1. Contact Date: _______ (M/D/Y)  
2. Staff Person:  
3. Contact Type:  
   □ 1 Phone     □ 3 Visit  
   □ 2 Mail      □ 8 Other  
4. Visit Type:  
   □ 2 Semi-Annual # _______  
   □ 3 Annual # _______  
   □ 4 Non-Routine  

5. Dosage/Adherence  
   5.1. Taking Standard WHI Dosage:  
      □ No          □ 1 Adherence rate  
      □ Yes         □ 1 Unable to do  
   5.2. Taking Altered Dosage:  
      □ No          □ 1 Adherence rate  
      □ Yes         □ 1 Unable to do  

Refer to the Hysterectomy Status in WHILMA:  
- If the Hysterectomy Status is "Yes", mark YES in 6 and go to 6.1.  
- If the Hysterectomy Status is "No", ask, "Have you had a hysterectomy?"  
   - If the participant reports a hysterectomy, mark YES in 6 and go to 6.1. (Contact the CCC before dispensing any study pills.)  
   - If participant says she has not had a hysterectomy, mark NO in 6 and go to 6.2.  

6. Has the participant had a hysterectomy?  
   □ 1 YES  
   □ 0 NO  

   6.1. "Even though you've had a hysterectomy, have you had any bleeding from your vagina since your last contact?"  
      □ 0 No  
      □ 1 Yes  

   6.2. Review Form 53 - HRT Calendar if available. "Have you had any vaginal bleeding since your last contact?"  
      □ 0 No  
      □ 1 Yes  

   "These next questions are about your vaginal bleeding."

   6.3. "How heavy was it?" (Use the heaviest time since the previous contact.)  
      □ 1 Spotting - Approx. 1 pad’s worth/day  
      □ 2 Light - Approx. 2-3 pads’ worth/day  
      □ 3 Moderate - Approx. 4-7 pads’ worth/day  
      □ 4 Severe - 8 or more pads’ worth/day  

   6.4. "When did the bleeding start?" (Use the earliest time since the previous contact.)  
      □ _______ (M/D/Y)  

   6.5. "Did the bleeding start and stop again?"  
      □ 0 No  
      □ 1 Yes  

   6.6. "Are you bleeding now?" (If bleeding even a little, mark “Yes.”)  
      □ 0 No  
      □ 1 Yes  

       6.7. "When did the bleeding stop?"  
      □ _______ (M/D/Y)
7. “Since your last contact, have you had any breast tenderness?”

- **No**
- **Yes**

7.1 “Was your breast tenderness mild, moderate, or severe?”

- **Mild**
- **Moderate**
- **Severe**

Refer to Clinic Practitioner.

8. “Since your last contact, have you had any operations on or noticed any other changes in your breasts (new lumps, nipple discharge, or skin changes)?”

- **No**
- **Yes**

Refer to Clinic Practitioner.

“**You may have already answered these questions on other forms, but I’d like to recheck these items to make sure it is safe for you to stay on your study pills.**”

9. “What was the date of your last mammogram?”

Month _________ Year _________

10. “Are you now taking, or has your doctor prescribed, any:”

10.1 “**Corticosteroids** (such as Prednisone, Decadron, Medrol in pill form)?”

- **No**
- **Yes**

10.2 “**Blood thinning medications** (such as Coumadin or Warfarin)?”

- **No**
- **Yes**

“**Other than your WHI study pills, are you now taking, or has your doctor prescribed, any hormones such as:**”

10.3 “**Estrogen**?”

- **No**
- **Yes**

10.4 “**Progesterone**?”

- **No**
- **Yes**

10.5 “**Testosterone**?”

- **No**
- **Yes**

10.6 “**Tamoxifen, Raloxifene** (Evista) or other medications known as SERMs?”

- **No**
- **Yes**

Refer any “Yes” responses in 10.1 - 10.6 to CP.

11. “Since your last contact, has a doctor told you that you had any of the following conditions?”

11.1 “**Endometrial hyperplasia**”

- **No**
- **Yes**

11.2 “**High triglycerides in your blood (triglycerides are not the same as cholesterol)**”

- **No**
- **Yes**

11.3 If yes: “**Were your triglycerides over 1,000 (mg/dl)?**”

- **No**
- **Yes**

11.4 “**Blood clot to your leg or lung**”

- **No**
- **Yes**

11.5 “**Melanoma of skin**”

- **No**
- **Yes**

11.6 “**Heart attack or stroke**”

- **No**
- **Yes**

11.7 “**Meningioma, or tumors in the brain**”

- **No**
- **Yes**

11.8 “**Breast cancer**”

- **No**
- **Yes**

11.9 “**Gall bladder disease**”

- **No**
- **Yes**

11.10 “**Problems with your pancreas**”

- **No**
- **Yes**

11.11 “**Transient ischemic attack (TIA or “mini-stroke”)**”

- **No**
- **Yes**

11.12 “**Sudden, serious changes in your eyes or vision**”

Refer any “Yes” responses in 11.1 - 11.12 to CP.

12. “Are there any worries, discomforts, or questions you would like to discuss?”

List below and discuss with participant. Refer to Clinic Practitioner if there are any concerns.

________________________________________________
________________________________________________
________________________________________________
________________________________________________
________________________________________________
________________________________________________
13. Resulting action from participant reports of symptoms or concerns in items 6-12. (This item must be completed. Mark all that apply.)
   [ ] Participant reassured and advised to continue with current study medications.
   [ ] Participant advised to return to clinic for evaluation. Date and time of next appointment:
   [ ] Consulting gynecologist notified.
   [ ] Participant referred to primary physician: Physician:
   [ ] Medications changed or stopped (complete Form 54 – Change of Medications)
   [ ] Other (Specify):

14. “I’d like to talk with you about your HRT study pills.”
14.1. “Since your last contact, how often did you take the study pills? Would you say…” (Mark the response most often true.) (Read responses to participant.)
   [ ] "Not at all"
   [ ] "Less than once per week"
   [ ] "1 - 2 days per week"
   [ ] "3 - 4 days per week"
   [ ] "5 - 6 days per week"
   [ ] "Every day of the week"

14.2. “It is common for people to miss taking pills. About how many days have you missed taking your pills in the last month?” (Use best estimate.)
   ___ days in the last month

14.3. “What helped you remember to take your pills?”
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

14.4. “People miss taking their study pills for many reasons. If there were days you did not take the pills, what were the reasons you didn’t?” (Mark all that apply.)
   [ ] Took all pills every day
   [ ] Experienced symptoms
   [ ] Forgot pill(s)
   [ ] Forgot bottle
   [ ] Needed/Took a break
   [ ] Afraid of health problems
   [ ] Family/Friend recommendation
   [ ] MD recommendation
   [ ] Didn’t have any pills
   [ ] Other

14.5. Strategies to improve adherence (Refer to forms instructions for specific examples.)
   [ ] Ask participant to describe reason(s) given.
   [ ] Provide reassurance, using validation, review of facts
   [ ] Recommend palliative measures, using specific examples.
   [ ] Recommend steps to improve adherence, such as ways to deal with problem at home, self-motivation, mobilizing social support
   [ ] Put issues into perspective-emphasize safety of study, importance of WHI in answering health problems

15.1 Should participant be put on Intensive Adherence Program (IAP)? (See instructions for entry criteria.)
   [ ] No
   [ ] Yes ➞ 15.2 Date to be recontacted ___/___/___ (M/D/Y)

16.1 Should participant be recontacted in one month by phone for clinical follow-up?
   [ ] No
   [ ] Yes ➞ 16.2 Date to be recontacted ___/___/___ (M/D/Y)
17. Comments:

_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________
_________________________________________________________________________________________________