
FORM:	53 - HRT CALENDAR
Version:	1 - July 8, 1994
Description:	Calendar completed by Hormone Replacement Therapy (HRT) participants and reviewed by the Clinic Gynecologist or Practitioner; 8-page booklet; data entered at Clinical Center (CC).
When Used:	During the first year of the HRT, or to document a bleeding problem in later years of the study.
Purpose:	To record any bleeding occurrences, the amount of bleeding and duration.

GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 53*) and Spanish (*Form 53S*) versions. The English version is in mark-sense format and the Spanish version is in a key-entry format.

For both forms, follow the instructions on the front of the form for marking the answers.

2. Write the participant's name and the date on the front page of the form. Place the participant barcode label on the third page of the form.
3. Give HRT Calendar to HRT participants at Screening Visit 2 (SV2) when you dispense enrollment HRT medications and to HRT participants at Screening Visit 3 (SV3) and the first semi-annual visit when you dispense HRT study medications.
4. Review the instructions with the participant. Remind her of the need for daily rather than retrospective recordings. Ask her to bring the calendar to her next visit, scheduled or unscheduled.
5. Review the returned calendar for any illegible or multiple marks, questions or clarifications with the participant.
6. If bleeding episodes have occurred, complete *Form 10 - HRT Management and Safety Interview*.
7. Complete the items in the office use box on the third page of the form. Place the calendar in the participant's file and forward to Data Entry for scanning.
8. Data Entry: Scan or key-enter pages 3-6 of the form and initial the third page of the form.
9. File the scanned or key-entered form in the participant's file.

Item Instructions

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| 1. | Date received | Date the CC receives the form from participant. |
| 2. | Completed by | Standard 3-digit WHI employee ID. (See common data items.) |
| 3. | Contact type | Mark appropriate oval or box. |
| 4. | Visit type | Contact at which you receive the form. Provide visit number as appropriate. (See common data items.) |
| 5. | Form administration | Method used to administer form to participant:
1 - Self: Participant completed form by herself.
2 - Group: Participant completed the form with a group of other participants.
3 - Interview: CC staff person completed <u>entire</u> form as interview.
4 - Assistance: Participant needed partial assistance from CC staff or others to complete the form. |
| | Month/year | The month and year the participant recorded her bleeding. |
| | Bleeding per day | The amount of bleeding each day of the month. The number of the day in the form corresponds to the day.

Spotting - spotting to light bleeding; one to three pads per day; less than a regular menstrual flow.

Moderate - four to seven pads per day; about the same as a regular menstrual flow.

Heavy - eight pads or more per day; more than a normal menstrual flow. |
| | Language | Data Entry: English or Spanish version of the form. (See common data items.) |