.
6.3.	How heavy	Amount of bleeding. Mark appropriate box. Ask the participant to use her best guess, if she is unsure. Use the criteria 1 pad = 1 tampon; spotting = 1 pad's worth/day. Record the heaviest amount since the previous contact.
6.4.	Date bleeding started	The date the participant reports that bleeding first started.
6.5.	Intermittent bleeding	No/Yes. Mark "1-Yes" if bleeding stopped and started over a period of time.
6.6.	Currently bleeding	No/Yes. Mark "1 - Yes" if participant is bleeding now, even if it is scant.
6.7.	Bleeding stop date	The date the participant reports that bleeding stopped and did not start again.
7.	Breast tenderness	No/Yes. If yes, complete item 7.1 and refer to CP.
7.1	Degree of breast tenderness	Mild/Moderate/ Severe.
8.	Changes in breast	No/Yes. The “Comments” section (Item 17) may be used to document reported changes. Refer all reports of new lumps, changes in skin, or nipple discharge to the CP or Gynecologist for evaluation.

9.	Mammogram date	Record date of last mammogram. Interviewers can use this question to discuss scheduling a mammogram or obtaining results of last mammogram. Data entry: Date not key-entered.
10.	New medications	Mark appropriate box for medications that participant is taking. Refer to Clinic Practitioner if the answer to any question is "yes." Clinic Practitioner should evaluate and refer, as needed, to *Vol. 2, Section 5.5.4 - Major Health Problems Requiring HRT Termination.*
10.1	Corticosteroids	No/Yes.
10.2	Blood thinning medications	No/Yes.
10.3	Estrogen	No/Yes.
10.4	Progesterone	No/Yes.
10.5	Testosterone	No/Yes.
10.6	Tamoxifen, Raloxifene or other SERMs	No/Yes.
11.	Health Conditions	Mark appropriate boxes for participant response to health conditions that could impact HRT use. Explain what the condition is if participant does not seem to understand. Refer to Clinic Practitioner if any answer is "yes" or if participant is unsure. The Clinic Practitioner should evaluate the condition, referring as needed to *Vol. 2, Section 5.5 - Major Health Problems.*
11.1	Endometrial hyperplasia	No/Yes.
11.2	High Triglycerides	No/Yes. If yes, complete Item 11.3.
11.3	Triglycerides over 1000	If Item 11.2 marked "Yes", Item 11.3 must be answered with "Yes" or "No" response.
11.4	Blood clot to leg or lung	No/Yes.
11.5	Melanoma of skin	No/Yes.
11.6	Heart attack or stroke	No/Yes.
11.7	Meningioma	No/Yes.
11.8	Breast cancer	No/Yes.
11.9	Gall bladder disease	No/Yes.
11.10	Pancreas	No/Yes.
12.	Worries or discomforts	Ask this question in an open, interested manner. List the problems that the participant identifies. Data Entry: Text not key-entered.
13.	Action	Resulting action based on participant responses to Items 6-12. Mark all that apply. Local guidelines for actions and referrals should be based on sound clinical judgment and algorithms in *Vol. 2, Section 5 - HRT* and *Section 5.5. - Major Health Problems.* Data Entry: Text for date/time of appointment, physician name and contact information, and other specific text is not key-entered.
14.	Adherence	Ask these questions regardless of participant's calculated or estimated adherence.

14.1.	How often take study pills	Ask this question as written and read the responses in order until the participant indicates her agreement with the response. If the participant indicates that she doesn't know or can't remember, ask her to provide her best estimate. If the participant responds with some version of "it varies", ask her to choose the response that is most frequently true.
14.2.	Days missed	Ask this question in a non-accusing manner. If participant is unsure ask her to give her best estimate. You could ask her how many days in a week she might miss her pill and write in the appropriate monthly amount.
14.3.	What helped you remember	Ask this positive question to remind participants of their success. Write notes about her successful strategies. Use these responses, if possible, to guide adherence strategies to offer in Item 14.5 – Strategies and for Intensive Adherence Program efforts, if indicated. Data Entry: Text not key-entered.
14.4.	Reasons missed	Ask this question in a non-accusing manner. Probe to identify reasons for non- or low-adherence. List and probe for physical, psychological, and social issues. Data Entry: Text in "Other Reasons" not key-entered.
14.5.	Strategies to improve adherence	Discuss strategies and options for improving participant adherence. Note that even good adherers should be reassured (and congratulated) on their efforts (second option). Use information in *Section 17.2.3 - Reasons for Poor Retention and/or Adherence* as a guide. To apply these strategies, use the following situation as an example: Reason (from Item 14.4): Forgot Pills. Description of reason: "I seem to forget to take my pills on Thursday mornings when I go to my garden club meetings. I leave earlier that day and don't have a chance to take it with my morning coffee." Reassurance: "It sounds like you are busier than usual that day and your schedule is disrupted." Palliative measures: "What helps you remember the pills on your usual days? What do you think might help you remember on Thursdays?" Steps to improve: "Could a fellow club member remind you? Could your husband remind you at home before you leave?" Putting concerns in perspective: "Thanks for devoting all this time and effort to taking the pills. We urge taking the pills consistently so much because this study hopes to answer some very important questions about women's health." Data Entry: Strategies not key-entered.
15.1	IAP referral	No/Yes. If adherence is less than 80%, or if you think participant could benefit from an Intensive Adherence Program, refer to CP or retention specialist for evaluation. If participant needs to have more intensive contact, each CC should establish criteria about who should follow-up, when referral to CP or other specialist is required, and which adherence problems could be addressed by the interviewer.
15.2	Recontact date	The date the participant needs to be recontacted.

16.1	Clinical Recontact	No/Yes. If participant is to be recontacted, each CC should establish criteria as to who should follow-up, when CP or GYN referral is required, and which symptoms could be addressed by the interviewer.
16.2	Recontect date	The date the participant needs to be recontacted.
17.	Comments	Use this section to record observations or document actions not noted above. Data Entry. Comments not key-entered.