Comments:	**- Affix label here-** Clinical Center/ID: __ __ __ __ - ___ ___ ___ - __ First Name _____M.I._____ Last Name _____

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

(Complete Question 5 before interview.)

5. Dosage/Adherence

5.1. Taking Standard WHI Dosage:

___ No

___ Yes → ____ Adherence rate / ____ Unable to do

5.2. Taking Altered Dosage:

___ No

___ Yes → ____ Adherence rate / ____ 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** →

6.1. **"Even though you've had a hysterectomy, have you had any bleeding from your vagina since your last contact?"**

☐ 0 No → *Go to Question 7.*

☐ 1 Yes → *Go to Question 7 and refer to Clinic Practitioner.*

☐ 0 **NO** →

6.2. Review *Form 53 - HRT Calendar* if available. **"Have you had any vaginal bleeding since your last contact?"**

☐ 0 No *(Go to Question 7.)* ☐ 1 Yes → *Complete interview, then refer to Clinic Practitioner.*

"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)

K _____

7. **"Since your last contact, have you had any breast tenderness?"**

☐ 0 No

☐ 1 Yes →

7.1 **"Was your breast tenderness mild, moderate, or severe?"**

☐ 1 Mild

☐ 2 Moderate → *Refer to Clinic Practitioner*

☐ 3 Severe

8. **"Since your last contact, have you had any operations on or noticed any <u>other</u> changes in your breasts (new lumps, nipple discharge, or skin changes)?"**

☐ 0 No

☐ 1 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)**?"** ☐ 0 No ☐ 1 Yes

10.2 **"Blood thinning medications** (such as Coumadin or Warfarin)?**"** ☐ 0 No ☐ 1 Yes

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

10.3 "**Estrogen?"**…….. ☐ 0 No ☐ 1 Yes

10.4 "**Progesterone?"**……. ☐ 0 No ☐ 1 Yes

10.5 "**Testosterone?"**…….. ☐ 0 No ☐ 1 Yes

10.6 "**Tamoxifen, Raloxifene …… (Evista) or other medications known as SERMs?"** ☐ 0 No ☐ 1 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"** ☐ 0 No ☐ 1 Yes

11.2 **"High triglycerides in your blood (triglycerides are not the same as cholesterol)"** ☐ 0 No ☐ 1 Yes ↓

11.3 If yes: **"Were your triglycerides over 1,000 (mg/dl)?"** ☐ 0 No ☐ 1 Yes

11.4 **"Blood clot to your leg or lung"** ☐ 0 No ☐ 1 Yes

11.5 **"Melanoma of skin"** ☐ 0 No ☐ 1 Yes

11.6 **"Heart attack or stroke"** ☐ 0 No ☐ 1 Yes

11.7 **"Meningioma, or tumors in the brain"** ☐ 0 No ☐ 1 Yes

11.8 **"Breast cancer"** ☐ 0 No ☐ 1 Yes

11.9 **"Gall bladder disease"** ☐ 0 No ☐ 1 Yes

11.10 **"Problems with your pancreas"** ☐ 0 No ☐ 1 Yes

11.11 **"Transient ischemic attack (TIA or "mini-stroke")"** ___ No ___ Yes

11.12 **"Sudden, serious changes in your eyes or vision"** ___ No ___ Yes

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.)

- ☐ 1 Participant reassured and advised to continue with current study medications.
- ☐ 2 Participant advised to return to clinic for evaluation. Date and time of next appointment:

  _____
- ☐ 3 Consulting gynecologist notified.
- ☐ 4 Participant referred to primary physician:

  Physician: _____

  _____
- ☐ 6 Medications changed or stopped (*complete Form 54 – Change of Medications)*
- ☐ 8 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.)*

- ☐ 0 **"Not at all"**
- ☐ 1 **"Less than once per week"**
- ☐ 2 **"1 - 2 days per week"**
- ☐ 3 **"3 - 4 days per week"**
- ☐ 4 **"5 - 6 days per week"**
- ☐ 5 **"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.)*

- ☐ 1 Took all pills every day
- ☐ 2 Experienced symptoms
- ☐ 3 Forgot pill(s)
- ☐ 4 Forgot bottle
- ☐ 5 Needed/Took a break
- ☐ 6 Afraid of health problems
- ☐ 7 Family/Friend recommendation
- ☐ 8 MD recommendation
- ☐ 9 Didn't have any pills
- ☐ 88 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

Use local CC guidelines to determine if referral to CP or other specialist is needed.

15.1 Should participant be put on Intensive Adherence Program (IAP)? (See instructions for entry criteria.)

- ☐ 0 No
- ☐ 1 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?

- ☐ 0 No
- ☐ 1 Yes → 16.2 Date to be recontacted ☐☐-☐☐-☐☐ (M/D/Y)

17. Comments: