1. Date Received: ☐☐-☐☐-☐☐ (M/D/Y) 2. Reviewed By: ☐☐☐	**- Affix label here-** Clinical Center/ID: __ __ __ __ - ___ ___ ___ - __ First Name _____M.I._____ Last Name _____

3. Contact Type: ☐1 Phone ☐2 Mail ☐3 Visit ☐8 Other	4. Visit Type: ☐2 Semi-Annual #☐☐ ☐3 Annual #☐☐ ☐4 Non-Routine	5. DOSE STD___ ALT___

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Please use ink.

This questionnaire is very important so that we can monitor your health and see how you are doing on your HRT study pills. Please take the time to answer each question carefully. Mark the appropriate box with an "x" (☒) or write the information in the space provided.

WOMEN'S HEALTH INITIATIVE

HRT Program

K_____

6. Have you 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
☐ 1 Yes

→ **Go to Question 7 below.**

☐ 0 No →

6.2. Review your HRT Calendar if available. Have you had any vaginal bleeding since your last contact?

☐ 0 No → **Go to Question 7 below.**

☐ 1 Yes ↓

These next questions are about your vaginal bleeding.

6.3. How heavy was it? **(Check the heaviest amount 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.)**

__-__-__
month day year

6.5. Did the bleeding start and stop again?

☐ 0 No ☐ 1 Yes

6.6. Are you bleeding now? **(If you are bleeding even a little, mark "yes.")**

☐ 0 No →
☐ 1 Yes

6.7. When did the bleeding stop?

__-__-__
month day year

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

☐ 0 No ☐ 1 Yes →

7.1. Was your breast tenderness:
☐ 1 Mild ☐ 2 Moderate ☐ 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

You may have already answered these questions on other forms, but we would 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, Warfarin)?	☐ 0 No	☐ 1 Yes

Other than your 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

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

12. Do you have any worries, discomforts, or questions you would like to discuss with the clinic staff? If yes, please list them here and we will call you to discuss these issues. _____

_____

_____

13. RSLT

☐ 1 CONT ☐ 2 RET: _____ ☐ 3 CONS ☐ 4 REF: _____ ☐ 6 CHG ☐ 8 OTH: _____

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14. We would like to know how you are taking your HRT study pills:

14.1. Since your last contact, how often did you take the study pills? **(Choose the response most often true.)** Would you say...

☐ 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? **(Give your 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, specify _____

Thank you! Please take a moment to review and answer any questions you may have missed.

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14.5 Strategies
___ DSCB
___ VAL
___ PAL
___ RECM
___ PERSP

15.1 IAP
☐ 0 No ☐ 1 Yes ⟶ 15.2 └┴┘-└┴┘-└┴┘ (M/D/Y)

16.1 RECNT
☐ 0 No ☐ 1 Yes ⟶ 16.2 └┴┘-└┴┘-└┴┘ (M/D/Y)