

Center:

Patient Initials:   
 Rand Number:

Form completed by:

Complete this form whenever there is a change in study medication schedule, including the discontinuation of some or all WAVE medications. Very short term changes (less than 1 week) need not be reported.

**A. TIMING OF THE CHANGE**

1. Visit *after* which the change in study medications takes effect: **F\_VISIT**

- |   |                                      |                                      |                                      |
|---|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 00 Randomization | <input type="checkbox"/> 01 1 month  | <input type="checkbox"/> 03 3 month  | <input type="checkbox"/> 06 6 month  |
| <input type="checkbox"/> 12 12 month      | <input type="checkbox"/> 18 18 month | <input type="checkbox"/> 24 24 month | <input type="checkbox"/> 30 30 month |

2. Date of this change in study medication: **deleted**

/  /   
 Month Day Year

**B. NATURE OF THE CHANGE** (include all study medications, not just those you are changing)

**1. Current Schedule**

**2. New Schedule**

a. HRT/HRT placebo: **deleted**

pills/week **deleted**

pills/week

b. Vitamin C/Vitamin C placebo:  
**deleted**

pills/week **deleted**

pills/week

c. Vitamin E/Vitamin E placebo:  
**deleted**

pills/week **deleted**

pills/week

d. MPA, 10mg: **deleted**

pills/week **deleted**

pills/week

e. MPA, 2.5mg: **deleted**

pills/week **deleted**

pills/week

f. Premarin, 0.3mg: **deleted**

pills/week **deleted**

pills/week

3. Is this change permanent? **F\_PERM**

Y  N  3

a. If not permanent, how long should the participant stay on this regimen?  
 (when dosage is changed again, complete a new W06) **F\_WEEKS**

weeks

**C. REASONS FOR THE CHANGE**

1. Vaginal bleeding? **deleted**

Y  N  3

6. GI distress? **deleted**

Y  N  3

2. Suspected or diagnosed cancer?  
**deleted**

Y  N  3

7. Non-vaginal bleeding?  
**deleted**

Y  N  3

3. Breast tenderness? **deleted**

Y  N  3

8. Severe headaches? **deleted**

Y  N  3

4. Mood change? **deleted**

Y  N  3

9. Open Label Medication?  
**deleted**

Y  N  3

5. Weight gain? **deleted**

Y  N  3

10. Immobility? **deleted**

Y  N  3

11. Other conditions: **deleted**

Y  N  3

a. If yes, specify:

**deleted**



**Derived Variables:**

F\_CHDY = days since randomization to the date of this medication change

CHHRT = change in the number of study HRT pills taken per week

CHVITC = change in the number of study vitamin C pills taken per week

CHVITE = change in the number of study vitamin E pills taken per week

CHMPAH = change in MPA 10mg pills taken per week

CHMPAL = change in MPA 2.5mg pills taken per week

CHPREM = change in premarin pills taken per week

MED = 1 if there is a medical reason for medication change

= 0 otherwise

OTHER = 1 if there is some other non-medical reason for medication change

= 0 otherwise