

<b>FORM:</b>	<b>85 - MAMMOGRAM</b>
<b>Version:</b>	8 – May 1, 2005
<b>Description:</b>	Completed by Field Center (FC); 1-page form; key-entered at FC.
<b>When used:</b>	Use annually during the first <u>two</u> years for HT Extension Study participants <u>only</u> .
<b>Purpose:</b>	To record results of mammograms in HT participants. The participant's primary care provider (PCP) is responsible for all follow-up care.

---

### GENERAL INSTRUCTIONS

1. Affix a participant barcode label to the form.
2. At the contact (phone or mail), complete Items 1 - 2.
3. Review *Form 150 – Hormone Use Update, #9* (“Mammogram in the last year”), if available, and use this information to request the mammogram report.
4. If the participant's *Form 150* does not include the mammogram facility or provider information, or if a mammogram has not been completed in the last year, contact the participant to obtain this information or to remind her to schedule a mammogram. Identify available mammogram facilities and follow-up with the participant, as needed.
5. When you receive the report, complete Items 3 - 7.
6. Process and key-enter the form in the manner that best fits the flow of your CC. Options include:
  - Key-enter Items 1 - 2 to initiate the form in the database and key-enter the remainder of the form after receiving the mammogram report. To do this:
    - Send the form to Data Entry after completing Items 1 - 2 and request a copy of the mammogram or refer the participant for mammography. Store the form in the participant file or a central holding area to await the report.
    - When you receive the report, complete the remainder of the form, attach the report to the form. Send the form to Data Entry for key-entry of the remainder of the form.
  - Key-enter the *entire* form after receiving the mammogram results. To do this:
    - Store the form in the participant's file or in a central holding area with other "waiting for results" forms.
    - When you receive the report, complete the entire form, and attach the report to the form. Send the form to Data Entry for key-entry.
7. Data Entry: Regardless of which processing option is chosen, review the form for completeness and return to the responsible FC staff person with any problems or questions. Key-enter after you resolve any questions.
 

Initial the first page of the form when you complete the key-entry. If you key-enter the form before the report is returned, initial the form as key-entered twice, once when you key-enter Items 1 - 2 and again when you key-enter the mammogram results.
8. After key-entry, file both the form and mammogram report in the participant's file.

### Item Instructions

- |    |                   |   |
|----|-------------------|---|
| 1. | Contact date      | Date the form is initiated.   |
| 2. | Staff person      | Standard 5-digit WHI Extension Study employee ID of FC staff.<br><br>Data Entry: Name is not key-entered.   |
| 3. | Date of mammogram | Date the mammogram was performed. Record the date of the mammogram from the mammogram report.   |
| 4. | Performed by      | Name of MD, clinic name, address, and phone number of who performed the mammogram.<br><br>Data Entry: Items not key-entered.  |
| 5. | Date reviewed     | Date FC reviewed the mammogram report.  |
| 6. | Reviewed by       | Standard 5-digit WHI Extension Study employee ID of FC staff who reviewed the mammogram report and completed Item 5.<br><br>Data Entry: Name is not key-entered.  |
| 7. | Summary           | <p>The summary of the results of the mammogram report. Mark the appropriate box for both the right and left breast. If multiple diagnoses are given, mark the box corresponding to the diagnosis of greatest severity.</p> <p>The American College of Radiology (ACR) has established the Breast Imaging Reporting and Database System (BI-RADS) to standardize interpretation of mammograms among radiologists. Refer to the WHI code and the corresponding BI-RADS category listed below.</p> <p>There will be instances when the BI-RADS code will not correspond to the narrative text and you will need to use your best judgment to assign a code that most accurately reflects the results of the mammogram report. The majority of the discrepancies where such judgment is appropriate will occur within BI-RADS categories 1 to 3.</p> <p>Code 0: <b>Negative (BI-RADS Category 1)</b><br/>Mammograms that do not require a repeat exam within 12 months or a referral for further evaluation are considered normal or negative. Generally, negative reports have no descriptive findings and might state that the “breasts are symmetrical”, have “no masses”, “architectural disturbances” or “suspicious calcifications”. A routine screening schedule is recommended. If nothing is described in the report -- “negative” would be the appropriate category to use.</p> <p>If the mammogram report indicates “BI-RADS Category 1 (Negative)” and the narrative of the mammogram report indicates, for example, the presence of “multiple secretary calcifications,” code Question 7 on <i>Form 85 – Mammogram</i> as “BI-RADS Category 2” (Benign Mammogram Findings”).</p> |

**Code 1: Benign Mammogram Findings (BI-RADS Category 2)**

Results of "mammary dysplasia," "adenosis," "fibrocystic breast tissue or disease," "coarse or "multiple secretory calcifications," or "fat-containing lymph," are considered normal but should be coded as benign. Reports of "fluid-filled cysts" that are greater than or equal to 5 mm in size (and are demonstrated on ultrasound to be smooth-surfaced) or "walled simple cysts" can be considered normal and coded as benign. Most lay reports (written in easy to understand language by the mammogram facility for the participant) will fall under this or the "Negative" category.

**Code 2: Probable Benign Findings (BI-RADS Category 3)**

This coding is usually chosen by the radiologist if a short interval follow-up is suggested. A finding placed in this category should have a very high probability of being benign. Mammogram reports might show a probable benign finding such as "calcification with benign features", "stability unknown", "circumscribed mass", or "cyst less than 5 mm." However, these situations are generally reevaluated in **less** than a year to assess for stability.

**Code 3: Suspicious (BI-RADS Category 4)**

A biopsy is usually considered by the provider ordering the mammogram for a Suspicious abnormality. These are generally lesions that do not have characteristic qualities of breast cancer, but have a definite probability of being malignant.

The expectation is that discrepancies between the narrative text and BI-RADS categories 4 and 5 require a higher level of consideration and consultation to determine the correct code for *Form 85 - Mammogram*. If the narrative text and the BI-RADS category do not match for a "suspicious abnormality (BI-RADS Category 4)" or "highly suggestive of malignancy (BI-RADS Category 5)" mammogram result, it will be necessary for the FC to investigate the appropriate code. These discrepant mammogram reports should be referred to your Principal Investigator and results investigated with the radiologist.

**Code 4: Highly Suggestive of Malignancy (BI-RADS Category 5)**

A Highly Suggestive of Malignancy code also has a high probability of being cancer and should lead to a timely tissue biopsy. This category, however, usually has typical characteristics of breast cancer.

**Code 9:** If the participant has had a mastectomy or bilateral mastectomies (or did not have a mammogram performed on either or both sides for some other reason), mark "not done" on the appropriate side(s) and document the reason on the form.

**Blank:** If the mammogram results are "inconclusive" or "indeterminate," leave Item 7.1 and/or 7.2 blank and document the reason for the blank item(s) on the form. Inconclusive or indeterminate results are often reported if additional mammography views or evaluations (i.e., ultrasounds) are warranted or if the mammogram films need to be compared to previous films.