
FORM:	50 - ON-STUDY BLEEDING
Version:	2 - July 8, 1994
Description:	Completed by Clinic Gynecologist or Practitioner; 1-page form; key-entered at Clinical Center (CC).
When used:	At any time participant reports any vaginal bleeding, either by phone or at a CC visit.
Purpose:	To document bleeding, amount of bleeding, action taken, and outcomes of action.

GENERAL INSTRUCTIONS

1. Affix a participant barcode label to the form.
2. Ascertain amount of bleeding from the participant and/or *Form 53 - HRT Calendar* and any other information necessary to enact bleeding protocols in *Vol. 2 - Procedures, Section 5 - Hormone Replacement Therapy*.
3. Record actions taken. If any medications were altered, initiate a *Form 54 - Change of Medications*.
4. Review the form for completeness and forward to Data Entry.
5. Data Entry: Review form for completeness and return to responsible clinical personnel with any problems or questions. Key-enter when complete or questions have been resolved. Initial when you complete the key-entry.
6. File key-entered form in the participant's file.

Item Instructions

1. Date of contact Date you completed the form.
2. Completed by Standard 3-digit WHI employee ID of staff person completing the form. (See common data items.)
3. Type of contact Mark appropriate oval or box. (See common data items.)
4. Visit type The contact at which you complete the form. Write visit number as appropriate. (See common data items.)
5. Flow amount The amount of vaginal bleeding each day. Mark appropriate oval or box based on participant's report and/or *Form 53*, from spotting to severe bleeding. Have participant give her best guess as to amount of bleeding using given criteria, where 1 pad = 1 tampon.
 - 1 - spotting - approximately 1 pad's worth/day
 - 2 - light - approximately 2-3 pads's worth/day
 - 3 - moderate - approximately 4-7 pad's worth/day
 - 4 - severe - 8 or more pad's worth/day
6. Date bleeding began Date bleeding started. Give best estimate based on participant's report and/or *Form 53*.
7. Bleeding intermittent No/Yes. Mark "1 - Yes" if bleeding was not constant or had multiple start/stop intervals over a number of days.
8. Currently bleeding No/Yes.
- 8.1. Date bleeding stopped Date bleeding stopped and did not start again.
9. Resulting action Action you took based on the participant's report of bleeding. Mark one oval or box.
 - 1 - Participant reassured and advised to continue with current study medications.
 - 2 - Participant advised to return to clinic for evaluation: Record date and time of appointment.
Data Entry: Do not key-enter data and time of appointment.
 - 3 - Consulting gynecologist notified.
 - 4 - Participant referred to primary physician: Write in physician's name and address.
Data Entry: Do not key-enter name, address, or phone number.
 - 5 - Participant should be recontacted in one month by phone.
If participant is to be recontacted, enter recontact date.
Data Entry: Do not key-enter date.
 - 8 - Other
If other action, specify action taken.
Data Entry: Key-enter action taken.