Sister Study Breast Cancer Follow-up Implementation Plan

1) When patient informs us of her diagnosis, send card with list of resources.

2) 12-18 months post-diagnosis (to allow time for treatment completion), send brief letter to let the patient know we will be calling her to ask questions about her breast cancer diagnosis and treatment. Enclose the Breast Cancer Follow-up Worksheet to help the patient prepare for the call.

3) Within one to two weeks after sending letter, telephone the patient to administer the computer-assisted telephone interview and ask patient to identify physicians (including, if any, a primary physician responsible for coordinating care) and treatment facilities. Discuss authorization for obtaining medical record information about breast cancer diagnosis and treatment and collecting samples of breast tissue remaining from biopsy or surgery.

4) After the telephone call, send patient a follow-up letter including the list of the physicians she identified and two authorization forms for the release of medical records/information and for the release of pathology blocks and slides. The mailing also includes a comprehensive FAQ covering both requests and instructions for completing and returning the materials. The letter instructs patients to mail the signed authorization forms and the physician list to the Sister Study in the enclosed return envelope.

5) If signed authorization forms have not been received from patient within four weeks, telephone the patient in an attempt to retrieve the forms.

6) After receiving patient's signed medical record authorization forms, telephone one or more of her physicians to let them know we will be requesting medical information, ask who should receive the request, and find out if reimbursement of costs by the Sister Study will be necessary.

7) Send letters to one or more physicians to request copies of relevant medical records and pathology reports and ask them to fill out an enclosed medical report form. Enclose a copy of the patient's signed medical record authorization form. Enclose a descriptive summary about the Sister Study.

8) If medical report forms and associated records have not been received from the physician within 3-6 weeks, telephone the physician to ask them to send the materials.

9) Review medical report forms and associated records received from the physicians. If any of the forms are missing information or records were not enclosed, contact the appropriate physicians in an attempt to retrieve the information.

10) Send letter and checklist to the pathologist to request two blocks containing representative samples of the breast carcinoma, two blocks containing normal breast tissue, and original diagnostic H&E slides. Enclose a copy of the patient's signed authorization form for release of pathology specimens.

11) After receiving pathology specimens, send a thank you letter to the pathologist to acknowledge receipt and provide information for retrieving the samples from study staff if needed.

DATE

FIRST NAME LAST NAME
ADDRESS 1
ADDRESS 2
CITY, STATE ZIP

Dear Ms. LAST NAME:

Thank you for providing an update on your health to the Sister Study. We were sorry to hear of your breast cancer diagnosis, and hope you are doing well. An important part of the Sister Study is to follow-up with each participant who has developed breast cancer to obtain additional information. In about two weeks, a member of the Sister Study staff will call to request information on your diagnosis and treatment, including names and addresses of your health care providers. Enclosed you will find a worksheet to help you prepare for the call. The worksheet will give you an idea of what we will be asking you. We will not be collecting the worksheet. If there is a question you cannot answer then just leave it blank. Some women find it helpful to complete the worksheet ***before*** the telephone call. Although you may have told us some of the details of your breast cancer diagnosis when you reported it to us, we need to collect the information now in a standard way.

We appreciate your on-going participation in the Sister Study, especially at this time. The information that you and other women are sharing is critical in helping us learn about the environmental and genetic causes of breast cancer, and factors that may influence long-term health in women who have been diagnosed with breast cancer.

Thank you for your support of this important research.

Sincerely,

Dale P. Sandler, Ph.D.
Principal Investigator

Encl: Breast Cancer Follow-up Worksheet

<SISID>

Breast Cancer Follow-up Worksheet - *This worksheet will help you prepare for your telephone interview. Please review these questions about your diagnosis and treatment, answering as best you can for each breast tumor found. Do not worry if you cannot provide all of the information. Have this form with you during your telephone interview to help you answer questions. If you have a copy of the pathology report related to your breast cancer diagnosis, it may help you answer these questions. You may want to keep it with this form for your interview.*

Diagnosis

What is the date a doctor first told you that you definitely had breast cancer?	☐☐ / ☐☐ / ☐☐☐☐ *month day year*		
At the time of your breast cancer diagnosis, had the cancer spread to your lymph nodes?	☐ Yes	☐ No	
At diagnosis, had the cancer metastasized or spread to other parts of your body?	☐ Yes	☐ No	
Was the tumor invasive or in situ cancer?	☐ Invasive	☐ in situ	
Was the tumor in ducts (ductal) or lobules (lobular) or both?	☐ Tumor in ducts	☐ Tumor in lobules	☐ Tumor in ducts and lobules
At the time of diagnosis, what was the size of the breast tumor?	☐☐ . ☐ cm		
Was the tumor estrogen receptor positive or "ER positive?"	☐ Yes, ER Positive	☐ No, ER Negative	
Was the tumor progesterone receptor positive or "PR positive?"	☐ Yes, PR Positive	☐ No, PR Negative	
Was the HER2 (HER2NEU) test positive or negative?	☐ Positive	☐ Negative	☐ HER2NEU test not performed

Treatment

Have you had surgery, not counting a biopsy, to remove the breast cancer?	☐ Yes	☐ No
Did you have chemotherapy for this breast cancer?	☐ Yes	☐ No
What chemotherapy drugs were you given for this cancer?	_____	
Have you taken Tamoxifen, Evista, or Raloxifene as part of your breast cancer treatment?	☐ Yes	☐ No

Continue on Reverse

Have you taken aromatase inhibitors like Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane) as part of your breast cancer treatment?	☐ Yes	☐ No
Since your breast cancer diagnosis, have you taken Herceptin (Trastuzumab)?	☐ Yes	☐ No
Have you had radiation therapy for this breast cancer?	☐ Yes	☐ No

Doctors and Medical Care Facilities: Please list the name, address, and telephone number for each treatment provider or location.

Provider	Name	Address	Telephone Number
Main doctor or facility responsible for breast cancer diagnosis and treatment		Street # _____ City/Town _____ State/Zip _____	
Oncologist or oncology center (if different from above)		Street # _____ City/Town _____ State/Zip _____	
Surgeon or surgery center		Street # _____ City/Town _____ State/Zip _____	
Pathologist		Street # _____ City/Town _____ State/Zip _____	
Therapeutic Radiologist or radiology center		Street # _____ City/Town _____ State/Zip _____	
Any other doctors or facilities involved in your breast cancer diagnosis and treatment		Street # _____ City/Town _____ State/Zip _____	

If you have any questions, please call the Sister Study toll-free at 1-877-4SISTER (1-877-474-7837). Thank you!

CASE Follow-up Telephone Interview

Table of Contents

IN: INTRODUCTION

IN0. My name is (NAME) and I am a staff member from the Sister Study. We are following up on your (phone call/note/email/form) indicating that you have been diagnosed with breast cancer. We are sorry to hear about this and hope you are doing well.

IN1. We'd like to ask you some additional questions about your diagnosis, the type of cancer, and about any treatment or surgery you may have received. We also will ask you for permission to contact your physician and/or the health care facility to obtain copies of your medical records pertaining to the diagnosis and treatment of your breast cancer. This should take about 15 minutes. You may not be able to answer all of the questions, but please just do your best.

ENTER '1' TO CONTINUE..... 1

IN2. You should have received a worksheet with the letter we sent to you. It may be helpful for you to refer to this during the interview.

Do you have the completed worksheet in front of you?

YES.....[IN5]..... 1
NO 2
CAN'T FILL OUT..[IN5]..... 3

[ASK IN3 IF IN2 = NO]

IN3. Do you need a few minutes to retrieve the worksheet or to review it and collect the information?

YES..... 1
NO .....[IN5]..... 2

[ASK IN4 IF IN3 = YES]

IN4. Would you like me to wait while you [review/retrieve] the worksheet or call you back?

WAIT – ENTER '1' WHEN READY .[IN5]..... 1
CALL BACK .....[IN13]..... 2

IN5. Do you have a copy of the pathology report related to your breast cancer diagnosis?

YES..... 1
NO ..... [CA1] 2
REF ..... [CA1] 7
DK..... [CA1] 8

[ASK IN6 IF IN5 = YES]

IN6. Did you use the pathology report to fill out your worksheet?

YES..... [CA1] 1
NO ..... [CA1] 2
REF ..... [CA1] 7
DK..... [CA1] 8

[IF PATIENT REFUSED ON EARLIER CALLTO PROVIDE INFORMATION ON DOCTORS OR MEDICAL FACILITIES BUT AGREED TO LET US CALL BACK (MR0d = YES), ASK:]

IN7. My name is (NAME) and I am a staff member from the Sister Study. We are following up on some materials we sent you related to your breast cancer diagnosis. When we spoke with you recently, you had reservations about allowing us to contact your physician and other health care facilities. However, you agreed to review the forms authorizing the Sister Study to obtain copies of your medical records pertaining to the diagnosis and treatment of your breast cancer. Did you receive the medical authorization forms we sent?

YES.....[IN9].....1
NO 2

IN8. We will resend the materials and call you back. ENTER '1' .....[IN13].....1

[ASK IN9 IF IN7 = YES]

IN9. Now that you have seen the forms, do you think you may be willing to give the Sister Study permission to contact your physician and other health care facilities?

YES..... 1
NO / UNSURE....[IN12].....2

[ASK IN10 IF IN9 = YES]

IN10. We need the names of the relevant doctors or health care facilities to prepare the medical release forms. I would like to get that information from you now and then we will send you new forms. We will not contact your doctors or health care facilities unless you give us permission to do so by signing the medical record release forms.

Do you need a few minutes to gather information about the doctors and medical facilities involved in the diagnosis and treatment of your breast cancer?

YES..... 1
NO .....[MR1].....2

[ASK IN11 IF IN10 = YES]

IN11. Would you like me to wait while you collect this information or call you back when you are ready?

WAIT – ENTER '1' WHEN READY [MR1].....1
CALL BACK .....[IN13].....2

[ASK IN12 IF IN9 = NO OR UNSURE]

IN12. If you change your mind about giving us information on the doctors or medical facilities, please call the Sister Study toll-free number (1-877-4SISTER) and follow directions for enrolled women.

ENTER '1' .....[END].....1

IN13. What is a convenient time to call you back?

[CLICK ON "APPOINTMENT" TAB]

MONTH	DAY	YEAR

TIME _____ AM PM

CA. DIAGNOSIS AND TREATMENT OF BREAST CANCER

CA1. [VERIFY DATE OF DIAGNOSIS, IF PROVIDED.]
You have indicated that a doctor first told you that you had breast cancer on *[fill date]*. Is this correct?

YES..... [CA2A]..... 1
NO 2
DK..... 8

[ASK CA1a IF NO DATE PROVIDED OR IF CA1=NO, DK]
[CHECK ANSWER TO CA1a AGAINST DOB]
CA1a. What is the date a doctor first told you that you definitely had breast cancer?

|__|__| |__|__|__|__|
MONTH YEAR
IF YEAR PROVIDED, GO TO CA2A

[ASK CA2 ONLY IF CA1 = NO OR DK AND CA1a YEAR = DK]
[CHECK ANSWER TO CA2 AGAINST DOB]
CA2. How old were you at the time of this diagnosis?

|__|__|
AGE

CA2A. Sometimes there is a delay between when a woman first notices a lump, or a mammogram shows an abnormality, and the final diagnosis of breast cancer. How much time went by between when you first realized there was a problem and when you were told the diagnosis was breast cancer?

< 1 MONTH – DIAGNOSED VERY CLOSE TO INITIAL IDENTIFICATION 00

|__|__| MONTHS

CA2B. It sometimes takes several doctor appointments to make sure of the breast cancer diagnosis and to run laboratory tests to identify its characteristics. When we refer to the 'time of diagnosis,' we mean this period of time during which your cancer was confirmed and characterized, not just the day you got the diagnosis.

When you were diagnosed with breast cancer, did you have any form of general health care coverage, including health insurance, pre-paid plans such as HMOs, or government plans such as Medicare or Medicaid?

YES..... 1
NO 2
REF 7
DK..... 8

CA2C. Sometimes it takes several tests and procedures after the diagnosis to find out how many tumors there are. After that medical work was completed, how many tumors had they found?
IF R SAYS DK, PROBE: How many tumors do you know about?

|__| BREAST TUMORS

[IF DK OR REF, COUNT AS 1 TUMOR FOR CA11-CA18, CA54 AND CS54]

CA3. At the time of your breast cancer diagnosis, had the cancer spread to your lymph nodes?

YES..... 1
NO 2
REF 7
DK..... 8

CA4. How many lymph nodes were tested?

0 ....[CA6]
|__|__| LYMPH NODES.....[CA5]
REF .... [CA4a]
DK..... ..... [CA4a]

[ASK CA4a ONLY IF CA4 IS REF OR DK:]
CA4a. **Approximately** how many lymph nodes were tested? Was it…?

0 nodes.....[CA6].....0
1-3 nodes 1
4-9 nodes 2
10-14 nodes 3
15-19 nodes 4
Or 20 or more nodes 5
REF 7
DK..... 8

[ASK CA5 ONLY IF CA4 IS NOT 0 OR IF CA4a IS NOT 0:]
CA5. How many lymph nodes were positive?

0 ....[CA6]
|__|__| LYMPH NODES.....[CA6]
REF .... [CA5a]
DK..... ..... [CA5a]

[ASK CA5a ONLY IF CA5 IS REF OR DK]
CA5a. **Approximately** how many lymph nodes were positive? Was it…?

0 nodes..... 0
1-3 nodes 1
4-9 nodes 2
10-14 nodes 3
15-19 nodes 4
Or 20 or more nodes 5
REF 7
DK..... 8

CA6. ***At the time*** of your breast cancer diagnosis, were you diagnosed with any other type of cancer or was cancer found anywhere else?

YES..... 1
NO .....[CA8].....2
REF .....[CA8].....7
DK.....[CA8].....8

[ASK CA7 IF CA6 = YES:]

CA7. What other type or types of cancer were you diagnosed with or where else was cancer found ***at the time*** of your breast cancer diagnosis? [
CHECK ALL THAT APPLY
IF R ANSWERS "SKIN CANCER," PROBE: Was this melanoma or non-melanoma skin cancer?
IF R GIVES A CLINICAL RESPONSE THAT DOES NOT MATCH A CATEGORY AND IS NOT A PART OF THE BODY, PROBE: "What specific part of the body did this cancer affect?"

ABDOMINAL	1
BASAL CELL SKIN CANCER	1
BLADDER	1
BLOOD	1
BONE	1
BOWEL	1
BRAIN	1
BREAST	1
CERVIX, CERVICAL	1
COLON, COLORECTAL	1
DUCTAL CARCINOMA IN SITU	1
ENDOMETRIAL	1
ESOPHAGEAL / ESOPHAGUS	1
HODGKIN'S DISEASE	1
INTESTINE, INTESTINAL	1
KAPOSI'S SARCOMA	1
KIDNEY AND RENAL PELVIS	1
LARYNX	1
LEUKEMIA	1
LIVER	1
LOBULAR CARCINOMA IN SITU (LCIS)	1
LUNG	1
LYMPH NODES	1
LYMPHOMA	1
MELANOMA SKIN CANCER	1
MULTIPLE MYELOMA	1
NON-HODGKIN'S LYMPHOMA	1
ORAL CAVITY AND PHARYNX	1
OVARY, OVARIAN	1
PANCREAS	1
RECTUM, RECTAL	1
SKIN CANCER – OTHER	1
SQUAMOUS CELL SKIN CANCER	1
STOMACH	1
THYROID	1
UTERUS, UTERINE	1
OTHER1 SPECIFY:	1
OTHER2 SPECIFY:	1
OTHER3 SPECIFY:	1

[BEGIN REPEATING RECORD]

[FOR EACH TYPE OF CANCER]:

CA7a. Was the [CANCER TYPE FROM CA7] cancer a primary tumor or was it a tumor that had metastasized or spread from your breast cancer or some other cancer

PRIMARY	1
METASTASIS—BREAST	2
METASTASIS—OTHER	3
METASTASIS—DK SOURCE	4
REF	7
DK	8

[END REPEATING RECORD]

CA8. ***Since the time*** you were first diagnosed with breast cancer, have you been diagnosed with any other cancers, or has cancer been found anywhere else, including another breast cancer?

YES..... 1
NO ..... [CA11].....2
REF ..... [CA11].....7
DK..... [CA11].....8

[ASK CA9 IF CA8 = YES:]

CA9. What type or types of cancer were you diagnosed with or where else was cancer found ***after*** your original breast cancer diagnosis? [
CHECK ALL THAT APPLY
IF R ANSWERS "SKIN CANCER," PROBE: Was this melanoma or non-melanoma skin cancer?
IF R GIVES A CLINICAL RESPONSE THAT DOES NOT MATCH A CATEGORY AND IS NOT A PART OF THE BODY, PROBE: "What specific part of the body did this cancer affect?"

ABDOMINAL 1
BASAL CELL SKIN CANCER 1
BLADDER 1
BLOOD..... 1
BONE 1
BOWEL 1
BRAIN..... 1
BREAST 1
CERVIX, CERVICAL 1
COLON, COLORECTAL 1
DUCTAL CARCINOMA IN SITU 1
ENDOMETRIAL 1
ESOPHAGEAL / ESOPHAGUS 1
HODGKIN'S DISEASE 1
INTESTINE, INTESTINAL 1
KAPOSI'S SARCOMA 1
KIDNEY AND RENAL PELVIS 1
LARYNX..... 1
LEUKEMIA 1
LIVER 1
LOBULAR CARCINOMA IN SITU (LCIS)1
LUNG 1
LYMPH NODES 1
LYMPHOMA 1
MELANOMA SKIN CANCER 1
MULTIPLE MYELOMA 1
NON-HODGKIN'S LYMPHOMA 1
ORAL CAVITY AND PHARYNX 1
OVARY, OVARIAN 1
PANCREAS..... 1
RECTUM, RECTAL 1
SKIN CANCER – OTHER 1
SQUAMOUS CELL SKIN CANCER.....1
STOMACH 1
THYROID 1
UTERUS, UTERINE 1
OTHER1 SPECIFY: 1
OTHER2 SPECIFY: 1
OTHER3 SPECIFY: 1

[BEGIN REPEATING RECORD]

[FOR EACH TYPE OF CANCER:]

CA9a. Was the [CANCER TYPE FROM CA9] cancer a primary tumor or was it a tumor that had metastasized or spread from your breast cancer or some other cancer?

PRIMARY 1
METASTASIS—BREAST..... 2
METASTASIS—OTHER 3
METASTASIS—DK SOURCE 4
REF 7
DK..... 8

[CHECK ANSWER TO CA9b AGAINST DOB]

[ASK CA9b – CA9c IF CA9 ≠ BREAST]

CA9b. What is the date a doctor first told you that you definitely had **this** [CANCER TYPE FROM CA9] cancer?

|__|__| |__|__|__|__|
MONTH YEAR
IF YEAR PROVIDED, GO TO CA9a OR CA10 IF NO OTHER CANCERS

[ASK CA9c ONLY IF CA9b YEAR = DK]

[CHECK ANSWER TO CA9c AGAINST DOB]

CA9c. How old were you at the time of this diagnosis?

|__|__|
AGE

[END REPEATING RECORD]

[IF CA8 = 1, ASK CA10, ELSE GO TO CA11]

CA10. Are you currently undergoing treatment for [this cancer/these cancers]?

YES..... 1
NO 2
REF 7
DK..... 8

CA11. The next questions are about the characteristics of your breast cancer.

[FOR WOMEN REPORTING MULTIPLE BREAST CANCERS DIAGNOSED AT DIFFERENT TIMES (CA9 = BREAST):]

We would like to find out about each of your breast cancer diagnoses. Please answer the following questions referring to your first breast cancer diagnosis in [month, year]. Later in this interview, we will ask similar questions about your [second/other] breast cancer [diagnosis/diagnoses].

[FOR WOMEN REPORTING MULTIPLE BREAST TUMORS DIAGNOSED AT TIME OF FIRST DIAGNOSIS: CA2C > 1 OR CA7 = BREAST]

You indicated that you had [FILL CA2c (+ 1 IF CA7 = BREAST)] breast tumors diagnosed in [month, year]. Please answer these questions separately for each tumor.

ENTER '1' TO CONTINUE..... 1

[BEGIN REPEATING RECORD IF (CA2C > 1) OR (CA7 = BREAST)]
[FOR EACH TUMOR REPORTED AT INITIAL DIAGNOSIS. IF ONLY ONE BREAST TUMOR REPORTED AT INITIAL DIAGNOSIS, ONLY GO THROUGH SERIES CA12 – CA18A ONCE]

CA12. [IF CA2C > 1 OR CA7 = BREAST:
For the first tumor… / second tumor …]
In which breast was the tumor found?

LEFT BREAST 1
RIGHT BREAST..... 2
REF 7
DK..... 8

CA13. Was this tumor
invasive or in situ cancer?

INVASIVE 1
IN SITU 2
REF 7
DK..... 8

CA14. Was the tumor in ducts (ductal) or
lobules (lobular) or both?

DUCTS 1
LOBULES 2
BOTH 3
OTHER..... 4
REF 7
DK..... 8

[ASK CA15 IF CA13 IS NOT IN SITU:]
CA15. At the time of diagnosis, what was the size of the tumor?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

|__|__|.|__| cm .....[CA15B]
REF .....[CA15C]..... 7
DK 8

[ASK CA15A ONLY IF CA15 = DK:]
CA15A. Even though you don't know the exact size, at the time of diagnosis, what was the **approximate** size of the tumor? Was it…?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

Less than or equal to 1.0 cm [CA16]1
1.1 to 2.0 cm. [CA16]..... 2
2.1 to 4.0 cm. [CA16]..... 3
4.1 cm or more 4
REF ..... [CA15C]..... 7
DK..... [CA15C]..... 8

[ASK CA15B IF CA15 OR CA15A > 4 CM, ELSE GO TO CA16:]

CA15B. I want to confirm, you said this tumor was more than 4 centimeters or more than an inch and a half. Is that correct?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

YES..... [CA16].....1
NO ..... [CA15].....2
REF ..... [CA16].....7
DK..... [CA16].....8

[ASK CA15C IF CA15 = DK OR REF AND CA15A = DK OR REF:]

CA15C. Could you tell us in your own words what you know about the size of this tumor?

RECORD VERBATIM:
_____

CA16. Was this tumor estrogen receptor positive, that is, "ER positive?"

YES (ER POSITIVE) 1
NO (ER NEGATIVE).....2
BORDERLINE / MARGINAL.....3
TEST NOT DONE.. 4
REF 7
DK..... 8

CA17. Was this tumor progesterone receptor positive, that is, "PR positive?"

YES (PR POSITIVE) 1
NO (PR NEGATIVE).....2
BORDERLINE / MARGINAL.....3
TEST NOT DONE.. 4
REF 7
DK..... 8

CA18. Was the HER2 (HER2NEU) test performed for this tumor?

YES..... 1
NO ..... [CA19].....2
REF ..... [CA19].....7
DK..... [CA19].....8

[ASK CA18A IF CA18 = YES:]

CA18A. Was the HER2 (HER2NEU) test positive?

YES.....1
NO 2
REF 7
DK.....8

[END REPEATING RECORD IF CA2C > 1 OR CA7 = BREAST]

CA19. Now we'd like to ask you a few questions about your treatment.

When you were undergoing diagnosis and treatment of your [IF CA9 = BREAST: first] breast cancer, did financial constraints keep you from receiving medical treatment your doctors recommended?

YES, SPECIFY: 1
_____
NO 2
REF 7
DK..... 8

IF YES, PROBE FOR DETAILS

CA20. Have you had surgery, not counting a biopsy, to remove the breast cancer?

YES.....1
NO ..... [CA24].....2
REF ..... [CA24].....7
DK..... [CA24].....8

[IF CA12 = RIGHT, ASK ABOUT RIGHT BREAST. IF CA12=LEFT, ASK ABOUT LEFT BREAST. IF CA12=BOTH, VERIFY BOTH BREASTS. IF DK OR REF ASK IF LEFT OR RIGHT.]

	[IF CA20 = YES AND CA12 = BOTH, ASK CA21 FOR EACH BREAST THEN SKIP TO CA23. IF CA20 = YES AND CA12 = LEFT OR RIGHT, ASK CA21 FOR THE AFFECTED BREAST, THEN GO TO CA22.]	**[ASK CA22 ONLY IF CA12 = LEFT OR RIGHT.]**	**[ASK CA23 FOR EACH BREAST WHERE CA21=1 OR 2]**
	CA21. For your [*left*/*right*] breast, did you have a mastectomy, or did you have a lumpectomy, or partial removal of breast tissue[? / IF CA9 = BREAST: the first time you were diagnosed with breast cancer?] [IF R HAD >1 SURGERY, PROBE: What was the last procedure you had/ IF CA9 = BREAST: the first time you were diagnosed with breast cancer?]	CA22. For your other breast, did you also have a mastectomy to **prevent** breast cancer, that is, a prophylactic mastectomy? IF YES, CONFIRM: This is the removal of a healthy breast to **prevent** cancer.	CA23. Did you have reconstructive breast surgery?
a. LEFT BREAST:	MASTECTOMY .....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .....2 REF .....7 DK 8	YES .....1 NO .....2 REF .....7 DK 8	YES.....1 NO .....2 REF .....7 DK.....8
b. RIGHT BREAST:	MASTECTOMY .....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .....2 REF .....7 DK 8	YES .....1 NO .....2 REF .....7 DK 8	YES.....1 NO .....2 REF .....7 DK.....8

CA24. Were you having regular menstrual periods at the time you were diagnosed with breast cancer in [month, year] and before you started treatment?

YES..... 1
NO 2
REF 7
DK..... 8

CA24a. Since the time of that diagnosis, have you had both your ovaries removed?

YES..... [CA25] 1
NO ..... [CA25] 2
NO-REMOVED BEFORE CANCER DX.. 3
REF ..... [CA25] 7
DK..... [CA25] 8

[ASK C24B ONLY IF CA24a = 3]
CA24b. What month and year did you have both ovaries removed?

|__|__| |__|__|__|__|
MONTH YEAR

CA25. Did you have chemotherapy for this breast cancer?

YES..... 1
NO ..... [CA31] 2
REF ..... [CA31] 7
DK..... [CA31] 8

[ASK CA25A IF CA25 = YES]
CA25A. Did you get your chemotherapy as part of a clinical trial?

YES..... 1
NO..... [CA26] 2
REF..... [CA26] 7
DK..... [CA26] 8

[ASK CA25B IF CA25A = YES]
CA25B. Do you know what drug or regimen you actually received?

YES..... 1
NO..... 2
REF..... 7
DK..... 8

[BEGIN REPEATING RECORD IF CA25 = YES]
CA26. [IF CA25A = YES AND CA25B ≠ YES]
What chemotherapy drugs were being tested in this trial?
[IF CA25A ≠ YES OR CA25B = YES]
What chemotherapy drugs were you given for this cancer?

(Self-Report: Drop Down List of medications)
REF..... 7
DK..... 8

CA26a. [IF CA25A = YES AND CA25B ≠ YES AND CA26 ≠ REF, DK]
Were there other chemotherapy drugs being tested in this trial?
[IF (CA25A ≠ YES OR CA25B = YES) OR (CA25B ≠ YES AND CA26 = REF, DK)]
Were you given other chemotherapy drugs for this cancer?

YES..... [CA26] 1
NO..... [CA27] 2
REF..... [CA27] 7
DK..... [CA27] 8

[END REPEATING RECORD]

CA27. What month and year did your chemotherapy begin for this cancer?

|__|__| |2|0|__|__|
MONTH YEAR

CA28. Have you completed your chemotherapy treatment for this cancer?

YES..... 1
NO ..... [CA30] 2
REF ..... [CA30] 7
DK..... [CA30] 8

[ASK C29 IF CA28 = YES:]
CA29. What month and year did your chemotherapy end?

			2	**0**	

MONTH YEAR

[ASK CA30 IF CA24 = YES:]
CA30. Did your menstrual periods stop when you were having chemotherapy treatments?

YES.....1
NO 2
REF 7
DK.....8

[ASK CA31 IF CA24 = YES:]
CA31. Since the time of your diagnosis, have you had shots or other medications that stopped your menstrual periods?

YES.....1
NO 2
REF 7
DK.....8

[ASK CA32 IF CA30 = YES OR CA31 = YES]
CA32. Did you go back to having regular menstrual periods?

YES.....1
NO 2
REF 7
DK.....8

CA33. Have you taken Tamoxifen, Evista, or Raloxifene as part of this breast cancer treatment?

YES..... 1
NO ..... [CA38].....2
UNSURE, WAS IN TRIAL[CA38] 3
REF ..... [CA38].....7
DK..... [CA38].....8

[ASK CA34 – CA35 IF CA33 = YES:]
CA34. What month and year did you begin taking Tamoxifen, Evista or Raloxifene?

			2	**0**	

MONTH YEAR

CA35. Are you currently taking Tamoxifen, Evista or Raloxifene?

YES..... [CA38].....1
NO 2
REF ..... [CA38].....7
DK..... [CA38].....8

[ASK CA36 IF CA35 = NO:]
CA36. What month and year did you stop taking Tamoxifen, Evista or Raloxifene?

			2	**0**	

MONTH YEAR

CA37. Omitted

CA38. Have you taken aromatase inhibitors like Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane) as part of this breast cancer treatment?

YES..... 1
NO ..... [CA43].....2
UNSURE, WAS IN TRIAL[CA43] 3
REF ..... [CA43].....7
DK..... [CA43].....8

[ASK CA39 - CA40 IF CA38 = YES:]

CA39. What month and year did you begin taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?

		2	**0**	
MONTH		YEAR		

CA40. Are you currently taking Arimidex (anastrozole) Femara (letrozole), or Aromasin (exemestane)?

YES..... [CA43].....1
NO 2
REF ..... [CA43].....7
DK..... [CA43].....8

[ASK CA41 IF CA40 = NO:]

CA41. What month and year did you stop taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?

		2	**0**	
MONTH		YEAR		

CA42. Omitted

CA43. Since your breast cancer diagnosis, have you taken Herceptin (Trastuzumab)?

YES.....1
NO ..... [CA48].....2
UNSURE, WAS IN TRIAL[CA48] 3
REF ..... [CA48].....7
DK..... [CA48].....8

[ASK CA44 – CA45 IF CA43 = YES:]

CA44. What month and year did you begin taking Herceptin (Trastuzumab)?

		2	**0**	
MONTH		YEAR		

CA45. Are you currently taking Herceptin (Trastuzumab)?

YES..... [CA48].....1
NO 2
REF ..... [CA48].....7
DK..... [CA48].....8

[ASK CA46 IF CA45 = NO:]

CA46. What month and year did you stop taking Herceptin (Trastuzumab)?

		2	**0**	
MONTH		YEAR		

CA47. Omitted

CA48. Have you had radiation therapy for this breast cancer?

YES..... 1
NO ..... [CA52B] 2
REF ..... [CA52B] 7
DK..... [CA52B] 8

[ASK CA49 – CA50 IF CA48 = YES:]

CA49. What month and year did your radiation therapy begin?

			2	0	

MONTH YEAR

CA50. Are you still going through radiation therapy for this breast cancer?

YES..... [CA52] 1
NO 2
REF ..... [CA52] 7
DK..... [CA52] 8

[ASK CA51 IF CA50 = NO:]

CA51. What month and year did your radiation therapy end?

			2	0	

MONTH YEAR

CA52. To which areas did you have radiation for this breast cancer?
CHECK ALL THAT APPLY

Breast: Whole Breast..... 1
Breast: "Limited field" just to where your tumor was..... 1
Chest wall 1
Underarm (Axillary nodes) 1
Other (internal breast nodes or other nodes not in your armpit) 1
Other, specify_____ ... 1
REF 7
DK..... 8

[ASK CA52A IF CA20 = YES]

CA52A. When was your radiation given? Was it…?
CHECK ALL THAT APPLY

Before surgery 1
During surgery 1
After surgery 1
REF 7
DK..... 8

[BEGIN REPEATING RECORD]

[FOR EACH TRIAL R WAS IN FOR INITIAL BC DIAGNOSIS]

CA52B. [IF CA33 ≠ 3 AND CA38 ≠ 3 AND CA43 ≠ 3 AND CA52A ≠1] Were you enrolled in a clinical trial or research study for this breast cancer treatment or management?
[IF CA33 = 3 OR CA38 = 3 OR CA43 = 3 OR CA25A = 1] You mentioned earlier that you were enrolled in a clinical trial or research study for this breast cancer treatment or management – is that correct?
[ALL - AFTER FIRST ITERATION] Were you enrolled in another clinical trial or research study for this breast cancer treatment or management?

YES..... 1
NO ..... [CA53] 2
REF ..... [CA53] 7
DK..... [CA53] 8

[ASK CA52C-CA52F IF CA52B = YES:]

CA52C. What was the name, sponsor, or identification number of the study, if known?

[RECORD VERBATIM:] _____

CA52D. What was being tested in this trial?
CHECK ALL THAT APPLY

Chemotherapy type, timing, or dose 1
Radiation type, timing, or dose 1
Hormonal treatment 1
Supportive care to prevent complications of treatment..... 1
Surgical treatments 1
OTHER, SPECIFY 1
_____
REF 7
DK..... 8

CA52E. Is your participation in that study ongoing?

YES..... [CA52B] 1
NO 2
REF ..... [CA52B] 7
DK..... [CA52B] 8

[ASK CA52F IF CA52E = NO:]

CA52F. Did you complete all the treatments for this study, leave the study before it ended, or did the trial end before you had finished all the treatments?

COMPLETED ALL TREATMENTS 1
LEFT BEFORE STUDY ENDED..... 2
TRIAL ENDED EARLY 3
REF 7
DK..... 8

[END REPEATING RECORD]

CA53. Are there any other treatments for this breast cancer you have had or plan to have that you can tell us about?

YES..... 1
[IF YES, RECORD VERBATIM:]
_____
NO 2

[IF CA9 = BREAST SKIP TO CS1, ELSE CONTINUE]

[TOTAL NUMBER OF TUMORS REPORTED: CA2C + (1 IF CA7 = BREAST)]

CA54. I have recorded that you have been diagnosed with a total of [FILL NUMBER] breast tumors to date. Is that correct?

YES	[MRIntro1]	1
NO		2
DK		7
REF	[MRIntro1]	8

[ASK CA55 IF CA54 = NO OR DK:]

CA55. Can you describe in your own words any breast cancer tumors that we did not ask you about?

RECORD VERBATIM: _____

DIAGNOSIS AND TREATMENT OF BREAST CANCER
SECOND SERIES OF QUESTIONS FOR WOMEN WITH MULTIPLE
BREAST CANCER DIAGNOSES AT DIFFERENT TIME POINTS

[IF CA9 = BREAST, CONTINUE, ELSE SKIP TO SECTION MR]

CS1. OMITTED

[CHECK ANSWER TO CS1A AGAINST DOB]

CS1A. You have indicated you were diagnosed with another breast cancer after your first diagnosis in [month, year]. What was the date a doctor first told you that you definitely had a second breast cancer?

|__|__| |__|__|__|__|
MONTH YEAR

IF YEAR PROVIDED, GO TO CS2A

[ASK CS2 ONLY IF CS1A YEAR = DK]
[CHECK ANSWER TO CS2 AGAINST DOB]

CS2. How old were you at the time of this diagnosis?

|__|__|
AGE

CS2A. Sometimes there is a delay between when a woman first notices a lump, or a mammogram shows an abnormality, and the final diagnosis of breast cancer. How much time went by between when you first realized there was a problem and when you were told the diagnosis was a second breast cancer?

< 1 MONTH – DIAGNOSED VERY CLOSE TO INITIAL IDENTIFICATION 00

|__|__| MONTHS

CS2B. It sometimes takes several doctor appointments to make sure of the breast cancer diagnosis and to run laboratory tests to identify its characteristics. When we refer to the 'time of diagnosis,' we mean this period of time during which your cancer was confirmed and characterized, not just the day you got the diagnosis.

When you were diagnosed with breast cancer for a second time, did you have any form of general health care coverage, including health insurance, pre-paid plans such as HMOs, or government plans such as Medicare or Medicaid?

YES..... 1
NO 2
REF 7
DK..... 8

CS2C. Sometimes it takes several tests and procedures after the diagnosis to find out how many tumors there are. After that medical work was completed for your second breast cancer, how many tumors had they found?
IF R SAYS DK, PROBE: How many tumors do you know about?

|__| BREAST TUMORS

[IF DK OR REF, COUNT AS 1 TUMOR FOR CS11-CS18 AND CS54]

CS3. At the time of your second breast cancer diagnosis, had the cancer spread to your lymph nodes?

YES..... 1
NO 2
REF 7
DK..... 8

CS4. How many lymph nodes were tested?

0 ....[CS6]
|__|__| LYMPH NODES..... [CS5]
REF ....[CS4a]
DK..... .....[CS4a]

[ASK CS4a ONLY IF CS4 IS REF OR DK:]
CS4a. **Approximately** how many lymph nodes were tested? Was it…?

0 nodes..... [CS11] 0
1-3 nodes 1
4-9 nodes 2
10-14 nodes 3
15-19 nodes 4
Or 20 or more nodes 5
REF 7
DK..... 8

[ASK CS5 ONLY CS4 IS NOT 0 OR IF CS4a IS NOT 0:]
CS5. How many lymph nodes were positive?

0 ....[CS11]
|__|__| LYMPH NODES.....[CS11]
REF ....[CS5a]
DK..... .....[CS5a]

[ASK CS5a ONLY IF CS5 IS REF OR DK]
CS5a. **Approximately** how many lymph nodes were positive? Was it…?

0 nodes..... 0
1-3 nodes 1
4-9 nodes 2
10-14 nodes 3
15-19 nodes 4
Or 20 or more nodes 5
REF 7
DK..... 8

CS6. OMITTED
CS7. OMITTED
CS7a. OMITTED
CS8. OMITTED
CS9. OMITTED
CS9a. OMITTED
CS10. OMITTED

CS11. The next questions are about the characteristics of your second breast cancer.

[FOR WOMEN REPORTING TWO BREAST TUMORS DIAGNOSED AT SAME TIME: (CS2C > 1)]
You indicated that you had [FILL CS2C] breast tumors diagnosed in [month, year]. Please answer these questions separately for each tumor.

ENTER '1' TO CONTINUE..... 1

[BEGIN REPEATING RECORD IF CS2C > 1]
[FOR EACH TUMOR REPORTED AT TIME OF SECOND DIAGNOSIS. IF ONLY ONE BREAST TUMOR REPORTED AT TIME OF SECOND DIAGNOSIS, ONLY GO THROUGH SERIES CS12 – CS18A ONCE.]

CS12. [IF CS2C > 1: For the first tumor… / second tumor …] In which breast was the tumor found?

LEFT BREAST 1
RIGHT BREAST..... 2
REF 7
DK..... 8

CS13. Was this tumor invasive or in situ cancer?

INVASIVE 1
IN SITU 2
REF 7
DK..... 8

CS14. Was the tumor in ducts (ductal) or lobules (lobular) or both?

DUCTS 1
LOBULES 2
BOTH 3
OTHER..... 4
REF 7
DK..... 8

[ASK CS15 IF CS13 IS NOT IN SITU:]
CS15. At the time of the second diagnosis, what was the size of the tumor?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

|__|__|.|__| cm ..... [CS15B]
REF .....[CS15C] 7
DK..... 8

[ASK CS15A ONLY IF CS15 = DK:]
CS15A. Even though you don't know the exact size, at the time of the second diagnosis, what was the **approximate** size of the tumor? Was it…?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

Less than or equal to 1.0 cm [CS16]1
1.1 to 2.0 cm. [CS16] 2
2.1 to 4.0 cm. [CS16] 3
4.1 cm or more 4
REF .....[CS15C] 7
DK.....[CS15C] 8

[ASK CS15B IF CS15 OR CS15A > 4 CM, ELSE GO TO CS16:]

CS15B. I want to confirm, you said this tumor was more than 4 centimeters or more than an inch and a half. Is that correct?

PROBE: AN INCH IS ABOUT 2.5 CENTIMETERS.
PROBE: IF A TUMOR IS VERY SMALL IT MAY BE MEASURED IN MILIMETERS.

YES..... [CS16] 1
NO ..... [CS15] 2
REF ..... [CS16] 7
DK..... [CS16] 8

[ASK CS15C IF CS15 = DK OR REF AND CS15A = DK OR REF:]

CS15C. Could you tell us in your own words what you know about the size of this tumor?

RECORD VERBATIM:
_____

CS16. Again, referring to the breast cancer diagnosed in [month, year], was this tumor estrogen receptor positive, that is, "ER positive?"

YES (ER POSITIVE) 1
NO (ER NEGATIVE).....2
BORDERLINE / MARGINAL.....3
TEST NOT DONE.. 4
REF 7
DK..... 8

CS17. Was this tumor progesterone receptor positive, that is, "PR positive?"

YES (PR POSITIVE) 1
NO (PR NEGATIVE).....2
BORDERLINE / MARGINAL.....3
TEST NOT DONE.. 4
REF 7
DK..... 8

CS18. Was the HER2 (HER2NEU) test performed for this tumor?

YES..... 1
NO ..... [CS19] 2
REF ..... [CS19] 7
DK..... [CS19] 8

[ASK CS18A IF CS18 = YES:]

CS18A. Was the HER2 (HER2NEU) test positive?

YES.....1
NO 2
REF 7
DK.....8

[END REPEATING RECORD IF CS2C > 1]

CS19. Now we'd like to ask you a few questions about your treatment the second time you were diagnosed with breast cancer.

When you were undergoing diagnosis and treatment of your second breast cancer, did financial constraints keep you from receiving medical treatment your doctors recommended?

IF YES, PROBE FOR DETAILS

YES, SPECIFY: 1
_____
NO 2
REF 7
DK..... 8

CS20. Have you had surgery not counting a biopsy to remove the second breast cancer?

YES.....1
NO .....[CS25].....2
REF .....[CS25].....7
DK.....[CS25].....8

[IF CS12 = RIGHT, ASK ABOUT RIGHT BREAST. IF CS12=LEFT, ASK ABOUT LEFT BREAST. IF CS12=BOTH, VERIFY BOTH BREASTS. IF DK OR REF ASK IF LEFT OR RIGHT.]

[IF MASTECTOMY REPORTED IN FIRST DIAGNOSIS (CA21a THROUGH CA22b), SKIP CS21a – CS22b AS NEEDED]

[IF CS20 = YES AND CS12 = BOTH, ASK CS21 FOR EACH BREAST THEN SKIP TO CS23. IF CS20 = YES AND CS12 = LEFT OR RIGHT, ASK CS21 FOR THE AFFECTED BREAST, THEN GO TO CS22.]		**[ASK CS22 ONLY IF CS12 = LEFT OR RIGHT.]**	**[ASK CS23 FOR EACH BREAST WHERE CS21=1 OR 2]**
CS21. For your [*left/right*] breast, did you have a mastectomy, or did you have a lumpectomy, or partial removal of breast tissue the second time you were diagnosed with breast cancer? [IF R HAD >1 SURGERY, PROBE: What was the last procedure you had the second time you were diagnosed with breast cancer?]		CS22. For your other breast, did you also have a mastectomy to **prevent** breast cancer, that is, a prophylactic mastectomy? IF YES, CONFIRM: This is the removal of a healthy breast to **prevent** cancer.	CS23. Did you have reconstructive breast surgery?
a. LEFT BREAST:	MASTECTOMY .....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .....2 REF .....7 DK 8	YES .....1 NO .....2 REF .....7 DK 8	YES.....1 NO .....2 REF .....7 DK.....8
b. RIGHT BREAST:	MASTECTOMY .....1 LUMPECTOMY OR PARTIAL REMOVAL OF BREAST .....2 REF .....7 DK 8	YES .....1 NO .....2 REF .....7 DK 8	YES.....1 NO .....2 REF .....7 DK.....8

CS24. Omitted
CS24a. Omitted
CS24b. Omitted

CS25. Did you have chemotherapy for your second breast cancer?

YES 1
NO ..... [CS31] 2
REF ..... [CS31] 7
DK ..... [CS31] 8

[ASK CS25A IF CS25 = YES]
CS25A. Did you get your chemotherapy as part of a clinical trial?

YES 1
NO ..... [CS26] 2
REF ..... [CS26] 7
DK ..... [CS26] 8

[ASK CS25B IF CS25A = YES]
CS25B. Do you know what drug or regimen you actually received?

YES 1
NO 2
REF 7
DK 8

[BEGIN REPEATING RECORD IF CS25 = YES]

CS26. [IF CS25A = YES AND CS25B ≠ YES]
What chemotherapy drugs were being tested in this trial?
[IF CS25A ≠ YES OR CS25B = YES]
What chemotherapy drugs were you given for your second breast cancer?

(Self-Report: Drop Down List of medications)
REF 7
DK 8

CS26a. [IF CS25A = YES AND CS25B ≠ YES AND CS26 ≠ REF, DK]
Were there other chemotherapy drugs being tested in this trial?
[IF (CS25A ≠ YES OR CS25B = YES) OR (CS25B ≠ YES AND CS26 = REF, DK)]
Were you given other chemotherapy drugs for your second breast cancer?

YES ..... [CS26] 1
NO ..... [CS27] 2
REF ..... [CS27] 7
DK ..... [CS27] 8

[END REPEATING RECORD]

CS27. What month and year did your chemotherapy begin for your second breast cancer?

			2	**0**	
MONTH			YEAR		

CS28. Have you completed this chemotherapy treatment?

YES 1
NO ..... [CS33] 2
REF ..... [CS33] 7
DK ..... [CS33] 8

[ASK CS29 IF CS28 = YES:]
CS29. What month and year did your chemotherapy end?

			2	**0**	
MONTH			YEAR		

CS30. Omitted
CS31. Omitted
CS32. Omitted

CS33. Have you taken Tamoxifen, Evista, or Raloxifene as part of your treatment for the second breast cancer?

YES 1
NO ..... [CS38] 2
UNSURE–WAS IN TRIAL [CS38] 3
REF ..... [CS38] 7
DK ..... [CS38] 8

[ASK CS34 – CS35 IF CS33 = YES:]
CS34. What month and year did you begin taking Tamoxifen, Evista or Raloxifene?

		2	**0**	

MONTH YEAR

CS35. Are you currently taking Tamoxifen, Evista or Raloxifene?

YES ..... [CS38] 1
NO 2
REF ..... [CS38] 7
DK ..... [CS38] 8

[ASK CS36 IF CS35 = NO:]
CS36. What month and year did you stop taking Tamoxifen, Evista or Raloxifene?

		2	**0**	

MONTH YEAR

CS37. Omitted

CS38. Have you taken aromatase inhibitors like Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane) as part of your treatment for the second breast cancer?

YES 1
NO ..... [CS43] 2
UNSURE–WAS IN TRIAL [CS43] 3
REF ..... [CS43] 7
DK ..... [CS43] 8

[ASK CS39 - CS40 IF CS38 = YES:]
CS39. What month and year did you begin taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?

		2	**0**	

MONTH YEAR

CS40. Are you currently taking Arimidex (anastrozole) Femara (letrozole), or Aromasin (exemestane)?

YES ..... [CS43] 1
NO 2
REF ..... [CS43] 7
DK ..... [CS43] 8

[ASK CS41 IF CS40 = NO:]
CS41. What month and year did you stop taking Arimidex (anastrozole), Femara (letrozole), or Aromasin (exemestane)?

		2	0	
MONTH		YEAR		

CS42. Omitted

CS43. Since your second breast cancer diagnosis, have you taken Herceptin (Trastuzumab)?

YES.....1
NO .....[CS48].....2
UNSURE, WAS IN TRIAL [CS48].....3
REF .....[CS48].....7
DK.....[CS48].....8

[ASK CS44 – CS45 IF CS43 = YES:]
CS44. What month and year did you begin taking Herceptin (Trastuzumab)?

		2	0	
MONTH		YEAR		

CS45. Are you currently taking Herceptin (Trastuzumab)?

YES..... [CS48] 1
NO 2
REF ..... [CS48] 7
DK..... [CS48] 8

[ASK CS46 IF CS45 = NO:]
CS46. What month and year did you stop taking Herceptin (Trastuzumab)?

		2	0	
MONTH		YEAR		

CS47. Omitted

CS48. Have you had radiation therapy for your second breast cancer?

YES.....1
NO .....[CS52B] 2
REF .....[CS52B] 7
DK.....[CS52B] 8

[ASK CS49 – CS50 IF CS48 = YES:]
CS49. What month and year did radiation therapy begin for your second breast cancer?

		2	0	
MONTH		YEAR		

CS50. Are you still going through radiation therapy for this breast cancer?

YES..... [CS52] 1
NO 2
REF ..... [CS52] 7
DK..... [CS52] 8

[ASK CS51 IF CS50 = NO:]
CS51. What month and year did your radiation therapy end?

		2	0	
MONTH		YEAR		

CS52. To which areas did you have radiation for your second breast cancer?

CHECK ALL THAT APPLY

Breast: Whole Breast..... 1
Breast: "Limited field" just to where your tumor was..... 1
Chest wall 1
Underarm (Axillary nodes) 1
Other 1
(internal breast nodes or other nodes not in your armpit)
Other, specify_____
REF 7
DK..... 8

[ASK CS52A IF CS20 = YES]
CS52A. When was your radiation given? Was it…
CHECK ALL THAT APPLY

Before surgery 1
During surgery 1
After surgery 1
REF 7
DK..... 8

[BEGIN REPEATING RECORD]
[FOR EACH TRIAL R WAS IN AT TIME OF SECOND BC DIAGNOSIS]
CS52B. [IF CS33 ≠ 3 AND CS38 ≠ 3 AND CS43 ≠ 3 AND CS52A ≠1] Were you enrolled in a clinical trial or research study for the treatment or management of your second breast cancer?
[IF CS33 = 3 OR CS38 = 3 OR CS43 = 3 OR CS25A = 1] You mentioned earlier that you were enrolled in a clinical trial or research study for the treatment or management of your second breast cancer – is that correct?
[ALL - AFTER FIRST ITERATION] Were you enrolled in another clinical trial or research study for treatment or management of your second breast cancer?

YES..... 1
NO ..... [CS53] 2
REF ..... [CS53] 7
DK..... [CS53] 8

[ASK CS52C-CS52F IF CS52B = YES:]
CS52C. What was the name, sponsor, or identification number of the study, if known?

[RECORD VERBATIM:] _____

CS52D. What was being tested in this trial?
CHECK ALL THAT APPLY

Chemotherapy type, timing, or dose 1
Radiation type, timing, or dose 1
Hormonal treatment 1
Supportive care to prevent complications of treatment..... 1
Surgical treatments 1
OTHER, SPECIFY 1
_____
REF 7
DK..... 8

CS52E. Is your participation in that study ongoing?

YES.....[CS52B] 1
NO 2
REF .....[CS52B] 7
DK.....[CS52B] 8

[ASK CS52F IF CS52E = NO:]
CS52F. Did you complete all the treatments for this study, leave the study before it ended, or did the trial end before you had finished all the treatments?

C OMPLETED ALL TREATMENTS 1
LEFT BEFORE STUDY ENDED..... 2
TRIAL ENDED EARLY 3
REF 7
DK..... 8

[END REPEATING RECORD]

CS53. Are there any other treatments for your second breast cancer you have had or plan to have that you can tell us about?

YES..... 1
[IF YES, RECORD VERBATIM:]
_____
NO 2

[TOTAL NUMBER OF TUMORS REPORTED: CA2C + (1 IF CA7 = BREAST) + (CS2C IF CA9 = BREAST)]

CS54. I have recorded that you have been diagnosed with a total of [FILL NUMBER] breast tumors to date. Is that correct?

YES.....[MRIntro1] 1
NO 2
DK..... 7
REF .....[MRIntro1] 8

[ASK CS55 IF CS54 = NO OR DK:]
CS55. Can you describe in your own words any breast cancer tumors that we did not ask you about?

RECORD VERBATIM: _____

MR. MEDICAL RELEASE, TUMOR TISSUE AND PHYSICIAN IDENTIFICATION

MRIntro1. The Sister Study would like to get additional details about your breast cancer diagnosis and treatment from your medical record, including a copy of your pathology report and a sample of your breast biopsy tissue that the pathologist may have saved. We can only get this information and tissue if you sign authorization forms. We would like to send you these forms along with answers to questions some women have about them. CONTINUE 1

MRIntro2. If you sign the medical record release forms, we will contact the doctors and facilities involved in your diagnosis and treatment and ask them to complete a short form and send us copies of the sections of your records that pertain to your breast cancer. We will not share with your doctor any of the information you have given to the Sister Study other than the fact that you have told us you were diagnosed with breast cancer and that you have been participating in the Sister Study. The information we get from your doctors and medical records will be used for research only and will be kept confidential. CONTINUE.....1

MRIntro3. We need the names of the relevant doctors or health care facilities to prepare the medical release forms. If it is okay with you, I would like to get that information from you now. You will have the opportunity to read the forms and decide for yourself if you would like to sign them. We will not contact your doctors or health care facilities unless you give us permission to do so by signing the forms.

[ANSWER QUESTIONS, REFERRING TO FAQS ABOUT MEDICAL RECORDS AND HIPAA]
CONTINUE.....1

MR0. May we ask you some questions about the doctors and medical facilities involved in the diagnosis and treatment of your breast cancer?
YES..... 1
NO..... [MR0d] 2

[ASK MR0a IF MR0 = YES]
MR0a. Do you need a few minutes to find your worksheet or to gather information about the doctors and medical facilities involved in the diagnosis and treatment of your breast cancer?
YES..... 1
NO..... [MR1] 2

[ASK MR0b IF MR0a = YES]
MR0b. Would you like me to wait while you collect this information or call you back when you are ready? WAIT – ENTER '1' WHEN READY [MR1] 1
CALL BACK 2

[ASK MR0c IF MR0b = CALL BACK]
MR0c. What is a convenient time to call you back? [CLICK ON "APPOINTMENT" TAB]

MONTH	DAY	YEAR

TIME _____ AM PM

[ASK MR0d IF MR0 = NO]
MR0d. I would like to send you some information about medical authorization forms and then contact you again in a few weeks. May I do that?
YES..... [CN2] 1
NO..... [CN3] 2

IDENTIFICATION OF DOCTORS/HEALTH CARE FACILITIES

MR1. Is there one doctor or health care facility that was responsible for most of your breast cancer diagnosis and treatment?

YES 1
NO ..... [MR2] 2

MR1A. What is the first and last name of your doctor?

[RECORD DOCTOR'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR1aF. _____
NA ..... [MR1aH] ..... NA
DK ..... [MR1aL] 7
REF ..... [MR1aL] 8
MR1aL. _____
DK ..... [MR1aH] 7
REF ..... [MR1aH] 8

MR1aH. What is the name of the health care facility of your doctor?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA ..... NA
DK 7
REF 8

MR1A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]
MR1B. What is [Dr. NAME/this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]
MR1C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR1D. What is the street address of [Dr. NAME/ FACILITY]?

MR1dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR1dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR1dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR1dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR1dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR1E IF STREET ADDRESS = DK:]
MR1E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR1F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR1FArea. |__|__|__|
REF..... 7
DK..... 8
MR1FPref. |__|__|__|
REF..... 7
DK..... 8
MR1FLine. |__|__|__|__|
REF..... 7
DK..... 8

[IF MR1B NOT = ONCOLOGIST, ASK:]

MR2. Was there an oncologist or oncology center involved in your breast cancer diagnosis or treatment?

YES 1
NO ..... [MR3] 2

MR2A. What is the first and last name of your oncologist?

[RECORD ONCOLOGIST'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR2aF. _____
NA ..... [MR2aH] ..... NA
DK ..... [MR2aL] 7
REF ..... [MR2aL] 8
MR2aL. _____
DK ..... [MR2aH] 7
REF ..... [MR2aH] 8

MR2aH. What is the name of the health care facility of your oncologist?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA .... NA
DK 7
REF 8

MR2A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR2B. Just to confirm, this was an oncologist?

IF NECESSARY, PROBE: What is [Dr. NAME / this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR2C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR2D. What is the street address of [Dr. NAME/ FACILITY]?

MR2dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR2dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR2dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR2dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR2dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR2E IF STREET ADDRESS = DK:]
MR2E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR2F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR2FArea. |__|__|__|
REF..... 7
DK..... 8
MR2FPref. |__|__|__|
REF..... 7
DK..... 8
MR2FLine. |__|__|__|__|
REF..... 7
DK..... 8

[IF MR1B AND MR2B NOT = SURGEON, ASK:]

MR3. Was there a surgeon or surgery center involved in your breast cancer diagnosis or treatment?

YES 1
NO ..... [MR4] 2

MR3A. What is the first and last name of your surgeon?

[RECORD SURGEON'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR3aF. _____
NA ..... [MR3aH] ..... NA
DK ..... [MR3aL] 7
REF ..... [MR3aL] 8
MR3aL. _____
DK ..... [MR3aH] 7
REF ..... [MR3aH] 8

MR3aH. What is the name of the health care facility of your surgeon?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA .... NA
DK 7
REF 8

MR3A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR3B. Just to confirm, this was a surgeon?

IF NECESSARY, PROBE: What is [Dr. NAME / this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR3C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR3D. What is the street address of [Dr. NAME/ FACILITY]?

MR3dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR3dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR3dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR3dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR3dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR3E IF STREET ADDRESS = DK:]
MR3E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR3F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR3FArea. |__|__|__|
REF..... 7
DK..... 8
MR3FPref. |__|__|__|
REF..... 7
DK..... 8
MR3FLine. |__|__|__|__|
REF..... 7
DK..... 8

[IF MR1B AND MR2B AND MR3B NOT = PATHOLOGIST, ASK:]

MR4. Do you know the name of the pathologist?

YES ..... [MR4A] 1
NO 2

MR4a1. Do you know where the pathology was done?

YES ..... [MR4aH] 1
NO ..... [MR5] 2

MR4A. What is the first and last name of your pathologist?

[RECORD PATHOLOGIST'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR4aF. _____
NA ..... [MR4aH] ..... NA
DK ..... [MR4aL] 7
REF ..... [MR4aL] 8
MR4aL. _____
DK ..... [MR4aH] 7
REF ..... [MR4aH] 8

MR4aH. What is the name of the health care facility of your pathologist?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA ..... NA
DK 7
REF 8

MR4A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[IF DOCTOR'S FIRST NAME IS NOT BLANK OR 'NA', ASK:]

MR4B. Just to confirm, this was a pathologist?

IF NECESSARY, PROBE: What is [Dr. NAME / this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT BLANK OR 'NA', ASK:]

MR4C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR4D. What is the street address of [Dr. NAME/ FACILITY]?

MR4dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR4dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR4dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR4dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR4dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR4E IF STREET ADDRESS = DK:]
MR4E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR4F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR4FArea. |__|__|__|
REF..... 7
DK..... 8
MR4FPref. |__|__|__|
REF..... 7
DK..... 8
MR4FLine. |__|__|__|__|
REF..... 7
DK..... 8

[IF MR1B, MR2B, MR3B AND MR4B NOT = RADIOLOGIST, ASK:]

MR5. Was there a radiologist or radiology center involved in your breast cancer diagnosis or treatment?

YES 1
NO ..... [MR6] 2

MR5A. What is the first and last name of your radiologist?

[RECORD RADIOLOGIST'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR5aF. _____
NA ..... [MR5aH] ..... NA
DK ..... [MR5aL] 7
REF ..... [MR5aL] 8
MR5aL. _____
DK ..... [MR5aH] 7
REF ..... [MR5aH] 8

MR5aH. What is the name of the health care facility of your radiologist?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA .... NA
DK 7
REF 8

MR5A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR5B. Just to confirm, this was a radiologist?

IF NECESSARY, PROBE: What is [Dr. NAME / this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR5C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR5D. What is the street address of [Dr. NAME/ FACILITY]?

MR5dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR5dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR5dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR5dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR5dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR5E IF STREET ADDRESS = DK:]
MR5E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR5F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR5FArea. |__|__|__|
REF..... 7
DK..... 8
MR5FPref. |__|__|__|
REF..... 7
DK..... 8
MR5FLine. |__|__|__|__|
REF..... 7
DK..... 8

[BEGIN REPEATING RECORD]

MR6. Were there any other doctors or health care facilities involved in your breast cancer diagnosis or treatment?
YES 1
NO ..... [MR7] 2

MR6A. What is the first and last name of your doctor?

[RECORD OTHER DOCTOR'S FIRST NAME AND LAST NAME. IF NO SPECIFIC DOCTOR, ENTER "NA."]

MR6aF. _____
NA ..... [MR6aH] ..... NA
DK ..... [MR6aL] 7
REF ..... [MR6aL] 8
MR6aL. _____
DK ..... [MR6aH] 7
REF ..... [MR6aH] 8

MR6aH. What is the name of the health care facility of your doctor?

[IF NO FACILITY NAME ENTER 'NA']

_____
NA ..... NA
DK 7
REF 8

MR6A1. Was this where you had a…

biopsy? 1
tumor removal? 1
pathology sample tested? 1
REF 7
DK 8

[ASK MR6A2 IF MR6A1 IS ALL NO, ELSE GO TO MR6B]

MR6A2. What medical or diagnostic services did you receive [from Dr. NAME / at FACILITY] for your breast cancer?

RECORD VERBATIM: _____
_____
_____

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR6B. What is [Dr. NAME/this doctor]'s specialty?

PRIMARY CARE 01
INTERNAL MEDICINE 02
SURGEON 03
ONCOLOGIST 04
PATHOLOGIST 05
RADIOLOGIST 06
OTHER 07
SPECIFY: _____
REF 97
DK 98

[IF DOCTOR'S FIRST NAME IS NOT 'NA', ASK:]

MR6C. Is [Dr. NAME/this doctor] in a group practice, that is, do other doctors practice at the same office, or is [Dr. NAME/this doctor] part of a medical facility or HMO?

YES, GROUP 1
NO, SOLO 2
REF 7
DK 8

MR6D. What is the street address of [Dr. NAME/ FACILITY]?

MR6dStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR6dStr2. _____
REF..... 7
DK..... 8

What is the city of [Dr. NAME/ FACILITY]? [IF CITY UNKNOWN, ASK:] What is the largest city or town near [Dr. NAME/ FACILITY]?

MR6dCity. _____
REF..... 7
DK..... 8

What is the name of the state of [Dr. NAME/ FACILITY]?

MR6dState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [Dr. NAME/FACILITY]?

MR6dZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR6E IF STREET ADDRESS = DK:]
MR6E. What is the nearest cross street or main intersection to [Dr. NAME/ FACILITY]?

_____
REF..... 7
DK..... 8

MR6F. What is the telephone number for [Dr. NAME/ FACILITY]?

MR6FArea. |__|__|__|
REF..... 7
DK..... 8
MR6FPref. |__|__|__|
REF..... 7
DK..... 8
MR6FLine. |__|__|__|__|
REF..... 7
DK..... 8

[END REPEATING RECORD]

[IF MR1A1, MR2A1, MR3A1, MR4A1, MR5A1, MR6A1 NOT = LOCATION OF BIOPSY, ASK:]

MR7. Where was the biopsy done?
[ENTER NAME OF HEALTH CARE FACILITY]

_____
REF.....[MR8] _____7
DK.....[MR8] _____8

MR7A. What is the street address of [FACILITY]?

MR7aStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR7aStr2. _____
REF..... 7
DK..... 8

What is the city of [FACILITY]?
[IF CITY UNKNOWN, ASK:] What is the largest city or town near [FACILITY]?

MR7aCity. _____
REF..... 7
DK..... 8

What is the name of the state of [FACILITY]?

MR7aState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [FACILITY]?

MR7aZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR7B IF STREET ADDRESS = DK:]

MR7B. What is the nearest cross street or main intersection to [FACILITY]?

_____
REF..... 7
DK..... 8

MR7C. What is the telephone number for [FACILITY]?

MR7cArea. |__|__|__|
REF..... 7
DK..... 8
MR7cPref. |__|__|__|
REF..... 7
DK..... 8
MR7cLine. |__|__|__|__|
REF..... 7
DK..... 8

[IF MR1A1, MR2A1, MR3A1, MR4A1, MR5A1, MR6A1 NOT = LOCATION OF TUMOR REMOVAL, ASK:]

MR8. In what medical facility was the tumor removed?
[ENTER NAME OF HEALTH CARE FACILITY]

_____
REF..... [MR9]..... 7
DK..... [MR9]..... 8

MR8A. What is the street address of [FACILITY]?

MR8aStr1. _____
REF..... 7
DK..... 8

[IF NO ADDITIONAL ADDRESS INFO PRESS [ENTER] TO CONTINUE]

MR8aStr2. _____
REF..... 7
DK..... 8

What is the city of [FACILITY]?
[IF CITY UNKNOWN, ASK:] What is the largest city or town near [FACILITY]?

MR8aCity. _____
REF..... 7
DK..... 8

What is the name of the state of [FACILITY]?

MR8aState. [USE STATE LOOKUP]
REF..... 7
DK..... 8

What is the zip code of [FACILITY]?

MR8aZip. |__|__|__|__|__|
REF..... 7
DK..... 8

[ASK MR8B IF STREET ADDRESS = DK:]

MR8B. What is the nearest cross street or main intersection to [FACILITY]?

_____
REF..... 7
DK..... 8

MR8C. What is the telephone number for [FACILITY]?

MR8cArea. |__|__|__|
REF..... 7
DK..... 8
MR8cPref. |__|__|__|
REF..... 7
DK..... 8
MR8cLine. |__|__|__|__|
REF..... 7
DK..... 8

MR9. We also would like to get a sample of your breast tissue that the pathologist may have saved. The pathologist will also require a signed authorization form to ensure that we have your permission to obtain some of your tissue samples. These samples will provide further information about specific breast cancer features and will be used for research purposes only. We will store your samples carefully and will return what we have to you or your doctor if you request it.

We will send you the form asking your permission to obtain some of your archived tumor tissue with additional information explaining how it will be used and stored. You will have the opportunity to read the authorization form and decide for yourself if you would like to sign it. We will not contact your pathologist to ask for samples unless you give us permission to do so by signing the authorization form.

[ANSWER QUESTIONS, REFERRING TO FAQS ABOUT TISSUE SAMPLES AND HIPAA]

CONTINUE ..... [CN1] 1

CN: CONCLUSION

[IF PATIENT PROVIDED DOCTOR INFORMATION, ASK:]

CN1. We will mail you a packet in about a week containing the Medical Record and Tissue Authorization forms and instructions for completing them. We ask that you follow the instructions carefully and return the signed forms to us in the enclosed postage-paid envelope as soon as you can.

CONTINUE .... [CN1a] 1

[ASK CN1a IF IN5 = 1, ELSE GO TO CN1c:]

CN1a. You mentioned earlier that you have a copy of your pathology records. Would you be willing to send us a copy of the report so we can confirm the details of your breast cancer diagnosis?

YES 1
NO ..... [CN1c] 2

[ASK CN1b IF CN1a = 1, ELSE GO TO CN1c:]

CN1b. Thank you. Please make a copy of your pathology results and enclose it in the postage-paid return envelope we will provide.

CONTINUE ..... [CN1c] 1

CN1c. If you have any questions, please call the Sister Study toll-free number (1-877-4SISTER) and follow directions for enrolled women.

CONTINUE ..... [END] 1

[IF PATIENT REFUSED TO PROVIDE INFORMATION ON DOCTORS OR MEDICAL FACILITIES BUT AGREED TO LET US CALL BACK, ASK:]

CN2. We will mail you information about medical record authorization forms and then contact you again in a few weeks. If you have any questions, please call the Sister Study toll-free number (1-877-4SISTER) and follow directions for enrolled women.

CONTINUE 1

[GO TO IN7 FOR RE-CONTACT AFTER APPROXIMATELY 14 DAYS IF PATIENT DOES NOT RETURN COMPLETED FORMS]

[IF PATIENT REFUSED TO PROVIDE INFORMATION ON DOCTORS OR MEDICAL FACILITIES BUT DID NOT AGREE TO LET US CALL BACK, ASK]

CN3. We will mail you information about medical record authorization forms for you to review. If you change your mind about giving us information on the doctors or medical facilities involved in your breast cancer diagnosis and treatment, please call the Sister Study toll-free number (1-877-4SISTER) and follow directions for enrolled women.

CONTINUE ..... [END] 1

Sister Study - Breast Cancer Follow-up, Authorization Packet Cover Letter

DATE

FirstName LastName
Address 1
Address 2
City, State, Zip

Dear Ms. [LastName]:

Thank you for talking with a Sister Study staff member about your breast cancer diagnosis and treatment. During the telephone call, [IF R HAS A COPY OF HER PATHOLOGY REPORT AND SAID SHE WAS WILLING TO PROVIDE A COPY: you mentioned you were willing to send us a copy of the pathology report related to your breast cancer diagnosis. Please make a copy of your report and **send it to us in the enclosed postage-paid envelope** (The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703). We also /ELSE: we] discussed the importance of collecting additional information and samples. In the enclosed folder you will find several important documents for you to sign that will give us permission to obtain information from your medical providers about your breast cancer diagnosis and treatment. Please return these documents to the Sister Study office.
With your permission, we will:

- request information about your breast cancer diagnosis and treatment. You have already shared some of this information, but your doctor and medical record are the best sources of detailed medical information about specific features of your breast cancer and treatment.

- request some of the breast tissue samples that were saved after your biopsy or surgery. With these samples, we can test for molecular markers that may help us understand the causes and characteristics of this disease. We will protect some of your samples for 10 years, and return what we have to your doctors if they are needed later for your care.

It is up to you to decide if you will give us permission to request information and samples from your medical providers. You can refuse all or part of that request and it will not affect your participation in the rest of the Sister Study. However, the information about your diagnosis and treatment is especially important. Any medical provider has the right to refuse to participate, just as you do. However, in our experience, most doctors and hospitals are very willing to provide information if they know the patient has given her permission.

We have also enclosed some answers to questions you may have about our request. If you have any other questions or want to speak with someone, please call the Sister Study Helpdesk at 1-877-474-7837. As we promised when you joined the Sister Study, we will take precautions to keep all of your personal information safe, private and confidential.

Thank you again for your participation in this research. I wish you a complete recovery and future good health.

Sincerely,

Dale P. Sandler

Dale P. Sandler, Ph.D.
Principal Investigator

<SISID>

THE SISTER STUDY
BREAST CANCER RESEARCH

1-877-4SISTER

WWW.SISTERSTUDY.ORG

Authorization Packet

THIS POCKET CONTAINS MATERIALS FOR YOU TO
COMPLETE AND RETURN
TO THE SISTER STUDY

AUTHORIZATION PACKET

THIS POCKET CONTAINS MATERIALS
FOR YOU TO KEEP

AUTHORIZATION PACKET

START HERE - HOW TO COMPLETE YOUR SISTER STUDY AUTHORIZATION FORMS

This folder contains authorization forms and other materials related to your breast cancer diagnosis. Please **read** these instructions carefully before proceeding.

The **left side** of the folder contains materials for you to complete and return to the Sister Study:

- AUTHORIZATION FOR RELEASE OF MEDICAL RECORD INFORMATION – **Read** carefully, **sign** and **date.**
- AUTHORIZATION FOR RELEASE OF PATHOLOGY SPECIMENS – **Read** carefully, **sign** and **date.**
- PROVIDER AND MEDICAL CARE FACILITY LIST – **Review** the information listed. **Fill in** any missing or incorrect information. **Check Yes or No for each provider** to authorize the doctor or treatment facilities to provide medical information to the Sister Study.
- If you have a copy of your pathology report and are willing to share it with us, please make a copy and enclose it as well. This will help us confirm the details of your breast cancer diagnosis.
- SELF-ADDRESSED, POSTAGE-PAID ENVELOPE – **After** you have completed the items above, **place them in the envelope**, **seal and return** to the Sister Study.

The **right side** of the folder contains materials for you to keep:

- AUTHORIZATION FOR RELEASE OF MEDICAL RECORD INFORMATION – **Keep this copy for your records.**
- AUTHORIZATION FOR RELEASE OF PATHOLOGY SPECIMENS – **Keep this copy for your records.**
- PROVIDER AND MEDICAL CARE FACILITY LIST – **Keep this copy for your records.**
- FREQUENTLY ASKED QUESTIONS – Refer to this booklet if you have questions. **Keep this for your records.**

After we receive your signed forms, we will contact the medical providers you indicate on the PROVIDER AND MEDICAL CARE FACILITY LIST.

Providers will be asked for detailed medical information about specific features of your breast cancer and treatment or for some of the breast tissue samples that were saved after your biopsy or surgery. Each provider will be sent a copy of the AUTHORIZATION FOR RELEASE OF MEDICAL RECORD or the AUTHORIZATION FOR RELEASE OF PATHOLOGY SPECIMENS that you sign.

If you have any questions, please call the Sister Study toll-free at 1-877-4SISTER (1-877-474-7837). Thank you!

Form #: 06
Version #: 01 (V. Date 12/02/08)
OMB No. 0925-0522

SISID xxxxxxx mrau

Authorization for Release of Medical Record Information

Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

Please read carefully, sign this copy, and place in the mailer to be returned to the Sister Study

Provider Name:
Street Address:
City: State: Zip:
Telephone:

I am voluntarily participating in the Sister Study, a nationwide study of sisters of women who had breast cancer. The study is designed to identify risk factors for breast cancer and factors that may influence the long-term health of women after treatment for breast cancer. The National Institute of Environmental Health Sciences, one of the National Institutes of Health, of the U.S. Department of Health and Human Services is conducting the study.

I authorize and request that you provide the Sister Study and its staff with the medical information they request about all health services provided to me. This authorization form covers any care I received at your facility. It also covers care I received from any medical provider associated with your facility or who provided care to me in your facility as well as any services or treatment that I received that may be in your records. The information requested pertains to my diagnosis or treatment of breast cancer and any other relevant information.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.

The Sister Study and its staff will use this information to supplement the information I have already given for the Sister Study. Once my information is released to the study, it is no longer covered by HIPAA, but is covered by the Public Health Service Act, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.

I authorize the study to use information I have given in the study to help you identify my records. I can revoke this authorization at any time by contacting a study representative in writing or by telephone at the address and telephone number listed below. Otherwise, this authorization expires 30 months from the date of signature.

Patient Name: _____

Date of Birth: |__|__| |__|__| |__|__|__|__|
MONTH DAY YEAR

Other Names under Which Records May be Filed: _____

_____

Social Security Number: |__|__|__| – |__|__| – |__|__|__|__|

Signature: _____ **Date:** _____

Proxy Signature: _____ **Relationship to Patient:** _____

Reason for Proxy: _____ **Patient deceased**

_____ **Patient incapacitated**

The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703
phone: 1-877-4SISTER (1-877-474-7837); email: info@sisterstudy.org

Form #: 06
Version #: 01 (V. Date 12/02/08)
OMB No. 0925-0522

SISID xxxxxxx mrau

Authorization for Release of Medical Record Information

Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

Please return the copy you sign. Keep this copy for your records.

Provider Name:
Street Address:
City: State: Zip:
Telephone:

I am voluntarily participating in the Sister Study, a nationwide study of sisters of women who had breast cancer. The study is designed to identify risk factors for breast cancer and factors that may influence the long-term health of women after treatment for breast cancer. The National Institute of Environmental Health Sciences, one of the National Institutes of Health, of the U.S. Department of Health and Human Services is conducting the study.

I authorize and request that you provide the Sister Study and its staff with the medical information they request about all health services provided to me. This authorization form covers any care I received at your facility. It also covers care I received from any medical provider associated with your facility or who provided care to me in your facility as well as any services or treatment that I received that may be in your records. The information requested pertains to my diagnosis or treatment of breast cancer and any other relevant information.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.

The Sister Study and its staff will use this information to supplement the information I have already given for the Sister Study. Once my information is released to the study, it is no longer covered by HIPAA, but is covered by the Public Health Service Act, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.

I authorize the study to use information I have given in the study to help you identify my records. I can revoke this authorization at any time by contacting a study representative in writing or by telephone at the address and telephone number listed below. Otherwise, this authorization expires 30 months from the date of signature.

Patient Name: _____

Date of Birth: |__|__| |__|__| |__|__|__|__|
MONTH DAY YEAR

Other Names under Which Records May be Filed: _____

_____

Social Security Number: |__|__|__| – |__|__| – |__|__|__|__|

Signature: _____ **Date:** _____

Proxy Signature: _____ **Relationship to Patient:** _____

Reason for Proxy: _____ **Patient deceased**

_____ **Patient incapacitated**

The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703
phone: 1-877-4SISTER (1-877-474-7837); email: info@sisterstudy.org

Form #: 07
Version #: 01 (V. Date 12/02/08)
OMB No. 0925-0522

SISID xxxxxxx ptau

Authorization for Release of Pathology Specimens

Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

Please read carefully, sign this copy, and place in the mailer to be returned to the Sister Study

Provider Name:
Street Address:
City: State: Zip:
Telephone:

I am voluntarily participating in the Sister Study, a nationwide study of sisters of women who had breast cancer. The study is designed to identify risk factors for breast cancer and factors that may influence the long-term health of women after treatment for breast cancer. The National Institute of Environmental Health Sciences, one of the National Institutes of Health, of the U.S. Department of Health and Human Services is conducting the study.

I authorize and request that you provide the Sister Study and its staff with some of the pathology specimens pertaining to my diagnosis of breast cancer. The Sister Study is not asking for all of my tissue because there may be medical uses for my tissue in the future. They will use up some but not all of the tumor tissue you send them, and will keep remaining tissue in a secure place for at least the next 10 years. If remaining tissue is needed back during that time, they will send it to me or to anyone I name, if requested in writing.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.

The National Institute of Environmental Health Sciences and its contractors will use these specimens to supplement the information I have already given for the Sister Study. Once my information is released to the study, it is no longer covered by HIPAA, but is covered by the Public Health Service Act, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.

I authorize the study to use information I have given in the study to help you identify my specimens. I can revoke this authorization at any time by contacting a study representative in writing or by telephone at the address and telephone number listed below. Otherwise, this authorization to obtain pathology specimens expires 30 months from the date of signature.

Patient Name: _____

Date of Birth: |__|__| |__|__| |__|__|__|__|
MONTH DAY YEAR

Other Names under Which Records May be Filed: _____

_____

Social Security Number: |__|__|__| – |__|__| – |__|__|__|__|

Signature: _____ **Date:** _____

Proxy Signature: _____ **Relationship to Patient:** _____

Reason for Proxy: _____ **Patient deceased**

_____ **Patient incapacitated**

The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703
phone: 1-877-4SISTER (1-877-474-7837); email: info@sisterstudy.org

Form #: 07
Version #: 01 (V. Date 12/02/08)
OMB No. 0925-0522

SISID xxxxxxx ptau

Authorization for Release of Pathology Specimens

Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

Please return the copy you sign. Keep this copy for your records.

Provider Name:
Street Address:
City: State: Zip:
Telephone:

I am voluntarily participating in the Sister Study, a nationwide study of sisters of women who had breast cancer. The study is designed to identify risk factors for breast cancer and factors that may influence the long-term health of women after treatment for breast cancer. The National Institute of Environmental Health Sciences, one of the National Institutes of Health, of the U.S. Department of Health and Human Services is conducting the study.

I authorize and request that you provide the Sister Study and its staff with some of the pathology specimens pertaining to my diagnosis of breast cancer. The Sister Study is not asking for all of my tissue because there may be medical uses for my tissue in the future. They will use up some but not all of the tumor tissue you send them, and will keep remaining tissue in a secure place for at least the next 10 years. If remaining tissue is needed back during that time, they will send it to me or to anyone I name, if requested in writing.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.

The National Institute of Environmental Health Sciences and its contractors will use these specimens to supplement the information I have already given for the Sister Study. Once my information is released to the study, it is no longer covered by HIPAA, but is covered by the Public Health Service Act, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.

I authorize the study to use information I have given in the study to help you identify my specimens. I can revoke this authorization at any time by contacting a study representative in writing or by telephone at the address and telephone number listed below. Otherwise, this authorization to obtain pathology specimens expires 30 months from the date of signature.

Patient Name: _____

Date of Birth: |__|__| |__|__| |__|__|__|__|
MONTH DAY YEAR

Other Names under Which Records May be Filed: _____

_____

Social Security Number: |__|__|__| – |__|__| – |__|__|__|__|

Signature: _____ **Date:** _____

Proxy Signature: _____ **Relationship to Patient:** _____

Reason for Proxy: _____ **Patient deceased**

_____ **Patient incapacitated**

The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703
phone: 1-877-4SISTER (1-877-474-7837); email: info@sisterstudy.org

Form #: 08
Version #: 01 (V. date 12/02/08)

SISID xxxxxxx drls

Provider and Medical Care Facility List

Please complete and return this form to the Sister Study with the enclosed authorization forms

Type of Medical Provider	*Please provide or correct the information displayed below*		*Check Yes or No for each Provider* I authorize and request that this doctor or treatment facility provide the Sister Study and its staff with the medical information they request about all health services provided to me.	
Main doctor or facility responsible for breast cancer diagnosis and treatment	Name: Address: Telephone:	<Doc1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Oncologist or oncology center	Name: Address: Telephone:	<Onc> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Surgeon or surgery center	Name: Address: Telephone:	<Surg> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Pathologist	Name: Address: Telephone:	<Path> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Therapeutic Radiologist or radiology center	Name: Address: Telephone:	<Rad> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Other doctors or facilities involved in your breast cancer diagnosis and treatment	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No

Form #: 08
Version #: 01 (V. date 12/02/08)

SISID xxxxxxx drls

Provider and Medical Care Facility List

Please return the copy you sign. Keep this copy for your records.

Type of Medical Provider	*Please provide or correct the information displayed below*		*Check Yes or No for each Provider* I authorize and request that this doctor or treatment facility provide the Sister Study and its staff with the medical information they request about all health services provided to me.	
Main doctor or facility responsible for breast cancer diagnosis and treatment	Name: Address: Telephone:	<Doc1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Oncologist or oncology center	Name: Address: Telephone:	<Onc> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Surgeon or surgery center	Name: Address: Telephone:	<Surg> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Pathologist	Name: Address: Telephone:	<Path> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Therapeutic Radiologist or radiology center	Name: Address: Telephone:	<Rad> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
Other doctors or facilities involved in your breast cancer diagnosis and treatment	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No
	Name: Address: Telephone:	<OthMD1> <Addr1> <Addr2> <City>, <ST> <phone>	☐ Yes	☐ No

ANSWERS TO YOUR QUESTIONS ABOUT MEDICAL RECORDS AND TISSUE SPECIMENS

ANSWERS TO YOUR QUESTIONS

Question Section — Page

General Information about the Sister Study and This Request

What is the Sister Study?

The Sister Study is the only long-term study in the United States and Puerto Rico of women ages 35 to 74 whose sisters had breast cancer. This study is conducted by the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health. The study is following 50,000 women for at least 10 years to learn how environment and genes may affect the chances of getting breast cancer.

What will the Sister Study tell us?

Researchers believe the Sister Study will help us better understand reasons women get breast cancer, especially reasons that concern environment and genes. With the new information about your breast cancer diagnosis and treatment, researchers hope to better understand how environment and genes affect risk for different types of breast cancer. They will also learn how these factors affect health and survival after a diagnosis. Knowledge gained from the Sister Study will be used to develop recommendations for preventing breast cancer in the future and promoting good health for women.

Who is running the study?

Researchers at the National Institute of Environmental Health Sciences (NIEHS) are running the study. NIEHS is one of the National Institutes of Health, part of the Department of Health and Human Services. The web site for NIEHS is http://www.niehs.nih.gov.

The Investigators are —

Dale P. Sandler, PhD
Chief of Epidemiology Branch

Clarice Weinberg, PhD
Chief of Biostatistics Branch

Lisa DeRoo, PhD
Epidemiology Branch

I have been diagnosed with breast cancer. Will I continue to be part of the Sister Study?

Yes. When a participant develops breast cancer, we still want to follow her health over time to learn about factors that may contribute to her healthy survival. We hope you will participate for the full length of the study. By continuing to follow women diagnosed with breast cancer we can learn if environmental, lifestyle, and genetic factors influence treatment outcomes, survival, and quality of life following a diagnosis of breast cancer. We can also learn about other aspects of women's health.

Who makes sure this study is safe and scientifically sound?

Research funded by the federal government is carefully reviewed and monitored. This study has been reviewed for its scientific quality by experts in the field (mainly university

scientists) and is overseen by a Scientific Advisory Board made up of scientists and community representatives. In addition, the Institutional Review Board (IRB) of the NIEHS reviews the study, identifying issues and concerns, and works with the investigators as needed to improve the study. The NIEHS IRB is diverse and includes ethicists, lawyers, physicians, scientists from NIEHS, as well as other scientists and members of the local community. Studies like the Sister Study must be reviewed and approved by the IRB before they can begin and then they are reviewed annually.

All institutions, including the National Institutes of Health (NIH), that receive funds from the U.S. Department of Health and Human Services to conduct or support research with human subjects must follow specific rules and are guided by ethical principles of a document known as The Belmont Report, which you can read at the website http://ohsr.od.nih.gov/guidelines/belmont.html. NIH has developed a system of education and approval procedures to assist investigators in understanding and complying with well-established ethical and regulatory requirements. The investigators and staff who are conducting the Sister Study receive ongoing education and monitoring to ensure that these requirements are fulfilled. If you would like more information on this important topic, please visit the NIH website at http://ohsr.od.nih.gov/info.

Who is collecting the data for NIEHS?

Social and Scientific Systems, Inc., a professional services research firm specializing in health studies and epidemiologic research, works closely with NIEHS investigators to recruit participants, collect data, and manage the day-to-day activities of the study. More information can be found at www.s-3.com.

How is My Privacy Protected?

Will my information be kept confidential? How will this be done?

All of the Sister Study staff sign confidentiality forms and undergo training in research ethics. We have put in place several protections for the privacy of your data. When your data are collected, they are labeled with an ID number. After your data are collected, your samples, questionnaires, and interview data are stored separately from all personal identifiers, such as your name, address, and telephone number. Your personal contact information is kept in separate files accessible only to Sister Study staff on a need-to-know basis.

The Sister Study has received a Certificate of Confidentiality that helps us protect the confidentiality of your data against compulsory legal demands (e.g., court orders and subpoenas) that seek the name or other identifying characteristics of a research subject.

What is a Certificate of Confidentiality and what does this mean for me?

A Certificate of Confidentiality helps researchers protect the privacy of subjects in biomedical, behavioral, clinical, or other research projects against compulsory legal demands (e.g., court orders and subpoenas) that seek the name or other identifying

characteristics of a research subject. A Certificate of Confidentiality can protect researchers from being forced to give out information that could identify you.

What protection does a Certificate of Confidentiality provide?

Confidentiality Certificates are issued by the U.S. Department of Health and Human Services to provide privacy protection to research subjects. These certificates are authorized by law in provision 301(d) of the Public Health Services Act (42 U.S.C. Section 241(d)). A Certificate can be used by the researcher to avoid compelled "involuntary disclosure" (e.g., subpoenas) of identifying information about a research subject.

What protection does a Certificate NOT provide?

A Certificate of Confidentiality does NOT prevent researchers from voluntarily disclosing information about a participant if it is considered necessary to protect a participant or someone else from serious harm, as in cases of child abuse. A Certificate of Confidentiality also does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns about your participation from you, and you consent in writing to having information about you released, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

How long is my information protected under the terms of the Certificate?

The Certificate covers the collection of sensitive research information for a defined time period (the term of the project); however, personally identifiable information obtained under protection of a Certificate is protected forever. In other words, we researchers can collect new data under the Certificate only during the agreed upon length of the study. But your privacy is protected even after the study has ended.

Will my insurance company or employer obtain the information I give you as part of the study?

No, we will not provide any study information to insurance companies or employers, as it is strictly protected by confidentiality rules. However, this does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research should you choose to do so on your own.

Why are you asking for my Social Security Number?

Social Security numbers are very important in a long-term follow-up study. We will use your Social Security number to link to national databases to obtain necessary medical and vital status information and to help us locate you if we lose contact. Your Social Security number also helps your health care providers accurately identify your medical records. We recognize that your Social Security number is private and many people are worried about sharing this number. We will make sure that only key study personnel have access to your Social Security

number, and then only for purposes directly related to the Sister Study. If you are still worried about providing your SSN, you may simply give the last four digits or omit it altogether even though this may make it harder for us to be sure we get the right records.

Tell Me More about Medical Records and Tissue Specimens

I've already given you information about my diagnosis and treatment. Why do you need to contact my health care providers?

We contact health care providers for valuable additional information about your breast cancer diagnosis and treatment. Specific features of your breast cancer such as cell type, behavior, size, and tumor location may hold clues to the causes we are trying to find. The best source of accurate information on specific breast cancer features and treatment is the medical record. While some women have this information, others may not. It is important to collect it the same way for all women.

You are requesting permission to obtain medical information and stored breast tissue specimens from my medical care providers. What if I would like to give permission for only one of these?

It is up to you whether you want to give us permission to obtain the information and samples we request. You may refuse all or part of our request. Your decision will not affect your participation in the rest of the Sister Study. If you are willing to provide the medical information but not the permission for tissue samples (or vice versa), the information you provide will still be helpful. However, having both sources of information would give the most complete picture of your breast cancer diagnosis, tumor characteristics and treatments, and would be most valuable to us in studying both the causes of breast cancer and factors that affect long-term health after a diagnosis.

What if I do not want my personal health information to be used in this research study?

You may refuse to give permission to obtain your medical information or change your mind later. Your decision will not affect your participation in the rest of the Sister Study. However, the purpose of the study is to learn how your health changes over the course of the years you are enrolled in the study. Information from your medical record is very important to us for understanding the details of your breast cancer diagnosis and treatment. We value your participation in the study, and giving us this additional information makes the other information you are providing even more valuable for our efforts to understand the causes of breast cancer.

What personal health information am I giving you permission to get?

We will ask for a copy of the diagnostic pathology report and for information about your diagnosis and treatment for breast cancer, including the results of physical examinations, medical history, lab tests, biopsies, surgeries, chemotherapy, radiation, and information from follow-up visits. This information, along with environmental and lifestyle information you provide separately will help us understand breast cancer risk factors as well as factors that affect outcomes after breast cancer diagnosis and treatment.

How will you use the details of my diagnosis?

We will use information from the medical record to classify your breast cancer into subtypes so that we can identify environmental and genetic risk factors that are specific for different types of breast cancer. Since most women with breast cancer can expect to live a long time and may have a range of health concerns, we will also use this information to study possible long-term influences on health.

How will you use the information on my treatment?

In order to determine if environmental factors and lifestyle influence how women do after a diagnosis of breast cancer, we have to take into account the influence of different treatments that women receive.

Why do you need the authorization form?

Health care information is private. Your providers cannot release information about you to a study like the Sister Study without your written permission. In 2003, a federal law called the Health Insurance Portability and Accountability Act (HIPAA for short) created new and stronger standards for protecting health care information. Your providers may have told you about some of these new requirements. One section of the law sets guidelines for the authorization forms that must be signed to allow a provider to release health care information. The Sister Study authorization form follows these guidelines.

How will you contact my doctor or hospital?

Providers will be contacted by telephone and then by mail with a copy of your signed authorization form and another form they will use to give us the information we need.

My providers are very busy. Isn't this a bother to them?

Your signature on the authorization form allows your doctor or hospital to participate in the study if they choose. Most health care providers are willing to participate in important research like the Sister Study. Usually, an office staff person can fill out the form.

What information will you give to my doctor about me?

To allow medical staff to find your records, we will give them your name, date of birth, approximate date of diagnosis and the signed authorization form. We may also share other information such as your Social Security number, treatment or your address if needed to help a doctor or hospital find the correct records.

Will this affect my Medicare, Medicaid, VA benefits, or any other public assistance I am receiving?

No. Signing or not signing this authorization form will not affect your eligibility for any program benefits.

Will this affect my medical care?

No. Signing or not signing this authorization form will not affect your current or future medical care.

Will my doctor bill me for the time he or she spent participating in the Sister Study?

No. If a doctor or hospital has a policy of charging for the information we request, the Sister Study will pay this charge directly. If you do receive a bill by mistake, please call the Sister Study toll-free at 1-877-4SISTER (1-877-474-7837).

What breast tissue samples are you asking for?

When patients undergo breast biopsy or surgery, breast tissue is removed and sent to the medical provider's pathology department for testing and diagnosis. After that process is finished, the remaining tissue samples are usually stored in the pathology department. We are asking your permission to contact your provider to obtain ***some*** of the remaining tissue samples for testing. These tests will provide further information about specific breast cancer features.

Will my doctor need these samples for my treatment?

Your decision to allow us to use ***some*** of the remaining tissue should not affect your treatment. ***While some pathology departments keep these samples indefinitely, others routinely destroy them after a few years***. We will obtain the tissue after your medical care provider has completed testing and diagnosis. When we request samples of your tumor tissue, we will remind the doctor to keep some of the tissue in case it is needed for your care in the future. In addition we will not use up all of the tissue that is sent to us and we will keep what remains for the duration of the study. If in the future you or your provider would like your samples returned, we will be happy to return what we have. Some doctors or hospitals have policies that will not allow them to send samples to us. If your provider does not send us some of your samples, this will not affect your participation in the Sister Study.

Will you provide the results of tests on my breast sample tissues to me or my doctors?

No. Your medical care provider has already tested your tissue samples and provided the results to you. The additional tests we will do are for research purposes only. They are not intended to be used as diagnostic tests or to make decisions about your medical care. The results will be combined with those of other women in the Sister Study and may not be ready for many years. The tests will not affect your care right now, but the research results may be helpful to women in the future.

How will my breast tissue samples be stored?

We will store your samples indefinitely in a secure building. The specimens will only have a number attached to them. They will not contain your personal identifiers.

Will my breast tissue samples be shared with other researchers?

We may share portions of these samples with other researchers for related research on women's health. These researchers will be bound by the conditions established by the Sister Study for the protection of your privacy and rights as a participant. We will not give other researchers any information that would allow them to identify you. Samples will only be shared for scientifically valid studies that meet approved standards for good science and for protecting the rights of participants. Samples that are shared can be used only for the specific research described in an approved research proposal and may not be used for other purposes without approval from the Sister Study. Your tissue samples will be used only for research and will not be sold.

What if at some point in the future my medical care providers need some of my tumor tissue back to help them choose the best treatment for me?

We encourage you to discuss with your doctor the possible future uses of your tissue, and the policies of the lab that now has your tissue, including how long they usually keep specimens. We will store the tissue you authorize to be sent to us in a secure setting for at least 10 years, being sure not to use up all of your tumor tissue. If at any time, for any reason, you would like to have some or all of the remaining tissue returned, and you request that in writing, we will gladly send it to you or to any recipient you name.

What if I change my mind about authorization for medical records or tissue specimens?

You can revoke an authorization at any time by contacting the Sister Study toll-free at 1-877-4SISTER (1-877-474-7837). You can contact the study by mail at the following address:

The Sister Study
1009 Slater Rd, Ste 120
Durham, NC 27703

If you decide to revoke authorization for collecting medical record information, we will stop any efforts to contact your provider to collect this information. If your provider has already given us information about you, we will remove the information from the study records unless it is already incorporated into research files in which your individual information cannot be identified even by a code number.

If you decide to revoke authorization for collection of your tissue specimens, we will stop any efforts to contact your provider to collect the specimens. If your provider has already sent them to us, and you request return from us in writing, we will send back all remaining materials to the provider or institution that sent them to us, or to any person you name, including yourself.

How Do I Find Out More?

Who do I contact if I have questions?

If you have any further questions or concerns about these requests, please call the Sister Study toll-free at 1-877-4SISTER (1-877-474-7837). If you have any questions about your rights as a research participant, please contact the NIEHS Institutional Review Board, at 1-919-541-4265.

How can I learn more and have my questions answered about the Sister Study?

Please call our toll-free number, 1-877-4SISTER or email info@sisterstudy.org. A Sister Study Help Desk staff member will answer your questions. Also, our website address is www.sisterstudy.org.

I would like to speak to a member of the Sister Study staff about the study.

A member of our staff will be happy to answer your questions about the study. You can reach a member of the Sister Study staff by calling our toll-free number 1-877-4SISTER and asking for the Sister Study Help Desk, or emailing us at info@sisterstudy.org.

Is there a physician on staff who could talk to me about breast cancer?

The Sister Study does not have a physician on staff. We are not in a position to provide medical advice. If you need to find a doctor or have questions about breast cancer, you should contact your doctor, your local health department, the American Cancer Society, or other organizations better qualified to provide you with breast cancer information. Links to some of these organizations are updated regularly on our website at www.sisterstudy.org.

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1009 SLATER ROAD, SUITE 120
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Artwork for User Defined (9" x 12")
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Produced by US Postal Service

Telephone Prompt

Call placed to breast cancer cases who have not returned forms 4 weeks after forms are mailed

1. Hello Ms LAST NAME, my name is… and I am calling on behalf of the Sister Study. Recently you spoke with a Sister Study staff member about your breast cancer diagnosis and treatment. We sent you some materials to ask if you would be willing to give the Sister Study permission to contact your medical providers to ask for additional information about your breast cancer diagnosis and treatment and to request some of the breast tissue samples that were saved after your biopsy or surgery.

   We have not yet received the forms back so we are calling to be sure you received these forms. Did you receive the authorization forms?

❑1 NOT A GOOD TIME	→	DETERMINE CALLBACK TIME, RECORD IN COMMENTS
❑2 YES	→	GO TO 2
❑3 YES, ALREADY RETURNED	→	Thank you very much. We'll hope to receive your forms in the next week or so. We may call you in a couple of weeks if they still haven't arrived. GO TO 4.
❑4 NO	→	CONFIRM ADDRESS, MAKE CORRECTIONS IF NEEDED

   _____

   _____

   Thank you, we will mail the forms in the next few days. If you have any questions when you receive the materials, please contact the helpdesk. GO TO 4.

2. Do you have any questions about the materials you received?

❑1 YES	→	ANSWER QUESTIONS USING FAQS. WHEN NO MORE Qs, GO TO 3
❑2 NO	→	GO TO 3.

3. Please help by taking some time now to complete these forms and return them in the postage-paid envelope.

❑1 R WILLING	→	Thank you for your help. We'll hope to receive your forms in the next week or so. We may call you in a couple of weeks if they still haven't arrived. GO TO 4.
❑3 R UNWILLING	→	To help us understand your concerns and to improve the study procedures, can you share with us any thoughts you had about these forms?

   _____

   It is your choice as to whether or not you want to give us permission to gather the additional information and samples we are requesting. Your decision will not affect your participation in the rest of the Sister Study. However, the information about your diagnosis and treatment is especially important. If you reconsider, simply return the forms in the postage-paid envelope we provided. As we promised when you joined the Sister Study, we will keep all of your personal information safe, private and confidential.

4. You can contact us at any time by sending an email to **info@sisterstudy.org** or by calling the Sister Study helpdesk toll-free at 1-877-4SISTER (1-877-474-7837). You can always visit our website at **www.sisterstudy.org** for more news about the Sister Study. Thank you again for your ongoing contribution to this important research. Good bye.

PROVIDER TELEPHONE SCRIPT –
CALL PLACED TO PROVIDERS OF BC CASES THAT HAVE PROVIDED SIGNED AUTHORIZATION FOR RELEASE OF MEDICIAL RECORDS

1. Hello, may I please speak to someone in medical records?

   Hello, my name is [Your Name] and I am calling on behalf of the Sister Study. The Sister Study is a cohort study of 50,000 women who have a sister with breast cancer, conducted by the National Institute of Environmental Health Sciences (NIEHS). If a participant develops breast cancer, we follow up with her doctors to collect additional information. We are calling about one of your patients, [name], who is a participant in The Sister Study. She has authorized us to collect detailed medical information. We want to send you a packet that includes the signed authorization forms and a Medical Report Form.

   [IF NOT THE CORRECT MEDICAL CARE FACILITY – END CALL]

   [RECORD COMMENTS] → _____
   _____
   _____

2. Who should receive the packet? → _____

3. Can you please verify the address? → _____
   [MAKE CORRECTIONS, IF NEEDED] _____
   _____

4. [DO NOT ASK THIS QUESTION]
   [DID PROVIDER MENTION THAT THERE WILL BE A COST INVOLVED WITH THIS SERVICE?]
   ❑1 YES → GO TO 5.
   ❑2 NO → GO TO 7.

   5. We are able to pay a small fee for your help.
      [DOCUMENT COST IF VOLUNTEERED] → $_____

   6. Do we need to pre-pay this fee?
      ❑1 YES [DOCUMENT PAYMENT DETAILS] → _____
      _____
      ❑2NO

7. Thank you, we will mail the forms and information about the Sister Study in the next few days. Good-bye. [END]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
Website: www.niehs.nih.gov

DATE

Provider Name
Address 1
Address 2
City, State Zip

RE: Patient Name: <Patient Name>
Date of Birth: <DOB>
Last four digits of SSN: XXX-XX-< SSN 4-digits>

Dear <Dr. Provider last name/Facility name>:

We recently spoke to one of your staff about obtaining the medical record for the above-named patient, who is a participant in The Sister Study. The Sister Study is a prospective study of 50,000 women whose sister had breast cancer, conducted by the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health (NIH). The purpose of the study is to identify environmental and genetic factors that contribute to breast cancer risk. The women in the study have provided us with detailed information on life and health history in questionnaires completed at baseline, and every two years since the study began in 2004. They also provided blood, urine, and home dust samples at baseline. For more information, please see the attached study summary.

Your patient, <name>, has told us that she was diagnosed with breast cancer in <month, year>. She has authorized us to collect information on her breast cancer diagnosis and treatment. We have enclosed a copy of the patient's signed *Authorization for Release of Medical Information* for your records. This form addresses issues pertinent to the Federal Health Insurance Portability and Accountability Act (HIPAA).

We are requesting copies of pertinent pathology reports and test results, as well as sections of the medical record covering breast cancer diagnosis and treatment. If possible, please also complete the medical report form, which asks for details that you are in the best position to provide. IF NUMBER OF DIAGNOSES > 1: We have included <N> forms because the patient reported <N> separate diagnoses to us. ALL: **Please send the requested records and completed medical report** IF NUMBER OF DIAGNOSES > 1: **forms** ELSE: **form** ALL: **within the next two weeks using the enclosed envelope:** The Sister Study, 1009 Slater Road, Suite 120, Durham, NC 27703.

Thank you in advance for your assistance to the Sister Study. While your participation is voluntary, it is very important to the study to verify what the participant has told us about her diagnosis, and to collect detailed information about her breast cancer diagnosis, tumor characteristics and treatment.

Please direct questions about this project to Heather Carroll, Sister Study Laboratory Supervisor, at (919) 287-4574 or (800) 948-7552, ext. 4574. Thank you in advance for your assistance.

Sincerely,

Dale P. Sandler

Dale P. Sandler, Ph.D.
Chief, Epidemiology Branch
Principal Investigator of the Sister Study

Encl. IF NUMBER OF DIAGNOSES > 1: 2+N, ELSE: 3

THE SISTER STUDY

A Study of the Environmental and Genetic Risk Factors for Breast Cancer

National Institute of Environmental Health Sciences • National Institutes of Health • Department of Health and Human Services

The NIEHS Sister Study is prospectively examining environmental and familial risk factors for breast cancer and other diseases in a high-risk cohort of 50,000 sisters of women who have had breast cancer. Such sisters have about twice the risk of developing breast cancer as other women. The frequency of any relevant genes and shared risk factors will also be higher, increasing the statistical power of the study. Sisters are expected to be highly motivated to participate in a long-term study. Studying sisters enhances our ability to assess the interplay of genes and environment in breast cancer risk and to identify potentially preventable risk factors. The prospective design allows us to assess exposures before the onset of disease thereby avoiding biases common to retrospective studies and creates a framework for testing new hypotheses.

Breast cancer-free sisters aged 35-74 years were recruited in the US and Puerto Rico through health professionals, breast cancer advocates, the Internet, recruitment volunteers, and a national media campaign. Study materials are available in English or Spanish. Recruitment strategies were designed to maximize inclusion of minorities and high-risk women. Data on potential risk factors and current health status were collected in telephone interviews and self-completed forms. Blood, urine, and environmental samples were collected and banked for future use in nested studies of women who develop breast cancer or other diseases and a sample of those who don't. Stored samples include whole blood, cryopreserved lymphocytes (15% random sample), plasma, serum, urine, toenail clippings, and household dust collected with alcohol wipes.

The cohort will be followed prospectively for 10 or more years. Contact information, vital status, and changes in health and exposures are updated in brief annually, and in greater detail every 2-3 years. Medical records, pathology reports, and tumor tissue blocks and slides are sought for those patients develop cancer. Medical records will also be sought to facilitate the study of other diseases of importance to women.

About 300 new cases of breast cancer are expected to occur in the cohort each year, with 1,500 cases after 5 years of follow-up. At that time, analyses will begin to assess the independent and combined effects of environmental exposures and genetic polymorphisms that affect estrogen metabolism, DNA repair, and response to specific environmental exposures. Future analyses will focus on known and potential risk factors (e.g. smoking, occupational exposures, alcohol, diet, obesity) and include measurement of phthalates, phytoestrogens, and metals in blood and urine, insulin, growth factors, vitamins and nutrients, and genes. Ancillary studies will explore risk for other diseases (e.g. heart disease, osteoporosis, other hormonal cancers, and autoimmune diseases) and explore genetic and environmental effects on breast cancer prognosis by continuing to follow women in the cohort who develop breast cancer. A related effort, the Two Sister Study is enrolling affected sisters diagnosed before age 50 and within 4 years of the unaffected sister's enrollment in the Sister Study. Parents of these sister pairs are invited to contribute saliva samples for DNA analysis.

The Sister Study opened nationally in October 2004. More than 50,000 women have completed all baseline activities.

Dale P. Sandler, Ph.D.
Principal Investigator

For more information, contact the Sister Study Helpdesk, toll-free, at:
1-877-4SISTER (1-877-474-7837)
or by sending an email to:
info@sisterstudy.org.

WWW.SISTERSTUDY.ORG

July 31, 2009

Sister Study Breast Cancer Medical Report Form

Patient Name: _____ **Date of Birth:** __/__/____ *mm/dd/yyyy*

Date this form completed: __/__/20__ *mm/dd/yyyy*

Doctor(s) and Address: *(please print)*

Doctor's Name: _____ Phone: ( ) _____

Doctor's Name: _____ Phone: ( ) _____

Affiliation: _____

Address: _____

City/Town: _____ State: _____ Zip: _____

Who Completed This Form? *(please print)*

Name: _____ Phone: ( ) _____

INSTRUCTIONS: Please provide a copy of the breast cancer medical reports listed below and check the corresponding box. Also, please fill in as much of the attached form as possible. Please return the medical reports and this form within the next **30 days** using the enclosed addressed envelope. Thank you!

Have you enclosed a copy of the following medical reports?

Please provide or correct pathologist information below.

Yes	No	
☐	☐	(1) Pathology report from the breast biopsy;
☐	☐	(2) Pathology report from the lumpectomy/mastectomy;
☐	☐	(3) Pathology report from the lymph node dissection;
☐	☐	(4) Estrogen and progesterone receptor assay report;
☐	☐	(5) Narrative discharge summary for the relevant admission(s);
☐	☐	(6) HER2NEU test results;
☐	☐	(7) Treatment Plan and/or summary;
☐	☐	(8) Other relevant records.

Name of Pathologist(s)/Lab: _____ Phone: ( ) _____

Name of Pathologist(s)/Lab: _____ Phone: ( ) _____

Address: _____

City/Town: _____ State: _____ Zip: _____

For Office Use Only: Date of Receipt _____ /_____ /_____ SIS ID #: _____

1. Date of Breast Cancer Diagnosis: _____/_____/__________
mm/dd/yyyy

2. Total number of tumors: __________

Instructions: Please complete one column of the Tumor Characteristics grid for each individual tumor per breast cancer diagnosis. If there was one tumor - complete column one only, two tumors - complete two columns only, and so forth.

	Tumor Characteristic	Tumor 1	Tumor 2	Tumor 3
3.	Pathology Accession Number(s)	______ ______ ______ ______	______ ______ ______ ______	______ ______ ______ ______
4.	Type	☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented	☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented	☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented
5.	Location	☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented	☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented	☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented
6.	Laterality	☐ Right ☐ Left ☐ Not documented	☐ Right ☐ Left ☐ Not documented	☐ Right ☐ Left ☐ Not documented
7.	Quadrant Location	☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented	☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented	☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented
8.	Evidence of Lymphatic-Vascular Invasion (LVI)	☐ Yes ☐ No ☐ Uncertain ☐ Not documented	☐ Yes ☐ No ☐ Uncertain ☐ Not documented	☐ Yes ☐ No ☐ Uncertain ☐ Not documented
9.	Tumor Size (single longest dimension in cm)	____ ____ . ____ cm	____ ____ . ____ cm	____ ____ . ____ cm
10.	Method of Determination of Tumor Size	☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented	☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented	☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented

Tumor 4	Tumor 5	Tumor 6
______ ______ ______ ______	______ ______ ______ ______	______ ______ ______ ______
☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented	☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented	☐ Invasive: _______% ☐ In situ: _______% ☐ Not documented
☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented	☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented	☐ Ductal ☐ Lobular ☐ Mixed—ductal dominant ☐ Mixed—lobular dominant ☐ No primary location evident ☐ Not documented
☐ Right ☐ Left ☐ Not documented	☐ Right ☐ Left ☐ Not documented	☐ Right ☐ Left ☐ Not documented
☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented	☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented	☐ Upper outer quadrant ☐ Lower outer quadrant ☐ Upper inner quadrant ☐ Lower inner quadrant ☐ Central ☐ Nipple ☐ Other, specify: ______ ☐ Not documented
☐ Yes ☐ No ☐ Uncertain ☐ Not documented	☐ Yes ☐ No ☐ Uncertain ☐ Not documented	☐ Yes ☐ No ☐ Uncertain ☐ Not documented
____ ____ . ____ cm	____ ____ . ____ cm	____ ____ . ____ cm
☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented	☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented	☐ Pathology ☐ Mammography ☐ Clinically ☐ Not documented

	Tumor Characteristic	Tumor 1	Tumor 2	Tumor 3
11.	Tumor Histology - Ductal	☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented
12.	Tumor Histology -Lobular	☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented
13.	Grade **1** = predominately well-differentiated **2** = moderately differentiated/ balanced pattern **3** = poorly differentiated **ND** = not documented	Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______	Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______	Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______
14.	Estrogen Receptor Assay (ERA) Type	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented
15.	Estrogen Receptor Assay (ERA) Results	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented
16.	ERA Value	**ERA Value:** ________	**ERA Value:** ________	**ERA Value:** ________
17.	Progesterone Receptor Assay (PRA) Type	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented

Tumor 4	Tumor 5	Tumor 6
☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Ductal NOS ☐ Invasive Ductal with Lobular Tendencies ☐ Mucinous ☐ Medullary ☐ Papillary ☐ Tubular ☐ Inflammatory ☐ Comedo ☐ Cribiform ☐ Solid ☐ Other, specify: ____________ ☐ Not documented
☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented	☐ Invasive Lobular NOS ☐ Invasive Lobular Classic ☐ Invasive Lobular Pleomorphic ☐ Invasive Lobular with Ductal Tendencies ☐ Other, specify: ____________ ☐ Not documented
Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______	Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______	Overall grade ______ Nuclear grade ______ Tubular grade ______ Mitotic grade ______
☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented
☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented
ERA Value: ________	**ERA Value:** ________	**ERA Value:** ________
☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented	☐ Biochemical ☐ Immunohistochemical (ERICA) ☐ Immunofluorescent ☐ Not performed ☐ Not documented

	Tumor Characteristic	Tumor 1	Tumor 2	Tumor 3
18.	Progesterone Receptor Assay (PRA) Results	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented
19.	PRA Value	**PRA Value:** ____________	**PRA Value:** ____________	**PRA Value:** ____________
20.	HER-2/NEU Assay Type	☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented	☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented	☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented
21.	Results of HER-2/NEU	☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented	☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented	☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented
22.	HER-2/NEU Value (IHC only)	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented
23.	DNA Ploidy	☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented	☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented	☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented
24.	S-Phase	☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented	☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented	☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented

Tumor 4	Tumor 5	Tumor 6
☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented	☐ Positive ☐ Negative ☐ Borderline/marginal ☐ Test not done ☐ Not documented
PRA Value: ____________	**PRA Value:** ____________	**PRA Value:** ____________
☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented	☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented	☐ Immunohistochemistry (IHC) ☐ FISH, gene amplification ☐ Both IHC and FISH ☐ Not performed ☐ Not documented
☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented	☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented	☐ Overexpressed ☐ Not overexpressed ☐ Test not done ☐ Not documented
☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Test not done ☐ Not documented
☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented	☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented	☐ Diploid/Euploid/Normal (DNA Index 1.0) ☐ Aneuploid/Abnormal (DNA Index>1.0) ☐ Test not done ☐ Not documented
☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented	☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented	☐ Low (or < reference) ☐ Intermediate ☐ High (or > reference) ☐ Equivocal ☐ Specify percentage: ______% ☐ Test not done ☐ Not documented

Surgical Treatment

	Left Breast	Right Breast
25. Date of post-diagnosis surgery	_____/_____/_____ mm/dd/yyyy	_____/_____/_____ mm/dd/yyyy
26. Type of surgery	☐ Lumpectomy ☐ Other Breast Conserving Therapy (BCT) ☐ Mastectomy ☐ No post-diagnosis surgery performed ☐ Not documented	☐ Lumpectomy ☐ Other Breast Conserving Therapy (BCT) ☐ Mastectomy ☐ No post-diagnosis surgery performed ☐ Not documented

Lymph Node Involvement and Metastatic Results

27. Lymph Node Involvement (Sentinel lymph node biopsy and final surgery combined)

Number sampled: _____

Number malignant: _____

28. Results of Metastatic Work Up:

☐ Completely negative
☐ Incomplete or equivocal
☐ Metastatic at diagnosis
☐ Work up not performed
☐ Not documented

Chemotherapy Treatment

29. Neo-adjuvant (pre-surgery) chemotherapy for breast cancer:

☐ Yes
☐ No
☐ Not documented

30. If yes,

Chemotherapy Regimen (see list below)	# Cycles	Start date mm/dd/yyyy	End date mm/dd/yyyy (if known)	Mark if therapy on-going	Prescribed dosing interval
Example: ATC	*2*	*02/01/2006*	*02/15/2006*	☐	*q 2 weeks*
				☐	
				☐	

31. Adjuvant chemotherapy for breast cancer:

☐ Yes
☐ No
☐ Not documented

32. If yes,

Chemotherapy Regimen (see list below)	# Cycles	Start date mm/dd/yyyy	End date mm/dd/yyyy (if known)	Mark if therapy on-going	Prescribed dosing interval
Example: CMF	*4*	*03/01/2006*		☒	*q 2 weeks*
				☐	
				☐	
				☐	
				☐	
				☐	

LIST OF CHEMOTHERAPY REGIMENS FOR QUESTIONS 30 & 32:

AC—Adriamycin/Cytoxan
AT—Adriamycin/Taxol
ATC—Adriamycin/Taxol or Taxotere/Cytoxan
T—Taxol
CMF—Cytoxan/Methotrexate/Fluorouracil
CAF/FAC—Cytoxan/Adriamycin/Fluorouracil
EC - Epirubicin/Cytoxan
Td—Taxotere
FEC—Fluorouracil/Epirubicin/Cytoxan
T+H—Taxol plus Herceptin
Abraxane
Other—please specify

Biological Treatment

33. Herceptin treatment for breast cancer?

☐ Yes
☐ No
☐ Not documented

34. If yes,

Drug Name	Start date mm/dd/yyyy	End date mm/dd/yyyy (if known)	Mark if therapy on-going
			☐
			☐

Hormonal Treatment

35. Hormonal treatments such as tamoxifen, raloxifene, or aromatase inhibitors [Arimidex (Anastrozole), Femara (Letrozole), Aromasin (Exemestane)]?

☐ Yes
☐ No
☐ Not documented

36. If yes,

(If dose changed, enter on a separate line)

Drug Name	Start date mm/dd/yyyy	End date mm/dd/yyyy (if known)	Dosage	Mark if therapy on-going
				☐
				☐
				☐
				☐

Radiation Treatment

37. Radiation therapy:

☐ Yes
☐ No
☐ Not documented

38. If yes,

Target Site of Radiation Treatment	Left Breast: Start date mm/dd/yyyy	Left Breast: End date mm/dd/yyyy (if known)	Left Breast: Mark if therapy on-going	Left Breast: Cumulative Dose (cGy)	Right Breast: Start date mm/dd/yyyy	Right Breast: End date mm/dd/yyyy (if known)	Right Breast: Mark if therapy on-going	Right Breast: Cumulative Dose (cGy)
Whole Breast	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	
Tumor Bed	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	
Chest Wall	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	
Supraclavic-ular (SCV)	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	
Axilla	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	
Intramam-mary nodes (IMN)	_____/_____/_____	_____/_____/_____	☐		_____/_____/_____	_____/_____/_____	☐	

Clinical Trial Enrollment

39. Enrolled in a clinical trial for breast cancer treatment/management:

☐ Yes
☐ No
☐ Not documented

40. If yes,

Name or ID number of trial: _____

Treatment(s) or procedure(s) tested: _____

_____

Treatment(s) or procedure(s) patient received as part of the trial (if known): _____

_____

Sponsor of trial (e.g. NIH, CALGB): _____

41. Did patient complete the trial?:

☐ Completed
☐ Ongoing
☐ Did not complete, dropped out
☐ Not documented

Genetic Testing

42. BRCA1 Genetic testing:
- ☐ Positive
  Specify Variant: _____
- ☐ Negative
- ☐ Equivocal
  Specify Variant: _____
- ☐ Test not done
- ☐ Not documented

43. BRCA2 Genetic testing:
- ☐ Positive
  Specify Variant: _____
- ☐ Negative
- ☐ Equivocal
  Specify Variant: _____
- ☐ Test not done
- ☐ Not documented

44. Other Genetic testing:

Type: _____

Result: _____

Molecular Profiling

45. Molecular Profiling and Proliferation assay:
- ☐ Yes
- ☐ No
- ☐ Not documented

46. If yes,

Assay Type (e.g. MammaPrint, OncotypeDx, MIB-1, E-cadherin)	**Score**

PROVIDER REMINDER CALL TELEPHONE SCRIPT –
SECOND CALL PLACED TO PROVIDERS OF BC CASES THAT HAVE NOT PROVIDED THE REQUESTED RECORDS AND REPORTS WITHIN 3-6 WEEKS.

1. Hello, may I please speak to [NAME GIVEN DURING PROVIDER CALL] in medical records?

   Hello, my name is [Your Name] and I am calling on behalf of the Sister Study. Several weeks ago we mailed a letter requesting medical records for [name], a participant in our study. Did you receive the letter and corresponding forms?

   ❑1 YES → GO TO 2.
   ❑2 NO → GO TO 5.

2. Do you have any questions?
   ❑1 YES → [RECORD QUESTIONS AND COMMENTS]
   _____
   _____
   _____

   ❑2 NO

3. Will you be able to send us the requested materials?
   ❑1 YES → Go to 4.
   ❑2 NO → [RECORD REASON] _____
   _____
   _____

   Thank you. Good-bye. [END]

4. If possible, we would like to receive the materials in the next two weeks. When do you estimate that you will be able to send us the materials?
   [RECORD TIMEFRAME] _____
   Thank you very much for your help. Good-bye. [END]

5. We will resend the packet to you.
   Can you please verify the address? → _____
   [MAKE CORRECTIONS, IF NEEDED] _____
   _____

   Thank you, we will re-mail the forms and information about the Sister Study in the next few days. Good-bye. [END]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
Website: www.niehs.nih.gov

DATE

DEPARTMENT OF PATHOLOGY
Provider Name
Address 1
Address 2
City, State Zip

RE: Patient Name : <Patient Name>
Date of Birth: <DOB>
Last four digits of SSN XXX-XX-<SSN 4-digits>
Accession number(s): <Accession #s>

To: PATHOLOGY DEPARTMENT

The above named patient is a participant in a research study and has given us permission to retrieve tissue blocks and slides pertaining to her breast cancer diagnosis in <month(s), year(s)>. The Sister Study, conducted by the National Institutes of Health, is a prospective study of 50,000 women whose sister had breast cancer. The study is evaluating the environmental and genetic factors that may contribute to breast cancer risk and exploring factors that may influence long-term health following treatment. Participants have provided detailed information on their life and health history in questionnaires completed at baseline and annually since enrollment. They also provided blood, urine, and environmental samples. The molecular marker data from tissue blocks and slides will be especially valuable to this research.

Enclosed is a copy of the patient's signed release form. We would be grateful if you would send:

1) For each breast tumor, two blocks containing representative samples of tumor tissue;
2) Two blocks containing normal breast tissue, if available;
3) Original diagnostic H&E slides (at least one slide for each block sent), if possible; and
4) The completed *Pathology Checklist* (enclosed).

We encourage you to retain some of the tumor tissue for possible future medical use, unless it would otherwise not be kept. Unused portions of blocks we receive will be archived in our biorepository for at least 10 years, but we will gladly return remaining tissue upon written request from the patient. **Please send the requested specimens and checklist to:**

The Sister Study
1007 Slater Rd, Ste 100
Durham, NC 27703
Attention: Cynthia Kleeberger

Please direct questions about the submission of blocks and slides to Cynthia Kleeberger, Laboratory Director of the Sister Study (919-287-4577, kleeber2@niehs.nih.gov). Questions about the Sister Study can be directed to Dr. Dale Sandler, Principal Investigator (919-541-4668, sandler@niehs.nih.gov). Thank you very much for your assistance.

Sincerely,

Dale P. Sandler

Dale P. Sandler PhD
Chief, Epidemiology Branch
Principal Investigator of the Sister Study

Sister Study Pathology Checklist

Patient Name: _____ **Date of Birth:** ___ / ___ / _____
(month) (day) (year)

Date this form completed: ___ / ___ / _____
(month) (day) (year)

Date of tumor biopsy/removal: ___ / ___ / _____
(month) (day) (year)

Facility Name and Address: *(please print)*

Facility Name: _____

Telephone: ( ) _____

Address: _____

Who completed this form? (*please print)*

Name: _____Telephone: ( ) _____

***INSTRUCTIONS**: Please check all of the following that apply. If more than one tumor was diagnosed, complete a separate checklist for each tumor.*
(Please note: H&E slides should correspond to the tissue blocks. If original H&E slides are not available, please DO NOT make new H&E slides.)

Normal Tissue Blocks and Original H&E Slides

□ I am sending _____ block(s) and _____ slide(s) containing normal breast tissue.
Block 1 Accession #_____Corresponding Slide 1 Accession # _____
Block 2 Accession #_____Corresponding Slide 2 Accession # _____

Tumor Tissue Blocks and Original H&E Slides

□ I am sending _____ block(s) and _____ slide(s) containing breast carcinoma tissue.
Block 1 Accession #_____Corresponding Slide 1 Accession #_____
Block 2 Accession #_____Corresponding Slide 2 Accession #_____

□ I have no original H&E slides.

Other information

□ Our hospital has no record of this patient.

□ We no longer have this material. You need to contact:

Name: _____
Hospital/Lab: _____
Street: _____
City/State/Zip: _____
Phone: _____

□ Comments: _____
_____
_____
_____

Thank you for your response. Please return this form and samples to:

The Sister Study
1007 Slater Road, Ste. 100
Durham, NC 27703
Attention: Cindy Kleeberger, *Laboratory Director*

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
Website: www.niehs.nih.gov

DATE

DEPARTMENT OF PATHOLOGY
Provider Name
Address 1
Address 2
City, State Zip

RE: Patient Name : <Patient Name>
Date of Birth: <DOB>

To: PATHOLOGY DEPARTMENT

Thank you for sending us the tissue blocks and slides from <name>, who is a participant in the Sister Study. The Sister Study aims to examine the environmental, lifestyle, and genetic factors that may make some women more likely than others to develop breast cancer and also to study factors that may influence the long-term health of women after treatment for breast cancer. With access to the pathology specimens that you and many other pathology departments have provided, we will also be able to examine the importance of specific molecular markers in breast cancer risk.

As stated in our initial letter, blocks we receive for our later analyses will be archived at the NIEHS biorepository for at least 10 years, but we will gladly return remaining tissue to you upon written request from the patient.

If you have any questions about the submission of blocks and slides please contact Cynthia Kleeberger, Laboratory Director of the Sister Study, phone (919) 287-4577, email kleeber2@niehs.nih.gov. We will be happy to return what we have.

Your cooperation and support of the Sister Study is greatly appreciated.

Sincerely,

Dale P. Sandler

Dale P. Sandler PhD
Chief, Epidemiology Branch
Principal Investigator of the Sister Study