Share Thoughts on Breast Cancer Study

You are receiving this questionnaire because our records show you were diagnosed with breast cancer. **If you received this questionnaire in error, please accept our apologies**. In addition, please check the box ☐ and return this blank questionnaire in the enclosed postage paid envelope.

INSTRUCTIONS

Thank you for agreeing to be part of this study. This study booklet has two parts:

Part 1: Study Questionnaire	(pages 1 – 21 in the booklet)
Part 2: Medical Record Consent	(pages 23 – 28 in the booklet)

The questionnaire asks questions about you, your health, and your treatment decisions. We hope to learn more about how people are treated for breast cancer, what information they are given, what influences the treatments and procedures they choose, and their experiences with care.

The survey takes about 30 minutes to complete. We have enclosed a $10 gift in appreciation for your time. You may keep this whether or not you decide to participate.

- Answer each question as best you can. Please do not leave any blank. (However, if you feel that you do not wish to answer a question, please write 'skip' next to it and continue on to the next question).
- For each of the following questions, please mark an "X" in the one box that best describes your answer. Please use a dark ink pen to complete this survey, and try to avoid making stray marks. For questions that ask you to write in numbers or letters, please write them neatly and clearly.
- Mark only **one** response for each question, **unless other instructions are given** (e.g. Please mark ALL that apply).
- As much as possible, please try to answer all of the questions in one sitting.
- There are no right or wrong answers so please give the answers that best describe your situation.

More Information about the Study

We invite you to participate in a study called "Share Thoughts on Breast Cancer." The purpose of this study is to learn about the experiences of patients after they have been diagnosed with breast cancer.

We are inviting you because you have been a patient at our medical center. We obtained your name and address from a list of patients with breast cancer who were seen at this medical center. Approximately 152 patients from this medical center will take part in the study.

If you agree to participate, we would like you to complete the questionnaire in this booklet. The questionnaire takes about 30 minutes to complete. Returning the completed questionnaire in the enclosed envelope will indicate you are willing to participate in the questionnaire part of the study.

We would also like to obtain information from your medical record. Please sign the enclosed informed consent form if you agree to give us permission to obtain information from your medical record. The detailed consent form is located at the end of the study booklet (starting on Page 23). You do not have to sign the consent form if you only want to participate in the questionnaire part of the study (Part 1).

We will keep the information you provide confidential, however federal regulatory agencies and the Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this portion of the study, and you will not benefit personally. However we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study. We have enclosed a $10 gift in appreciation for your time. You may keep this whether or not you decide to participate.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you have any questions about the research study itself, please contact {participating site investigator name} at {email} or {telephone}. If you experience a research-related injury, please contact: {participating site investigator name, phone}. If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

PART 1: Study Questionnaire

SECTION A: YOUR GENERAL HEALTH

A1. In general, would you say your health is….

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

A2. In general, would you say your quality of life is….

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

A3. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

☐ Completely ☐ Mostly ☐ Moderately ☐ A Little ☐ Not at all

A4. Before you were told you have breast cancer, had you ever been told by a doctor that you had any of the following health conditions?

a. Chronic bronchitis or emphysema	☐ Yes	☐ No
b. Heart disease such as coronary artery disease or congestive heart failure	☐ Yes	☐ No
c. Cancer, excluding skin cancer and breast cancer	☐ Yes	☐ No
d. Diabetes	☐ Yes	☐ No
e. High blood pressure	☐ Yes	☐ No
f. Stroke	☐ Yes	☐ No
g. Arthritis	☐ Yes	☐ No
h. High blood cholesterol	☐ Yes	☐ No
i. Rotator cuff, frozen shoulder or other shoulder diagnosis	☐ Yes	☐ No

Now, a few questions about your breast cancer.

A5. How many times have you had breast cancer?

☐ One time

☐ More than one time

A6. Approximately when did a doctor first tell you that you had breast cancer?

☐☐ ☐☐☐☐ month/year

A7. On which side was breast cancer detected?

☐ Left breast only

☐ Right breast only

☐ Both left and right breasts

A8. Since this breast cancer was treated, has a doctor told you that your cancer has come back?

☐ Yes ☐ No

A9. To the best of your knowledge, are you now cancer-free?

☐ Yes ☐ No

SECTION B: YOUR CANCER CARE PROVIDERS

B1. Before beginning treatments, did you get a second opinion about treatment options for your breast cancer?

- ☐ Yes
- ☐ No

B2. How many medical centers did you go to for breast cancer treatments? *Breast cancer treatments include surgery to remove breast cancer, chemotherapy, radiation therapy, or hormone therapy.*

- ☐ 1 medical center
- ☐ 2 medical centers
- ☐ 3 or more medical centers

B3. During your cancer treatment, was there one health professional who COORDINATED your cancer care?

- ☐ Yes
- ☐ No
- ☐ Don't know

B4. Which of the following best describes the way you would prefer to make a decision about your cancer treatment?

- ☐ I prefer that I make the decision about treatment with little or no input from my doctors
- ☐ I prefer that I make the decision about treatment, after considering my doctor's opinion
- ☐ I prefer that my doctor and I make the decision about treatment together on an equal basis
- ☐ I prefer that my doctor make the decision about treatment, but strongly considers my opinion
- ☐ I prefer that my doctor make the decision about treatment with little or no input from me

B5. Overall, how would you rate the quality of your health care since you found out you had breast cancer?

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

Now we would like you to think about <u>all of your breast cancer care</u> from the time you found out that you had breast cancer.

Please mark the response that best describes your experience.

B6. How often did your doctors listen carefully to you?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B7. How often did your doctors explain things in a way you could understand?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B8. How often did you think that your health problems related to your breast cancer or its treatments were handled quickly enough?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B9. How often were you able to see the specialists such as cancer doctors you wanted to see for your breast cancer?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B10. How often did the doctors, nurses, and other medical staff providing your care seem to work well together as a team?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B11. How often did your doctors seem to be aware of treatments for your breast cancer that other doctors had ordered?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B12. How often did you know who to ask when you had any questions related to your breast cancer or its treatments?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

B13. How often did you feel that your doctors, nurses, and other medical staff did everything they could to treat your health problems related to your breast cancer or its treatments?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

SECTION C: SURGICAL TREATMENTS AND DECISIONS

This section asks about SURGERIES you may have had.

C1. When decisions were being made about breast cancer surgery, how important was it that the type of surgery you had…

Please mark only one box for each line.	Not at all Important		Somewhat Important		Very Important
a…..would keep you from worrying about the cancer coming back	☐	☐	☐	☐	☐
b…..would allow you to avoid the possibility of a second surgery to remove the cancer	☐	☐	☐	☐	☐
c……would not make you feel bad about your body, like it was disfigured	☐	☐	☐	☐	☐
d……would not interfere with your sex life in the long term	☐	☐	☐	☐	☐
e……would allow you to avoid exposing yourself to radiation	☐	☐	☐	☐	☐
f……would allow you to avoid going back and forth to radiation treatments	☐	☐	☐	☐	☐
g…..would allow you to feel feminine	☐	☐	☐	☐	☐
h…..would reduce the chances of cancer coming back	☐	☐	☐	☐	☐

C2. Which statement best describes the role you played when the decision was made about surgery for your breast cancer? *If you had more than one surgery, please answer about the first surgery you had to remove your cancer/tumor.*

Choose one:

- ☐ I made the decision with little or no input from my doctors
- ☐ I made the decision after considering my doctors' opinions
- ☐ My doctors and I made the decision together
- ☐ My doctors made the decision after considering my opinion
- ☐ My doctors made the decision with little or no input from me
- ☐ None of the above – I never discussed surgery with my doctors

C3. What breast cancer surgeries have you had?
Please mark all that apply.

- ☐ Lumpectomy (removal of the cancer and some surrounding tissue)
- ☐ Repeat surgery after a lumpectomy to make sure all of the tumor was removed
- ☐ Mastectomy (removal of 1 breast)
- ☐ Nipple-sparing mastectomy (breast removed but nipple left in place)
- ☐ Bilateral mastectomy (removal of both breasts) → **C4. Who first brought up the idea to have your "other breast" removed?**
  - ☐ Myself
  - ☐ Medical oncologist
  - ☐ Plastic surgeon
  - ☐ Cancer surgeon
  - ☐ Nurse
  - ☐ Genetic counselor
  - ☐ Family/friend
  - ☐ Another breast cancer patient
  - ☐ Other (please write in): _____

Some women have surgeries to reconstruct their breast or improve the appearance of their breast(s) after breast cancer.

C5. Did any doctor, nurse, or other health professional explain or discuss breast reconstruction with you?

- ☐ No → **Go to question C7**
- ☐ Yes → **C6. When was it first discussed - before or after your surgery to remove breast cancer?**
  - ☐ Before my breast cancer surgery
  - ☐ After my breast cancer surgery

C7. Have you had or do you plan to have any procedures to reconstruct or improve the appearance of your breasts? *Sometimes several procedures are done.*

- ☐ No → **Go to question C10**
- ☐ Don't Know → **Go to question C10**
- ☐ Yes

C8. Was this or will this be at the same medical center as your surgery to remove breast cancer?

- ☐ Same medical center as my breast cancer surgery
- ☐ Different medical center than my breast cancer surgery
- ☐ Don't know

C9. Which procedure did you have or do you plan to have?

Please mark all that apply.

- ☐ One-step implant (implant placed at the same time as my mastectomy)
- ☐ Two-step implant (expander first, followed by implant later)
- ☐ "Flap" reconstruction using tissue from back, belly, buttocks, or thighs to create a new breast
- ☐ Breast reduction/augmentation or breast lift of the side without cancer to help it more closely match the treated side
- ☐ Don't know

C10. Did you have a procedure that used liposuction to transfer fat from another part of your body to the breasts as part of reconstruction?

- ☐ Yes, after mastectomy
- ☐ Yes, after lumpectomy
- ☐ No → **Go to question C14**
- ☐ Don't Know → **Go to question C14**

C11. From what parts of your body was the fat removed?

Please check all places from which fat was removed.

- ☐ Stomach or abdomen
- ☐ Buttocks
- ☐ Hips
- ☐ Thighs
- ☐ Other (specify) _____

C12. On how many different occasions did you have fat removal done?

- ☐ 1 (just one time)
- ☐ 2
- ☐ 3 or more times

C13. To the best of your knowledge, did you have any complications from the procedure?

- ☐ Yes (Please describe) _____
- ☐ Maybe (Please describe) _____
- ☐ No

C14. Have you needed any additional breast surgeries (besides your surgery to remove your breast cancer and reconstruction or cosmetic procedures)?

Please mark <u>all</u> that apply.

- ☐ Replacement of implant due to a problem
- ☐ Surgery due to an infected surgical wound, skin breakdown or seroma
- ☐ Other additional surgery (Please describe):

_____

- ☐ No, I have not needed any additional breast surgeries

C15. At any time after your breast surgery has a <u>doctor</u> told you that you have any of the following arm or shoulder conditions? If so, what treatments did you have, if any?

	Did the doctor tell you that you had this?	If yes, did you have surgery or physical therapy for it?	If yes, do you still have symptoms?
a. Rotator cuff problem	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
b. Frozen shoulder or adhesive capsulitis	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
c. Lymphedema	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
d. Other doctor-diagnosed arm or shoulder problem (Please specify:)	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

_____

SECTION D: OTHER TREATMENTS AND DECISIONS

D1. Besides surgery, what other cancer treatments have you had?

	Did you have this?	If yes, was this before or after the surgery that removed your breast cancer?
Chemotherapy	☐ Yes → ☐ No	☐ Before surgery only ☐ After surgery only ☐ Both before and after surgery ☐ Don't know
Radiation Therapy	☐ Yes → ☐ No	☐ Before surgery only ☐ After surgery only ☐ Both before and after surgery ☐ Don't know
Hormone Therapy (e.g. Tamoxifen, Raloxifene, Arimidex, Aromasin, or Femara)	☐ Yes → ☐ No	☐ Before surgery only ☐ After surgery only ☐ Both before and after surgery ☐ Don't know
Other type of treatment, please describe: _____	☐ Yes → ☐ No	☐ Before surgery only ☐ After surgery only ☐ Both before and after surgery ☐ Don't know

D2. Which statement best describes the role you played when the decision was made about <u>chemotherapy</u> for your breast cancer?

Choose <u>one</u>:

☐ I made the decision with little or no input from my doctors

☐ I made the decision after considering my doctors' opinions

☐ My doctors and I made the decision together

☐ My doctors made the decision after considering my opinion

☐ My doctors made the decision with little or no input from me

☐ None of the above - I never discussed chemotherapy with my doctors

The next two questions are about chemotherapy. If you did not have chemotherapy please go to question D5.

D3. When decisions were being made about chemotherapy, how important was it that the timing of the chemotherapy (before or after surgery or both)….

Please mark only one box for each line.

	Not at all Important		Somewhat Important		Very Important
a.….would allow you to know that your cancer had shrunk	☐	☐	☐	☐	☐
b…..would improve your chances of having a lumpectomy	☐	☐	☐	☐	☐
c……would make sure the cancer was removed by surgery as soon as possible	☐	☐	☐	☐	☐

D4. To your knowledge, did you have any long-term symptoms or problems related to chemotherapy?

	Did a doctor tell you that you had this?	If yes, did you have treatment (medicines, therapy or other specific treatments)?	If yes, do you still have symptoms?
a. Neuropathy or nerve problems	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
b. Cardiomyopathy or congestive heart failure	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
c. Trouble thinking or concentrating	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
d. Other problem, please describe:	☐ Yes → ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

D5. Did you have or are you planning to have genetic testing on a blood test or on your cancer tissue itself?

Please mark all that apply.

	Plan to have	Already had	Was this before or after your breast surgery?	Do you know the result?
BRCA gene testing or other blood testing to look for BRCA 1 and 2 and other genes related to breast cancer (eg. TP53, PTEN, CKEK2, ATM)	☐	☐ →	☐ Before ☐ After	☐ Negative ☐ Positive ☐ Ambiguous or Uncertain Significance ☐ Don't Know
Oncotype/ MammaPrint/ Prosigna (PAM50) testing (a test on cancer tissue to determine the activity of multiple genes involved in the likelihood that cancer will come back)	☐	☐ →	☐ Before ☐ After	☐ Low ☐ Intermediate ☐ High ☐ Don't Know
☐ I don't plan to have any genetic testing				

D6. Now, thinking about all the treatment decisions you made for your breast cancer, please mark how much each statement is true for you.

Please mark only one box for each line.

Overall...	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
a. I was clear about the best choice for me	☐	☐	☐	☐	☐
b. The decision was easy for me to make	☐	☐	☐	☐	☐
c. I felt sure about what to choose	☐	☐	☐	☐	☐
d. I felt that I had enough support and advice to make a choice	☐	☐	☐	☐	☐
e. I feel I made an informed choice	☐	☐	☐	☐	☐
f. I am satisfied with my decisions	☐	☐	☐	☐	☐
g. I made decisions before I was ready	☐	☐	☐	☐	☐

SECTION E: CANCER FOLLOW-UP CARE

Now, we would like to ask you some questions about the doctor who provides your cancer follow-up care after you completed your cancer treatment. *This would be the doctor you would see to get follow-up medical tests or to treat symptoms and treatment-related side effects.*

E1. ***After completing your cancer treatment,*** **how certain were you about which doctor was in charge of your cancer follow-up care?**

Please check the <u>one</u> best answer.

- ☐ Very certain
- ☐ Somewhat certain
- ☐ Neither certain nor uncertain
- ☐ Somewhat uncertain
- ☐ Very uncertain
- ☐ I have not yet completed my cancer treatment → **Go to question F1**

E2. What type of doctor do you see for <u>most</u> of your cancer follow-up care? *This would be the doctor you see to get follow-up medical tests or to treat symptoms and treatment-related side effects.*

Please check the <u>one</u> best answer.

- ☐ Medical oncologist
- ☐ Radiation oncologist
- ☐ Surgeon
- ☐ Primary care physician
- ☐ Internal medicine physician
- ☐ Nurse practitioner or physician assistant
- ☐ Other type of doctor - please describe: _____

E3. ***After completing your cancer treatment*****, did any doctor, nurse, or other health professional give you <u>a written or computer print-out summary</u> of the cancer treatments that you received?**

- ☐ Yes
- ☐ No
- ☐ Don't know

E4. ***After completing your cancer treatment*, did any doctor, nurse, or other health professional give you written or computer print-out instructions about where you should return or who you should see for routine cancer check-ups after completing your cancer treatments?**

- ☐ Yes
- ☐ No
- ☐ Don't know

SECTION F: ROLE OF FAMILY AND OTHERS

F1. Which statement best describes the role *your family* played when decisions were made about treatment for your breast cancer?

- ☐ I made the decisions with little or no input from my family
- ☐ I made the decisions after considering my family's opinion
- ☐ My family and I made the decisions together
- ☐ My family made the decisions after considering my opinion
- ☐ My family made the decisions with little or no input from me

F2. Was a family member or friend with you at any time when you were discussing treatment options with your doctors?

- ☐ Yes
- ☐ No

F3. Please mark one box for each of the following questions about your comfort with health information.

Please mark only one box for each line.	Always	Often	Sometimes	Occasionally	Never
a. How often do you have someone help you read hospital materials?	☐	☐	☐	☐	☐
b. How often can you fill out medical forms by yourself?	☐	☐	☐	☐	☐
c. How often do you have problems learning about your medical condition because of difficulty understanding written information?	☐	☐	☐	☐	☐
d. How often do you have problems understanding medical statistics?	☐	☐	☐	☐	☐
e. How often do you have problems taking your medications properly by yourself?	☐	☐	☐	☐	☐

SECTION G: HOW YOU HAVE BEEN FEELING RECENTLY

G1. Below is a list of statements that other people with your illness have said are important. Please mark one box per line to indicate your response as it applies to the <u>past 7 days.</u>

Please mark <u>only one</u> box for <u>each</u> line.

In the past 7 days..... **<u>PHYSICAL WELL-BEING</u>**	Not at all	A little bit	Some-what	Quite a bit	Very much
a. I have a lack of energy	☐	☐	☐	☐	☐
b. I have nausea	☐	☐	☐	☐	☐
c. Because of my physical condition, I have trouble meeting the needs of my family	☐	☐	☐	☐	☐
d. I have pain	☐	☐	☐	☐	☐
e. I am bothered by side effects of treatment	☐	☐	☐	☐	☐
f. I feel ill	☐	☐	☐	☐	☐
g. I am forced to spend time in bed	☐	☐	☐	☐	☐
<u>SOCIAL/FAMILY WELL-BEING</u>					
h. I feel close to my friends	☐	☐	☐	☐	☐
i. I get emotional support from my family	☐	☐	☐	☐	☐
j. I get support from my friends	☐	☐	☐	☐	☐
k. My family has accepted my illness	☐	☐	☐	☐	☐
l. I am satisfied with family communication about my illness	☐	☐	☐	☐	☐
m. I feel close to my partner (or the person who is my main support)	☐	☐	☐	☐	☐
n. I had trouble doing all of my regular leisure activities with others	☐	☐	☐	☐	☐

Regardless of your current level of sexual activity, please answer the following question below.

If you prefer not to answer it, please mark this box and go to the next section. → ☐

o. I am satisfied with my sex life	☐	☐	☐	☐	☐

G1. (Continued) Please mark one box per line to indicate your response as it applies to the <u>past 7 days</u>.

Please mark <u>only one</u> box for <u>each</u> line.

In the past 7 days.....

<u>EMOTIONAL WELL-BEING</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
p. I feel sad	☐	☐	☐	☐	☐
q. I am satisfied with how I am coping with my illness	☐	☐	☐	☐	☐
r. I am losing hope in the fight against my illness	☐	☐	☐	☐	☐
s. I feel nervous	☐	☐	☐	☐	☐
t. I worry about dying	☐	☐	☐	☐	☐
u. I worry that my condition will get worse	☐	☐	☐	☐	☐
v. I feel uneasy	☐	☐	☐	☐	☐
<u>FUNCTIONAL WELL-BEING</u>					
w. I am able to work (include work at home)	☐	☐	☐	☐	☐
x. My work (include work at home) is fulfilling	☐	☐	☐	☐	☐
y. I am able to enjoy life	☐	☐	☐	☐	☐
z. I have accepted my illness	☐	☐	☐	☐	☐
aa.I am sleeping well	☐	☐	☐	☐	☐
bb.I am enjoying the things I usually do for fun	☐	☐	☐	☐	☐
cc.I am content with the quality of my life right now	☐	☐	☐	☐	☐

G1. (Continued) Please mark one box per line to indicate your response as it applies to the <u>past 7 days</u>.

Please mark <u>only one</u> box for <u>each</u> line.

In the past 7 days.....

<u>ADDITIONAL CONCERNS</u>		**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
dd.	I have been short of breath	☐	☐	☐	☐	☐
ee.	I am self-conscious about the way I dress	☐	☐	☐	☐	☐
ff.	One or both of my arms are swollen or tender	☐	☐	☐	☐	☐
gg.	I feel sexually attractive	☐	☐	☐	☐	☐
hh.	I am bothered by hair loss	☐	☐	☐	☐	☐
ii.	I worry that other members of my family might someday get the same illness I have	☐	☐	☐	☐	☐
jj.	I worry about the effect of stress on my illness	☐	☐	☐	☐	☐
kk.	I am bothered by a change in weight	☐	☐	☐	☐	☐
ll.	I am able to feel like a woman	☐	☐	☐	☐	☐
mm.	I have certain parts of my body where I experience pain	☐	☐	☐	☐	☐

G2. Please rate your ability to do the following activities in the past 7 days by marking one box per line.

Please rate the difficulty experienced in the past 7 days:	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
a. Open a tight or new jar	☐	☐	☐	☐	☐
b. Do heavy household chores (e.g., wash walls, floors)	☐	☐	☐	☐	☐
c. Carry a shopping bag or briefcase	☐	☐	☐	☐	☐
d. Wash your back	☐	☐	☐	☐	☐
e. Use a knife to cut food	☐	☐	☐	☐	☐
f. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	☐	☐	☐	☐	☐
g. During the past week, how much difficulty have you had sleeping because of pain in your arm, shoulder or hand?	☐	☐	☐	☐	☐

Please rate the severity of the following symptoms in the past 7 days:	None	Mild	Moderate	Severe	Extreme
h. Arm, shoulder or hand pain	☐	☐	☐	☐	☐
i. Tingling (pins and needles) in your arm, shoulder or hand	☐	☐	☐	☐	☐

G3. Please mark the response below that indicates how true each statement is for you.

Please mark only one box for each line.	Not at all	A little bit	Some-what	Quite a bit	Very much
a. I worry about my breast cancer coming back in the same breast	☐	☐	☐	☐	☐
b. I worry that breast cancer may occur in my other breast	☐	☐	☐	☐	☐
c. I worry that breast cancer will spread to other parts of my body	☐	☐	☐	☐	☐

SECTION H: A FEW MORE QUESTIONS ABOUT YOU

H1. Which of the following members of your family had been diagnosed with breast cancer at the time of your breast cancer diagnosis? *Please include only family members who are related by blood.*

Please mark ALL that apply.

- ☐ Mother
- ☐ Sister
- ☐ Daughter
- ☐ Grandmother → ☐ Maternal ☐ Paternal
- ☐ Aunt → ☐ Maternal ☐ Paternal
- ☐ Don't know
- ☐ No family members had been diagnosed with breast cancer

H2. Please indicate which item below best describes your experience with your menstrual period 12 months prior to your diagnosis with breast cancer.

- ☐ I had no menstrual periods in the 12 months prior to my breast cancer diagnosis
- ☐ I had regular (or the usual timing of) menstrual periods in the 12 months prior to my breast cancer diagnosis
- ☐ I had a change in the timing of menstrual periods in the 12 months prior to my breast cancer diagnosis

H3. Did you receive a medication to stop your menstrual periods?

- ☐ Yes
- ☐ No

H4. What is your date of birth? : month/day/year ☐☐ / ☐☐ / ☐☐☐☐

H5. About how tall are you? ☐ feet ☐☐ inches *or* ☐.☐☐ meters

H6. About how much did you weigh <u>at the time of your breast cancer diagnosis</u>?

☐☐☐ pounds *or* ☐☐☐ kilograms

H7. About how much do you weigh <u>now</u>?

☐☐☐ pounds *or* ☐☐☐ kilograms

H8. On average, how many cigarettes did you smoke a day at the time of your breast cancer diagnosis?

- ☐ None, I have never smoked
- ☐ None, I used to smoke but had stopped
- ☐ Less than one pack a day
- ☐ About one pack a day
- ☐ More than one pack a day

H9. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No

H10. What is the highest degree or level of school you have completed?

- ☐ 8th grade or less
- ☐ Some high school, but did not graduate
- ☐ High School Graduate or G.E.D.
- ☐ Some College or 2-year degree
- ☐ College Graduate
- ☐ More than a college degree
- ☐ Prefer not to answer

H11. When you were diagnosed with breast cancer, what was your marital status?

Please mark ONE.

- ☐ Married
- ☐ Widowed
- ☐ Divorced
- ☐ Separated
- ☐ Never married
- ☐ Living with a partner/significant other

H12. What is your <u>current</u> marital status?

Please mark ONE.

- ☐ Married
- ☐ Widowed
- ☐ Divorced
- ☐ Separated
- ☐ Never married
- ☐ Living with a partner/significant other

H13. Which of the following best describes your race or ethnicity?

Please mark ALL that apply.

- ☐ Asian
- ☐ Black, African-American, African or Afro-Caribbean
- ☐ Hispanic, Latino or Spanish origin
- ☐ Middle Eastern or North African
- ☐ Native American, American Indian or Alaskan Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Some other race (Please specify) _____
- ☐ Prefer not to answer

H14. When you were diagnosed with breast cancer, what type of medical insurance did you have?

Please mark ALL that apply.

- ☐ No insurance
- ☐ Employer provided insurance
- ☐ Self-purchased insurance
- ☐ Spouse's insurance
- ☐ Medicaid or state provided insurance
- ☐ Medicare
- ☐ Other _____

H15. What is your yearly household income before taxes?

- ☐ Less than $20,000
- ☐ $20,001 - $35,000
- ☐ $35,001 - $50,000
- ☐ $50,001 - $75,000
- ☐ $75,001 - $100,000
- ☐ Greater than $100,000
- ☐ Prefer not to answer

H16. Were you employed at the time of your breast cancer diagnosis?

- ☐ Yes
- ☐ No

H17. When you were diagnosed with breast cancer, how many people were supported by the total income for your household, including yourself?

- ☐ 1 (just you)
- ☐ 2
- ☐ 3
- ☐ 4 or more

H18. How do you prefer to be contacted to learn about potential future research studies? *Please check ALL that apply.*

- ☐ E-mail
- ☐ Cell phone text messaging
- ☐ Social media (such as Facebook, Twitter, or Pinterest)
- ☐ Letter or post card in the mail
- ☐ A computer created phone message
- ☐ Personal phone call from research staff or my doctor
- ☐ Talking face-to-face with research staff or my doctor when I am visiting the clinic
- ☐ Other (please describe) _____
- ☐ I am not interested in being contacted about future research studies

H19. If a researcher was studying a condition or health problem that you care about, how interested would you be in participating if it required…..

	Not Interested	Somewhat Interested	Very Interested
a. Completing a survey two or more times?	☐	☐	☐
b. Giving a blood sample?	☐	☐	☐
c. Taking part in a study that involves talking by phone or over the internet (for example, to get advice about your health)?	☐	☐	☐
d. Taking part in a study where you have to take a medication?	☐	☐	☐
e. Taking part in a study that involves meeting at a local community center or school?	☐	☐	☐
f. Taking part in a study that involves you and other people in your family?	☐	☐	☐
g. Taking part in a study in which you would stay in the hospital for 1 or more days?	☐	☐	☐

H20. Who filled out this questionnaire?

☐ The person it was addressed to

☐ Someone else, but for the person it was addressed to

☐ Other (please describe): _____

H21. Today's date: month/day/year ☐☐ / ☐☐ / ☐☐☐☐

Thank you very much for filling out the study questionnaire!

If you are willing, we would appreciate it if you would provide your contact information for future communications, for example, if we wanted to clarify one of your answers:

Name (please print): _____

Street/City/State/Zip: _____

E-mail: _____

Telephone: ☐☐☐ - ☐☐☐ - ☐☐☐☐

PART 2: Medical Record Consent. PLEASE CONTINUE TO THE NEXT PAGE

PART 2: Medical Record Consent

To give signed consent for us to obtain information from your medical record for research purposes only, please review the consent form on the following pages.

* If you agree to participate in the medical records part of the study, please sign and date the form in the space indicated at the end of the form. Keep the loose copy for your files.

* When you have finished, please put this study booklet in the pre-paid envelope and mail it back to us.

INFORMED CONSENT DOCUMENT FOR MEDICAL RECORDS INFORMATION

Project Title: **Greater Plains Collaborative Breast Cancer Study Part 2: Medical Records Information**

Principal Investigator: Elizabeth Chrischilles

Research Team Contact: Nicholas Rudzianski at 319-335-9783 or toll-free at 866-520-8983

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have had breast cancer.

The purpose of this research study is to learn more about the experiences of patients after they have been diagnosed with breast cancer. We hope to learn more about how people are treated for the disease, what information they are given, what influences the treatments they choose, and their experiences with care.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 152 people will take part in this study conducted by investigators at The University of Iowa. A total of 1,300 people are expected to participate from a total of eight medical centers that are participating in this study.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study you will indicate this by signing and dating this form. Once we receive the signed and dated form from you we will obtain information from your medical record, including:

- Information about your breast cancer diagnosis such as type of breast cancer
- Details of your cancer treatments including surgery, radiation, chemotherapy, hormone therapy, and diagnostic tests
- Information about any breast reconstruction procedures
- Information about your past medical history such as other health conditions that can affect peoples' experience with cancer care
- Laboratory tests and vital signs

We will also keep your name and address on file so that we can contact you for future studies. Agreeing to participate in the current study does not obligate you to participate in any future studies. If we invite you for a future study, we will send you a new consent document for that study.

WHAT ARE THE RISKS OF THIS STUDY?

As with any study collecting personal information, there is always a risk of loss of confidentiality.

There may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because it will generate new information about breast cancer care and how that relates to symptoms and effects patients have after treatment is over.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You are paid $10 as compensation for your time even if you decide to not complete the questionnaire or give us permission to obtain information from your medical records.

WHO IS FUNDING THIS STUDY?

The Patient-Centered Outcomes Research Institute is funding this research study. This means that The University of Iowa is receiving payments from the Patient-Centered Outcomes Research Institute to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the Patient-Centered Outcomes Research Institute for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of The University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, any paper forms will be stored in locked file cabinets in a locked office and all computer files will be protected by passwords. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

Authorization about Use and Disclosure of Health Information for Research Purposes
This research involves the use and sharing of your health information. Your health information is protected by a federal privacy law called Health Insurance Portability and Accountability Act (HIPAA). HIPAA gives you the right to decide who can collect, use, or share your protected health information.

HIPAA also requires this information to be kept secure and private. This form describes how the information collected about you for this research will be used and shared with others if you choose to participate in this research.

What Information is "Protected Health Information" (PHI)?

Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. Health information is considered "protected health information" (PHI) when it may be possible to figure out who the person is. For example, when a person's health information is combined with identifiers like name, address, phone number and social security or individual taxpayer identification (ITIN) number, then the information is considered PHI.

What information about me will be accessed, collected and recorded in the research record?
The following information about you and your health will be used for this research:

- Information about your breast cancer diagnosis such as type of breast cancer
- Details of your cancer treatments including surgery, radiation, chemotherapy, hormone therapy, and diagnostic tests
- Information about any breast reconstruction procedures
- Information about your past medical history such as other health conditions that can affect peoples' experience with cancer care
- Laboratory tests and vital signs

Who will be allowed to access and record my health information in the research record?

The following people and entities will have access to your health information and PHI for this research:

- The research team and their collaborators who may work with our researchers in conducting and analyzing the research data. The collaborating sites include: University of Texas Southwestern Medical Center; University of Kansas Medical Center (KUMC); University of Wisconsin Carbone Cancer Center; University of Nebraska Medical Center; University of Minnesota; Medical College of Wisconsin; Marshfield Clinic Research Foundation; University of Iowa.
- Patient-Centered Outcomes Research Institute, the sponsor, and the people or groups they hire to help perform this research. The sponsor may review your health information to assure the quality of the information used in research.
- The Institutional Review Board (IRB) at The University of Iowa. This group protects the rights and welfare of research volunteers.
- Government/regulatory agencies or its international equivalent, such as the Office of Human Research Protections, whose job is to oversee the conduct of human subject research.
- Members from organizations that provide independent accreditation and oversight of hospitals and research.
- Other research oversight boards, office and support personnel such as accounting and billing (for studies involving compensation); post-approval monitors; study monitors of record; etc.

For this study we will:

- Store your data in a secured way using normal business practices (like using password protected computers, limiting the number of authorized personnel who can see your identifiers, using a code number instead of your name, or removing your identifiers when possible to do so);

- Share your health information only when we must;
- Share only the information that is needed to satisfy the request;
- Request anyone who receives your health information from us to protect your privacy; and
- Not use your name in any publication or presentation of the research results.

Absolute confidentiality cannot be guaranteed because persons outside the research team may need to look at the research records that include your identifying information. Once your information is shared, we cannot promise that it will remain private. Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. They may pass information on to other groups or individuals not named here. If that happens, your information will no longer be protected by the HIPAA privacy laws.

Because we need your permission to use your health information, you cannot participate in this study unless you sign this form. If you choose not to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Refusing to sign won't affect your access to other medical care, your payments, eligibility for benefits, or ability to enroll in any health plans. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Elizabeth Chrischilles, University of Iowa College of Public Health, S424 CPHB, 145 N. Riverside Drive, Iowa City, Iowa, 52242.

If you cancel your permission to use and share your information, you may no longer participate in this research. We may still use and share information that was collected before receiving your cancellation. If we have sent your health information to a third party, such as the research sponsor, or we have removed your identifying information, it may not be possible to prevent its future use.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Your permission to use and share your health information will not expire unless you cancel it.

Can I ask to see the PHI that is collected about me for this research?

The federal HIPAA rules state you have the right to access your medical records. A copy of this research consent/HIPAA authorization form may be placed in your medical record. Additionally, information about medications, tests and other procedures conducted as part of the research study may also be placed in your medical record if relevant to your clinical care, and may be viewed by individuals with access to your medical record (e.g. other health care providers).

Any research information that is placed in your medical record will be kept indefinitely.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Nicholas Rudzianski at 319-335-9783 or toll-free at 866-520-8983. If you experience a research-related injury, please contact: Nicholas Rudzianski 319-335-9783 or toll-free at 866-520-8983.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 05/08/16.

_____ _____

(Signature of Subject) (Date)

---END of the consent form for your medical record information to be used in this study--

We would appreciate it if you would also review the information on the next page and consider whether you want us to use information about you for future studies.

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 201501798
APPROVAL DATE: 05/14/15
EXPIRATION DATE: 05/08/16

FUTURE STUDIES

Researchers at the University of Iowa would like to save the information collected in this study for future research about breast cancer and other topics related to women's health. If you agree, your information might be used in two different ways:

- The researchers at the University of Iowa may share information that is labeled with a code that does not identify you. The people doing research in the future would not know who you are.
- The researchers at the University of Iowa might share your name and contact information with other researchers who would invite you to be in future studies. Before your name and contact information are shared, an institutional review board (IRB) must give their approval. An IRB is a group that evaluates the ethics of research projects to help protect the rights and welfare of volunteers who participate.

Agreeing to the future use of your information is entirely voluntary. You can take part in this breast cancer study even if you decide to not allow your information to be saved for future research. Please indicate your choices below. You can check either "Yes" or "No" to either or both ways to save your information. If you agree now to future use of your information, but decide in the future that you would like to have it removed from future research, you should contact Dr. Elizabeth Chrischilles at 319-384-1575. However, if some research with your information has already been completed, the information from that research may still be used.

I agree that information from this study that does not identify me can be used for research in the future.	☐ Yes ☐ No
I am willing to have my name and contact information given to researchers who might want to contact me about future studies.	☐ Yes ☐ No

Do not sign this form if today's date is on or after EXPIRATION DATE: 05/08/16.

_____
Printed Name

_____ _____
Signature Date

To be completed by research team member only:

Check the method by which consent is being obtained:

☐ Consent is being obtained by mail without a discussion between a research team member and the subject. (Research team member does not sign this document)

☐ Consent is being obtained in person or by mail after a discussion between a research team member and the subject. (Research team member signs below.)

Statement of Person Who Obtained Consent

(This section is only to be signed by a research team member after discussion with subject.)

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person Who Obtained Consent) (Date)

Thank you very much for participating in this study!

- ❒ **If you agreed to Part 2 of the study, make sure you printed and signed your name, and entered the date on Page 27.**
- ❒ **Make sure you indicated your choices for future research, printed and signed your name, and entered the date on Page 28.**
- ❒ **Please keep the copy of the Informed Consent Document that was inserted in this booklet. Do not return the copy – it is for your records.**
- ❒ **Please return this booklet to us in the pre-paid envelope that was included.**
  - ➢ **If you did not receive a pre-paid envelope or it was misplaced, please mail the booklet to:**

Share Thoughts on Breast Cancer Study
College of Public Health
Department of Epidemiology
2136 Westlawn
Iowa City, IA 52242

Please add any comments about this study in the box below:

Other information:

- If you have any questions, please contact Nick Rudzianski at 319-335-9783 or toll-free at 866-520-8983.