**FORM:** **54 - CHANGE OF MEDICATIONS**

**Version:** 2 - March 5, 1997

**Description:** Completed by Clinical Center (CC) Clinic Practitioner (CP); 1-page form; key-entered at CC.

**When used:** When CC staff make or agree to a change in study pill schedule or dosage for HRT and/or CaD participants. Note: Do not use this form when a participant makes her own changes to her regimen.

**Purpose:** To record change in study pill dosage, or temporary additions or cessations of study pill or open-label medications and the reason(s) why these actions occurred.

## GENERAL INSTRUCTIONS

1. Initiate form when study medication, dosage, or schedule need to change because of symptoms, adverse events, or local clinical judgment.

2. Affix a participant bar-code label to the form.

3. Complete Items 1 - 8.

4. Review the form for completeness.

5. Forward the form to Data Entry.

6. Data Entry: Review the form for completeness and return to responsible clinical staff with any problems or questions. Key-enter after you resolve any questions. Initial when you complete the key-entry.

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

**Item Instructions**

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|---|---|---|
| 1. | Date of action | Date participant is asked to change her study pill dosage. |
| 2. | Staff ID | Standard 3-digit WHI employee ID of person who completed the form. (See common data items.) |
| 3. | Contact type | Mark appropriate oval or box. (See common data items.) |
| 4. | Visit type | Contact at which participant changes her study pill dosage. Mark appropriate oval or box. Provide visit number as appropriate. (See common data items.) |
| 5. | Previous schedule participant followed | The study pill dosage the participant took since the last dosage change. This may not be the dosage she was asked to take.<br>Data Entry: Do not key-enter. |
| 6.1. | New study medication schedule | Mark all study pills that the participant will be taking as of this contact. |
| 6.2. | New dosage | Enter the number of pills per week by each study pill the participant is taking. Include all study pills, even those you are not changing. |
| 7. | Permanent dosage change | No/Yes. Mark "1 - Yes" if you are making a permanent change in the participant's study pill dosage. |
| 7.1. | How long should participant follow this dosage | Duration of new dosage in weeks. Use the shortest length of time if the participant is taking more than one study pill. |
| 8. | Reason for study medication change | |
| 8.1. | HRT | Mark all that apply. Specify for "4 - Symptom intolerance" and "8 - Other."<br>Data Entry: Key-enter problem specified in "4" or "8." |
| 8.2. | CaD | Mark all that apply. Specify for "4 - Symptom intolerance" and "8 - Other."<br>Data Entry: Key-enter problem specified in "4" or "8." |