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<b>FORM:</b>	<b>84 - CLINICAL BREAST EXAM</b>
<b>Version:</b>	4 – September 15, 1999
<b>Description:</b>	Completed by Clinic Gynecologist or Practitioner; 2-page form; key-entered at Clinical Center (CC).
<b>When used:</b>	During screening and annual visits for breast evaluations.
<b>Purpose:</b>	To record the findings of the clinical breast exam and any resulting referrals.

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### GENERAL INSTRUCTIONS

1. Include form in the appropriate annual visit form packets. Use as needed for non-routine evaluations.
2. At the visit, affix a participant barcode label to the form.
3. Complete Items 1 - 5.
4. Perform the examination and complete the remainder of the form. Refer to *Vol. 2 - Procedures, Section 9.7 – Clinical Breast Exam (CBE)*.
5. If the CBE was performed by an outside provider, complete items 6.1 – 6.4. Obtain a written copy of the CBE report and abstract the information onto the form, as appropriate. If information to complete a data item is not included in the written report, do not assume it was done; leave the data item blank. If a written report cannot be obtained, a verbal report from the provider's clinician is acceptable. Complete item 6.4.
6. Evaluate findings for safety and continuation of study pills.
7. Review the form for completeness.
8. Insert the form in the participant's file and forward to Data Entry.
9. 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.
10. File the key-entered form in the participant's file.

### Item Instructions

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|----------------|--|---|
| 1.             | Contact date   | The date the form is initiated, which is usually the date the exam was performed at the clinic.   |
| 2.             | Completed by   | Standard 3-digit WHI employee ID of person performing the CBE or ID of staff member completing form if CBE done elsewhere. (See common data items.)   |
| 3.             | Contact type   | Mark appropriate box. (See common data items.)  |
| 4.             | Visit type   | Contact at which breast exam is done. Mark appropriate box. Write in visit number as appropriate. (See common data items.)  |
| 5.             | Date   | Date the breast exam was performed.   |
| 6.             | CBE exam   | CC Staff/Other. Mark appropriate box to indicate who performed exam. If done at CC, go onto Item 7. If not done by CC staff, complete items 6 – 6.4, as appropriate.  |
| 6.1.           | Report taken by  | Standard 3-digit WHI employee ID of person obtaining information. (See common data items.)  |
| 6.2.           | Name/address   | Name, address and phone number of provider who performed the breast exam.<br>Data entry: Do not key-enter.  |
| 6.3.           | Abnormal findings  | No/yes. Mark appropriate box and follow instructions as indicated. If answer is “1=yes,” identify the nature of the problem and refer to CP to assure appropriate follow-up, so that participant doesn’t continue HRT if contraindicated. Document follow-up in items 9 and 10.   |
| 6.4.           | Verbal report  | If a written report cannot be obtained, a verbal report may be taken. The report must be provided by a clinician. Document the clinician’s name and title.<br>Data Entry: Do not key-enter.   |
| 7.             | Summary of CBE   | Record clinical exam notes on the form. Mark appropriate notations of findings on breast diagram for future reference.  |
| 7.1.-<br>7.4.  | Nipple discharge, skin involvement, axillary mass, breast mass | No/Yes, probably benign/Yes, possibly malignant. Mark appropriate box for each category. Findings such as fibrocystic tissue changes, scar tissue from previous biopsies, and/or bilateral symmetrical thickenings that do not have malignant potential in your clinical judgment should be recorded as 0 – “No,” noted on the diagram, and described on the form.<br><br>If participant has a mastectomy or bilateral mastectomies, complete as much of the form as possible. For example, if a participant had a right-sided mastectomy complete 7.1, 7.2 and 7.4 on the left side. 7.3 on the right-side might still be completed. Document on the form that a mastectomy was done and the date. |
| 7.5. -<br>7.6. | Primary mass   | No/Yes. Mark appropriate box to describe characteristics of primary mass on right and left sides. These items do not need to be completed for fibrocystic tissue changes/disease or symmetrical thickenings that appear benign.   |
| 7.7            | > One mass   | No/Yes. Mark appropriate box.   |

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8. BSE taught or reinforced No/Yes. Comprehensive breast self-exam (BSE) teaching is not required at follow-up visits (see *Vol. 2 - Procedures, Section 9 - Clinical Measurements*).
9. Referral for follow-up No/Yes.
- 9.1. Referred by Standard WHI employee ID (see common data items). If referred by primary care provider, use code for "outside employee". Write name on line (see common data items).  
Data Entry: Name is not key-entered.
- 9.2. Date of referral Date the participant was referred for follow-up care.
- 9.3. Referred to Name, address, and phone number of person to whom you referred the participant.  
Data Entry: Name and address not key-entered.
10. Final follow-up Normal/Benign changes/Possibly malignant/Cancer. Mark appropriate box for either right or left side to document results of the referred work-up.  
If "3 - Cancer" is marked, the participant must discontinue her study pills permanently. Complete *Form 7 – Participation Status*.