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Very little is known about the incidence, onset, time course, and symptomatology of premature menopause induced by breast cancer therapy. No prospective study has been reported. Accrual in the present study was begun on January 1, 1998 but has not reached target numbers, and therefore, accrual has continued. In order to continue following the current cohort, an application has been submitted for additional funding. Preliminary analyses of the 559 current participants have been done.

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Menstrual Cycle Maintenance and Quality of Life after Breast Cancer Treatment: A Prospective Study

Jeanne Petrek, MD

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INTRODUCTION

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE: A PROSPECTIVE STUDY

INTRODUCTION

The frequent morbidity associated with most cancers and their treatments make the measurement of health-related quality of life a critical mechanism for determining the toll of the entire disease. Young breast cancer patients additionally may face treatment-induced menopause and with it may experience hot flashes, mood changes, sleep disturbances, vaginal dryness, and the cascading effect of anxiety and depression. In the United States, Wake Forest University has particular expertise in quality of life with naturally occurring menopause. Wake Forest is the Coordinating Center in this issue for the Women's Health Initiative, funded by the National Institute of Health, which has accrued more than 100,000 study subjects.

Very little is known about the incidence, onset, time course, and symptomatology of premature menopause induced by breast cancer therapy. No prospective study exists. The purpose of the present study is to identify determinants of treatment-related amenorrhea and its effect on quality of life in a cohort of young breast cancer patients.

BODY

STATEMENT OF WORK

Task 1. Months 1-2 - COMPLETED

a) Focus groups for final questionnaire wording

Focus groups were held at Wake Forest University under the direction of Dr. Sally Shumaker, the Principal Investigator of the clinical coordinating center. As well as the wording for the baseline data questionnaires, the proposed procedural sequences were decided with attention to the women's preferences for baseline and follow-up procedures.

See work output in the revised annual report 1998 and 1999. This Manual of Procedures contains more than 200 pages and consists of chapters on organizational structure; protocol; recruitment prescreening and eligibility; consenting process; baseline data collection visits; collecting participant information; chart review forms; study data forms and questionnaires; instructions for menstrual diaries; follow up contacts; data management; and quality control. This assures that the research study procedure is conducted absolutely identically in accruing women throughout the country and over the duration of the study.

Done as first reported in the revised annual report 1998.

b) Pilot calendar and questionnaires in Texas and New York City population

The questionnaires and menstrual bleeding calendars were tested on non-protocol patients in Texas and New York City and were found to be satisfactory. This included follow up forms for baseline data and questionnaires, for six-month follow-up and for one-year follow-up attached in the revised annual report 1998.

Done as first reported in the revised annual report 1998.

c) Hire personnel.

Personnel were hired on schedule and within the budgeted salary amount.

Done as first reported in the revised annual report 1998.

d) Keep lists of potential patients.

Patients were identified from registrations of various services within each of the hospitals: Surgery, Radiation Therapy, Medical Oncology, Psychiatry, Nutrition and General Medicine.

Done as first reported in the revised annual report 1998.

Patients continue to be accrued through lists maintained in the various services within Memorial Sloan-Kettering Cancer Center.

Task 2. Months 2-24

a) Identify and Enroll patients – Time Line Amended

As noted, by September of 1998, 185 patients had been enrolled. This was considerably less than half of the targeted accrual by Month 9 after accrual began and steps were taken to increase the self-referral patients, as noted in the body of the revised annual report 1998.

Task 2: Time Extended

By September 1999, 456 patients had been enrolled in the study. This was less than the original targeted accrual numbers. Lt. Col. J. Pearson of the Office of Regulatory Affairs granted an extension for continued accrual. (attached in 1999 report)

In September 2000, 559 participants were enrolled in the study. To date, recruitment has gone smoothly, although we have encountered a higher than expected ineligibility rate across the participating centers. In our original proposal, we had anticipated 30% ineligibility in women aged 18-45 years due to a hysterectomy, irregular periods, or metastatic disease at diagnosis. In reality, however, our ineligibility rate has been approximately 45-48% across all centers. The primary exclusion criterion has been a prior hysterectomy, which has occurred in approximately 40% of the ineligible potential participants in this age group, particularly among the Southern population. As a result, although we have had a low overall refusal rate of 5-10% among all eligible women, our pool of eligible women has been lower than anticipated. Thus, we have fallen short of our original recruitment goal of 800 participants. Recruitment will continue through the remainder of the year. In order to continue to recruit and follow prospectively a cohort of 800 young women, an application has been submitted for additional funding. (Breast Cancer Center for Excellence Proposal: Quality of Life and Functional Status across the Life Course).

<u>Participant Accrual</u>

Memorial Sloan-Kettering – 381 participants
Wake Forest – 49 participants
MD Anderson/Texas – 129 participants

Current recruitment ended at Wake Forest University and MD Anderson on December 31, 1999, which was the end of their contractual obligations for recruitment. Memorial Sloan-Kettering will continue to recruit through tumor registries, physician referrals, and self-referrals. Wake

Forest and MD Anderson will finish follow up for existing patients but will not recruit. In addition, further strategies have been implemented to recruit referral through physicians at Memorial Sloan-Kettering. One or more of the following strategies continues to be utilized in recruiting participants into the study:

1. Patient Identification through Tumor and Surgical Registries.
   Once women with stage 1-3 breast cancer have been identified, the patients' oncologists/surgeons are contacted by clinic staff to obtain approval to approach the patient. If the physician approves, the patient is approached at the clinic site, or the patient is sent a letter describing the purpose of the study, which will be followed by a telephone call. Approval was obtained from the IRB for permission to make follow up calls to these patients. The clinic staff person will screen the person to ensure she meets the eligibility criteria, and then will ask the patient to participate in the study is she is eligible.

2. Referral through Physicians.
   The clinical center's participating investigators, oncologists, surgeons, and radiologists also identifies participants. In most instances, these physicians will have already explained the study to the participant, and the clinic staff contacts the patient to invite her to participate in the study. The patient is screened to ensure that she meets all eligibility criteria.

3. Self-Referral
   Women may hear about the study through the many strategies that have been implemented to recruit participants nationally. They are screened for study eligibility, and asked to join the study if the eligibility criteria are met. The patients will sign the informed consent, a medical record release, and will complete all baseline study questionnaires.

The Clinical Coordinating Center at the Wake Forest School of Medicine continues to monitor recruitment and issues monthly recruitment reports to each participating institution.

Task 3. Months 8-45

a) Mail out and receive back study calendars and other data instruments.

Questionnaires and menstrual calendars have been received on schedule for 6, 12, 18, 24, and 30-month follow up. (See appendices A-F)

See the next section for current follow-up figures and retention rates.

b) Enter data in ongoing fashion.

Data monitoring and tracking

The Coordinating Center performs editing procedures to ensure the quality of the data collected

by the Clinical Centers. These are as follows: 1) initial screening of the data, using logic and range checks that are built into the data entry system and 2) edits which assess the serial integrity of the data.

Much of the data collected from study subjects comes from regularly scheduled mailings. Time windows have been defined for these scheduled mailings. A tracking system is in place to facilitate on-time collection of data.

c) Crosscheck data and clean.

Adherence and retention rates

Recruitment to this study began January 1, 1998. As of September 2000, 559 participants have been enrolled. To date, 53 participants have been dropped from the protocol (9.8%). This includes 7 participant deaths. Of the surviving 46 patients, reasons for dropping include: lost interest in the study (15 participants), could not be reached after repeated attempts (11), lack of time (7), overwhelmed by treatment and/or family responsibilities (3), and 10 asked to be dropped for miscellaneous reasons (eg. husband asked her to stop participating). Of the 506 active participants, adherence to completing study follow-up forms and bleeding calendars has averaged to 89% and 90% respectively, up through the 18 months assessment point. We attribute these high adherence rates to a detailed tracking system for the receipt of the study forms, and an incentive program to keep people interested in the program. Our tracking system alerts our study project managers when forms are not received by 21 days past their expected return date. This triggers a protocol where patients receive a postcard or telephone call, depending on their adherence history, to remind them of their overdue forms. Our data collector works with the patients to get the forms returned, and to address any concerns patients might have about the protocol and study requirements. Patients are also given the option of completing their calendars or forms on the telephone, if they prefer. Most patients complete follow-up forms by mail, however.

We have also instituted several adherence and retention and incentive strategies to keep women interested in the study. These have included sending all participants birthday cards, and holiday cards in December. A quarterly newsletter is also sent all to all participants, (the most recent spring 2000; Appendix G). This provides participants with the number and state of participants, information about literature related to breast cancer, information about the staff at the participating medical centers, recipes and information shared by our participants. We have also mailed all participants small tokens, such as books, key chains, kitchen magnets, and post-it boards.

In addition, to the above mechanisms, we also have a toll free 800 number for women to call and ask questions about their forms or the study. Participants are also provided with the e-mail addresses our program managers. Adherence rates have increases with the implementation of all these adherence strategies, and we will continue to find ways to retain the study cohort over the course of the follow-up period.

d) Write annual report.

October 1998 Annual Report complete.
October 1998 Annual Report revised.
October 1999 Annual Report complete.
October 2000 Annual Report complete.
October 2001 Final Report in progress.

KEY RESEARCH ACCOMPLISHMENTS

- The result of this research provides much needed longitudinal data on the quality of life of young patients following treatment from breast cancer.
- Analysis of the current data will assist in predicting which chemotherapy programs may be most likely to cause premature menopause following breast cancer treatment.
- Results enable critical questions regarding the risks of childbearing after breast cancer to be addressed.
- This study will provide a foundation for future research in the quality of life of young breast cancer survivors.

PRELIMINARY RESEARCH ACCOMPLISHMENTS

- Analyses have been initiated to examine amenorrhea at 12 months after enrollment. At 12 months post-baseline questionnaire at enrollment, 61% of the patients have had menstrual cycles in months 9-12.
- 45 – 50% of the patients are reporting menopause-related symptoms, primarily hot flashes and vaginal dryness, by the 12-month questionnaire assessment.
- Rates of self-reported arm and hand swelling are increasing over time (24% at 6 months and 30% at 12 months).

REPORTABLE OUTCOMES

Ongoing results of the study were reported at the Era of Hope; Department of Defense Breast Cancer Research Meeting in Atlanta, Georgia held in June 2000. The study was chosen as one of the platform presentations. In addition a poster was presented with statistics similar to those in the previous section. See the abstract for the meeting. (Appendix H).

The study was presented at the American Society of Clinical Oncology Annual meeting in New Orleans, Louisiana held in May 2000. See the abstract (Appendix I).

Additional funding has been applied for to continue to follow prospectively this cohort of 800 young women. (Breast Cancer Center for Excellence Proposal: Quality of Life and Functional Status across the Life Course).

CONCLUSIONS

As of September 2000, 559 have been recruited to the study. The average age of our current participants was 39 years at the time of enrollment. Approximately 86% are Caucasian, 6% are African –American, 4% are Hispanic, 3% are Asian-Pacific Islander, and 1% are Native American. Although only 14% are minorities, this is in line with other national studies. Targeted efforts have been made to recruit minority women, such as media attention in Spanish language and ethnic newspapers (See appendices of 1999 annual report). The women are well educated, with 64% having received at least a four-year college degree. The majority of our participants are married (70%), or living in a marriage-like relationship (5%). Approximately 9% are divorced or separated and 1% are widowed. Fifteen percent of the patients have never been married. Approximately 55% were working full-time at the time of diagnosis, and 13% were working part-time. Only 17% were full-time homemakers, disabled (6%), students (1%), or unemployed (3%). Approximately 70% have children under the age of 18.

Preliminary Data

Stage of cancer at diagnosis was Stage I: 42%, Stage II: 38%, and Stage III: 10%. Only 1% of patients had tumors located in both breasts. Approximately 94% had axillary node dissection. The type of surgery completed was 23% lumpectomy, 52% mastectomy, 23% both lumpectomy and mastectomy, and 2% no surgery. Twenty-eight percent of the patients had immediate reconstructive surgery concurrent with the mastectomy. Chemotherapy alone was administered to 31% of the cohort, (primarily IV Cytoxan and Adriamycin), radiation to 7.5%, and chemotherapy and radiation was received by 56% of the cohort.

At 12 months post-baseline, (for the women who have reached that follow-up time point), 2.5% of the patients have indicated a recurrence in the treated breast or axilla, and an additional 25 have indicated breast cancer metastases in distant sites.

For the majority of patients, improvements in well being, particularly physical and functional well being are being observed between baseline, and 6 and 12 months. However, 45 – 50% of the patients are reporting menopause-related symptoms, primarily hot flashes and vaginal dryness, by the 12-month assessment. Rates of self-reported arm and hand swelling are also increasing over time (24% at 6 months and 30% at 12 months).

Analyses have been initiated to examine amenorrhea at 12 months after enrollment. At 12 months post-baseline questionnaire at enrollment, 61% of the patients have had menstrual cycles in months 9-12. Seven percent had no chemotherapy and received radiation only. In examining, continued menstrual cycling in relation to potential future pregnancy, approximately 31% of the patients had indicated they had wanted a first child, or additional children, 6 months prior to their diagnosis, and an additional 11% of the women were undecided. As of September 2000, 8 participants have reported pregnancies (ie. 3 ended in miscarriages, and 5 women are still pregnant), and 1 other patient gave birth to a healthy baby in May 2000. Based on the rate of

pregnancy that was desired among the cohort at baseline, we estimate, conservatively, that approximately 10 – 15% (n=100) of our sample will attempt to become pregnant as they progress further post-treatment.

References:

Menstrual Cycle Maintenance and Quality of Life After Breast Cancer Treatment: A Prospective Study

None

Appendix A

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE

6-Month Follow-up Survey

Clinical Coordinating Center

Wake Forest University School of Medicine
Department of Public Health Sciences
Winston-Salem, North Carolina 27157-1063
(336) 716-2116

Funded by
The U.S. Army Medical Research and Material Command:
Breast Cancer Research Program A

Patient I.D. __ __ - __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

PART I

MEDICAL and REPRODUCTIVE HISTORY FOLLOW-UP QUESTIONNAIRE

The following questions ask about health professionals you may have seen in the past 6 months. This information will help us describe in general terms the kinds of services being used.

1. In the past six months, which of the following doctors or other health professionals have you seen? **(Please Check all that apply)**

- ☐ None
- ☐ Acupuncturist
- ☐ Allergist
- ☐ Cardiologist
- ☐ Chiropractor
- ☐ Dentist
- ☐ Dermatologist
- ☐ Ear/Nose/Throat Doctor
- ☐ Eye Doctor
- ☐ Marital Counselor
- ☐ Gastroenterologist
- ☐ General Practitioner
- ☐ Gynecologist
- ☐ Infertility Specialist
- ☐ Internist
- ☐ Massage Therapist
- ☐ Neurologist
- ☐ Sexual Therapist
- ☐ Family Therapist
- ☐ Nutritionist
- ☐ Obstetrician
- ☐ Medical Oncologist/Chemotherapist
- ☐ Orthopedic Surgeon
- ☐ Homeopathic/Herbalist/Naturopathic
- ☐ Pain Control Professional
- ☐ Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
- ☐ Physical Therapist
- ☐ Plastic Surgeon
- ☐ Psychiatrist
- ☐ Clinical Psychologist
- ☐ Radiologist
- ☐ Rheumatologist
- ☐ Social Worker
- ☐ Organized Support Group
- ☐ Surgeon
- ☐ Urologist
- ☐ Other: ____________________

2. In the past 6 months, have you been seen at an emergency room?

☐ No

☐ Yes → For what reason: ____

____

3. In the past 6 months, have you been hospitalized or had surgery? Please mark <u>one</u> box for each line item (a) and (b).

	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			

4. Has anything else changed regarding either your mental or physical health status? Please mark <u>one</u> box for each line item (a) and (b).

	No	Yes	What has changed?
(a) Mental Health?			
(b) Physical Health?			

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

5. Have you had any biopsies in the past 6 months?

☐ No

☐ Yes →If yes, what was biopsied?________________________________

Why was this biopsied?________________________________

____

6. In the past 6 months, have you had a recurrence of breast cancer?

☐ No

☐ Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?

____

7. Have you been diagnosed with any other cancer in the past 6 months?

☐ No

☐ Yes → If yes, what type?________________________________

How was this diagnosis made? (For example, biopsy, lab tests)?

____

8. Today's date is: ☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

Patient I.D. ___ - ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

PART II REPRODUCTIVE HISTORY

The following questions ask about your menstrual cycles and reproductive history. We are very interested in this information so that we can understand more about women's health during their childbearing years. Some of the questions ask you to give dates or the number of times when certain things happened. If you are not sure about the exact date or number of times, please give your best estimate.

1. What was the date of the first day of your last menstrual period (your best guess)?

☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

2. In the past 6 months, have you been sexually active with a male partner:

☐ No →Go to question 6
☐ Yes →Go to question 3

3. Which method of birth control are you and your partner using currently? **(Check all that apply.)**

☐ No method
☐ Condoms (rubbers)
☐ Birth control pills
☐ Foams/jellies/suppositories
☐ Sponge
☐ Withdrawal (pulling out)
☐ Diaphragm
☐ Safe periods (rhythm or counting days)
☐ Norplant
☐ Cervical cap
☐ Tubal ligation (tubes tied)
☐ Vasectomy
☐ Other (Please describe: ___________)
☐ Don't know

4. In the past month, how many times have you had sexual intercourse without using contraception?

☐☐ Times

5. In the past 6 months, have you become pregnant?

☐ No
☐ Yes → If yes, are you pregnant now?

☐ No
☐ Yes

6. In the past month, have you had any hot flashes or night sweats (hot flashes that occur during sleep)?

☐ No
☐ Yes ----> If yes, how many have you had in the **past week**?

☐☐☐ hot flashes/night sweats

Patient I.D. ___ - ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

PART III **CURRENT MEDICATIONS**

1. Please list below all of the **prescription medications** you are taking currently. (Write "none" if you are not taking any prescription medications at this time.)

Drug Name	Dosage
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________

2. Please list below all of the **non-prescription medications or supplements** you are taking currently. (Write "none" if are not taking any non-prescription medications or supplements at this time.)

Drug Name	Dosage
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________
______________________	______________________

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

SWELLING FORM

The following questions concern swelling in your arm and/or hand. Please mark the appropriate box(es) for each question.

1. In the past 6 months, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 2)
☐ Don't know → (Go to question 8)

2. Do you believe the start of your swelling was related to any of the following?

Yes	No	Don't Know	
☐	☐	☐	Radiation treatment
☐	☐	☐	Breast reconstruction
☐	☐	☐	Infection or injury to arm / hand
☐	☐	☐	Weather changes
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Airplane travel
☐			Other: Please describe: ______________________

2a. How soon after you had surgery and/or began treatment did this swelling occur?

- ☐ Less than 1 week
- ☐ 1 week to 4 weeks
- ☐ 1 month to 3 months
- ☐ 4 months to 6 months
- ☐ 7 months to 9 months
- ☐ 10 months to 12 months
- ☐ 13 months to 15 months

2b. Where does (did) the swelling occur? **(Check all that apply)**

- ☐ Hand
- ☐ Upper Arm
- ☐ Lower Arm

2c. Do (did) you consider the swelling to be mostly?

- ☐ Mild
- ☐ Moderate
- ☐ Severe

3. Does (did) the swelling interfere with any of the following?

Yes	No	
☐	☐	Clothing that you wear
☐	☐	Your ability to do routine activities, such as household chores or grooming.
☐	☐	Exercise
☐	☐	Your appearance
☐		Other, please describe: ______________________________

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

4. Does (did) swelling seem to get worse with any of the following?

Yes	No	Don't Know	
☐	☐	☐	Hot weather
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Sauna / Jacuzzi / Hot bath
☐	☐	☐	Airplane travel
☐	☐	☐	Specific foods
☐	☐	☐	Mental / emotional stress
☐			Other: Please describe: ______________________________

____

5. Prior to your breast cancer diagnosis, did you notice swelling in your hand and/or arm with any of the following? **(Check all that apply)**

Yes	No	Don't Know	
☐	☐	☐	Exercise
☐	☐	☐	Household Chores
☐	☐	☐	Heat/Humidity
☐	☐	☐	Eating salty foods
☐	☐	☐	Drinking alcoholic beverages
☐			Other: Please describe: ______________________________

____

6. Did you seek treatment for this swelling in the past 6 months?

☐ No → If no, why not?

____

____

☐ Yes → If yes, what type of treatment did you receive? **(Check all that apply)**

- ☐ Compression therapy by machine
- ☐ Glove / Sleeve Compression / Garment
- ☐ Physical therapy
- ☐ Manual lymphatic drainage
- ☐ Bandaging technique
- ☐ Other, please describe: ______________________________

____

7. Do you have swelling now?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 7a)

7a. If yes, how long have you had swelling?

- ☐ Less than 1 week
- ☐ 2 - 4 weeks
- ☐ 1 - 3 months
- ☐ 4 - 6 months
- ☐ 7 - 9 months
- ☐ 10 - 12 months

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

8. In the past 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin injuries in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 9)

☐ Yes → (Continue to question 8a)

☐ Don't Know → (Continue to question 9)

8a. If yes, did you receive antibiotics?

☐ Yes

☐ No

☐ Don't know

9. In the past 6 months, did you have any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 10)

☐ Yes → (Continue to question 9a)

☐ Don't Know → (Continue to question 10)

If yes, did you:

9a. receive antibiotics by mouth?

☐ No

☐ Yes

☐ Don't know

If yes, did you:

9b. receive antibiotics by injection?

☐ No
☐ Yes
☐ Don't know

10. Do you have pain in the affected arm and/or hand? **(Check one box for each site)**

	Yes	No
hand		
arm		
hand and arm		

Patient I.D. ___ - ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___

SYMPTOMS QUESTIONNAIRE

Below are statements about symptoms some people may experience. For each statement, check the appropriate box for the response that best describes how bothersome the symptom was for you **during the past month**. If you did not have the problem, check the box under the column titled "symptom did not occur". Please do not skip any questions. **Mark only one box on each line.**

If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = **symptom did not interfere with usual activities.**
Moderate = **symptom interfered somewhat with usual activities.**
Severe = **symptom was so bothersome that usual activities could not be performed.**

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
1. Fatigue or low energy level				
2. Mouth ulcers				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Lightheadedness when standing up				
9. Faintness or dizziness at rest				
10. Headaches				
11. Swelling of ankles or feet				
12. Diarrhea				

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
13. Constipation				
14. Abdominal pain/cramps				
15. Vaginal dryness				
16. Muscle pain/ache/or cramp				
17. Weight gain				
18. Weight loss				
19. General aches and pains				
20. Hot flashes				
21. Joint pains				
22. Night sweats				
23. Aches in back of neck and skull				
24. Forgetfulness				
25. Difficulty concentrating				
26. Increased appetite				
27. Short temper				
28. Decreased efficiency				
29. Loss of interest in work/activities				
30. Lowered work performance				
31. Blind spots, fuzzy vision				
32. Breast sensitivity/tenderness				
33. Avoidance of social affairs				
34. Cold sweats				
35. Decreased appetite				
36. Feelings of suffocation				
37. Difficulty healing				
38. Bloating				

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

QUALITY OF LIFE FORM

1. In general, would you say your health is: **(Check one)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

3. Climbing several flights of stairs.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		Yes	No
4.	Accomplished less than you would like.	☐	☐
5.	Had difficulty performing the work or other activities, for example, it took extra effort.	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

		Yes	No
6.	Accomplished less than you would like.	☐	☐
7.	Didn't do work or other activities as carefully as usual.	☐	☐

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework and family activities)? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

10. Have you felt calm and peaceful? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

11. Did you have a lot of energy? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

12. Have you felt downhearted and blue? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you *<u>during the past 7 days</u>*.

Physical Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
13. I had a lack of energy.	1	2	3	4	5
14. I had nausea.	1	2	3	4	5
15. I had trouble meeting the needs of my family.	1	2	3	4	5
16. I had pain.	1	2	3	4	5
17. I was bothered by side effects of treatment.	1	2	3	4	5
18. In general, I felt sick.	1	2	3	4	5
19. I was forced to spend time in bed.	1	2	3	4	5

20. How much does your Physical Well-Being affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all — Very Much So

Social/Family Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
21. I felt distant from my friends	1	2	3	4	5
22. I got emotional support from my family.	1	2	3	4	5
23. I got support from my friends and neighbors.	1	2	3	4	5
24. My family had accepted my illness.	1	2	3	4	5
25. Family communication about my illness was poor.	1	2	3	4	5

If you have a spouse/partner, or are sexually active, please answer questions 26-27. Otherwise, go to question 28.

26. I felt close to my partner (or main support).	1	2	3	4	5
27. I was satisfied with my sex life.	1	2	3	4	5

28. How much does your Social/Family Well-Being affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all — Very Much So

Relationship With Doctor	Not At All	A Little Bit	Some-What	Quite a bit	Very Much
29. I had confidence in my doctor(s).	1	2	3	4	5
30. My doctor was available to answer my questions.	1	2	3	4	5

31. How much does your Relationship with your Doctor affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Emotional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
32. I felt sad.	1	2	3	4	5
33. I was proud of how I'm coping with my illness.	1	2	3	4	5
34. I was losing hope in the fight against my illness.	1	2	3	4	5
35. I felt nervous.	1	2	3	4	5
36. I worried about dying.	1	2	3	4	5

37. How much does your Emotional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Functional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
38. I was able to work (include work in home).	1	2	3	4	5
39. My work (include work in home) was fulfilling.	1	2	3	4	5
40. I was able to enjoy life "in the moment."	1	2	3	4	5
41. I had accepted my illness.	1	2	3	4	5
42. I was sleeping well.	1	2	3	4	5
43. I enjoyed my usual leisure pursuits.	1	2	3	4	5
44. I was content with the quality of my life right now.	1	2	3	4	5

45. How much does your Functional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
46. I was short of breath.	1	2	3	4	5
47. I was self-conscious about the way I dressed.	1	2	3	4	5
48. My arms were swollen or tender.	1	2	3	4	5
49. I felt sexually attractive.	1	2	3	4	5
50. I was bothered by hair loss.	1	2	3	4	5
51. I worried about the risk of cancer in other family members.	1	2	3	4	5
52. I worried about the effect of stress on my illness.	1	2	3	4	5
53. I was bothered by a change in weight.	1	2	3	4	5
54. I was able to feel like a woman.	1	2	3	4	5

55. How much do these Additional Concerns affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all — Very Much So

YOUR APPEARANCE

This section asks you about your general perceptions regarding your body. Right now, how satisfied are you with these parts of your body? Please check the appropriate box for the response that best describes your satisfaction with each body part.

	Very dissatisfied	Somewhat dissatisfied	Neutral	Somewhat satisfied	Very satisfied
56. Hair					
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How much do you agree or disagree with the following statement? (Check the appropriate box.)

64. The appearance of my breast area is important to me.

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

65. I view myself as a:

- ☐ Very overweight person
- ☐ Moderately overweight person
- ☐ Normal weight person
- ☐ Moderately thin person
- ☐ Very thin person

PART III. SEXUALITY

These next questions are about the way health problems may interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems may affect women's sexuality.

66. Have you been sexually active with a partner during the last 6 months?

- ☐ No ----> (If no, skip to Question 79).
- ☐ Yes ----> (If yes, continue to Question 67).

67. How many times have you had sexual intercourse in the past month?

- ☐ 0 times
- ☐ 1 - 4 times
- ☐ 5 - 10 times
- ☐ 11 or more

Patient I.D. __ - __ __ - __ __ __ __
Patient Acrostic: __ __ __ __

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Never	**Almost Never**	**Sometimes**	**Almost Always**	**Always**
68. How often were you aware of wetness in your vagina as you became sexually excited?					
69. How often did it take a long time for your vagina to become wet or slippery as you became sexually excited?					
70. During sexual relations, how frequently did you notice dryness of your vagina?					
71. How often did you feel pain or discomfort during vaginal penetration?					
72. How often did you feel satisfied after sexual activity?					
73. How often were you satisfied with the frequency of sexual activity?					
74. How frequently did you feel tense or nervous after a sexual experience?					

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Strongly disagree	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly agree**
75. I avoided having my breast area fondled or kissed.					
76. My partner avoided fondling or kissing my breast area.					
77. I notice I didn't hug or kiss my partner much.					
78. I notice my partner didn't hug and kiss me much.					

PART IV. SLEEP HABITS

The next group of questions ask about your sleep habits. Please check the appropriate box for the one response that best describes how often you experienced these situations in **THE PAST 4 WEEKS**.

79. Did you have trouble falling asleep?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

80. Did you wake up several times a night?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

81. Did you wake up earlier than you planned to?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

82. Did you have trouble getting back to sleep after you woke up too early?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

83. Overall, how was your typical night's sleep during the past 4 weeks?

- ☐ Very sound or restful
- ☐ Sound or restful
- ☐ Average quality
- ☐ Restless
- ☐ Very restless

84. About how many hours of sleep did you get on a typical night during the past 4 weeks?

- ☐ 5 or less hours
- ☐ 6 hours
- ☐ 7 hours
- ☐ 8 hours
- ☐ 9 hours
- ☐ 10 or more hours

PART V. SPIRITUAL BELIEFS

The following questions are about spiritual beliefs. Please check the appropriate box indicating how true the statement has been for you during **THE PAST WEEK.**

	Not at all	A little bit	Somewhat	Quite a bit	Very much
85. I felt peaceful.					
86. I had a reason for living.					
87. I felt a sense of purpose in my life.					
88. I was able to reach down deep into myself for comfort.					
89. I felt a sense of harmony within myself.					
90. I found comfort in my faith.					
91. I found strength in my faith.					

92. Where would you place yourself on the following scale, if "0" means that your life is just the way it was before your breast cancer, "+5" means that everything is totally different but better, and "-5" means that everything is totally different but worse. ***(Please circle ONE number).***

-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
Worse					Same as before					Better

PART VI. EMOTIONAL FEELINGS

The following questions consist of groups of statements. After reading each group of statements carefully, check the box next to the one statement in each group which **best** describes the way you have been feeling **the past week, including today**. If several statements within a group seem to apply equally, check each one. **Be sure to read all the statements in each group before making your choice.**

93. ☐ I do not feel sad.
    ☐ I feel sad.
    ☐ I am sad all the time and I can't snap out of it.
    ☐ I am so sad or unhappy that I can't stand it.

94. ☐ I am not particularly discouraged about the future.
    ☐ I feel discouraged about the future.
    ☐ I feel I have nothing to look forward to.
    ☐ I feel that the future is hopeless and that things cannot improve.

95. ☐ I do not feel like a failure.
    ☐ I feel I have failed more than the average person.
    ☐ As I look back on my life, all I can see is a lot of failures.
    ☐ I feel I am a complete failure as a person.

96. ☐ I get as much satisfaction out of things as I used to.
    ☐ I don't enjoy things the way I used to.
    ☐ I don't get real satisfaction out of anything anymore.
    ☐ I am dissatisfied or bored with everything.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

97. ☐ I don't feel particularly guilty.
☐ I feel guilty a good part of the time.
☐ I feel quite guilty most of the time.
☐ I feel guilty all of the time.

98. ☐ I don't feel I am being punished.
☐ I feel I may be punished.
☐ I expect to be punished.
☐ I feel I am being punished.

99. ☐ I don't feel disappointed in myself.
☐ I am disappointed in myself.
☐ I am disgusted with myself.
☐ I hate myself.

100. ☐ I don't feel I am any worse than anybody else.
☐ I am critical of myself for my weaknesses or mistakes.
☐ I blame myself all the time for my faults.
☐ I blame myself for everything bad that happens.

101. ☐ I don't have any thoughts of killing myself.
☐ I have thoughts of killing myself, but I would not carry them out.
☐ I would like to kill myself.
☐ I would kill myself if I had the chance.

102. ☐ I don't cry anymore than usual.
☐ I cry more now than I used to.
☐ I cry all the time now.
☐ I used to be able to cry, but now I can't cry even though I want to.

103. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

104. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

105. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all anymore.

106. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

107. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

108. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

109. ☐ I don't get more tired than usual.
     ☐ I get tired more easily than I used to.
     ☐ I get tired from doing almost anything.
     ☐ I am too tired to do anything.

110. ☐ My appetite is no worse than usual.
     ☐ My appetite is not as good as it used to be.
     ☐ My appetite is much worse now.
     ☐ I have no appetite at all anymore.

111. ☐ I haven't lost much weight, if any, lately.
     ☐ I have lost more than five (5) pounds.
     ☐ I have lost more than ten (10) pounds.
     ☐ I have lost more than fifteen (15) pounds.

112. ☐ I am no more worried about my health than usual.
     ☐ I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
     ☐ I am very worried about physical problems and it's hard to think of much else.
     ☐ I am so worried about my physical problems that I cannot think about anything else.

113. ☐ I have not noticed any recent change in my interest in sex.
     ☐ I am less interested in sex than I used to be.
     ☐ I am much less interested in sex now.
     ☐ I have lost interest in sex completely.

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

SOCIAL SUPPORT FORM

The following are questions about the support that is available to you.

1. At the present time, about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)? **(Please write the number in the boxes below.)**

☐☐ Number of close friends and close relatives

People sometimes look to others for companionship, assistance, or other types of support. Currently, how often is each of the following kinds of support available to you if you need it? (Check one box for each statement.)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Someone to help you if you were confined to bed.					
3. Someone you can count on to listen to you when you need to talk.					
4. Someone to give you good advice about a crisis.					
5. Someone to take you to the doctor if you needed it.					
6. Someone who shows you love and affection.					
7. Someone to have a good time with.					
8. Someone to give you information to help you understand a situation.					
9. Someone to confide in or talk to about yourself or your problems.					

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
10. Someone who hugs you.					
11. Someone to get together with for relaxation.					
12. Someone to prepare your meals if you were unable to do it yourself.					
13. Someone whose advice you really want.					
14. Someone to do things with to help you get your mind off things.					
15 Someone to help with daily chores if you were sick.					
16. Someone to share your most private worries and fears with.					
17. Someone to turn to for suggestions about how to deal with a personal problem.					
18. Someone to do something enjoyable with.					
19. Someone who understands your problems.					
20. Someone to love you and make you feel wanted.					

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

For the following questions, please check the box that is the most true for you at the present time. (Check only one box for each statement.)

Of the people who are important to you, how many:

	None	One	Some	Most	All
21. Don't understand you.					
22. Get on your nerves.					
23. Ask too much of you.					
24. Argue with you.					
25. Don't include you.					
26. Show that they don't like you.					
27. Boss you.					
28. Try to get you to do things you don't want to do.					

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

PERSONAL HABITS FORM

These questions are about habits that may affect your health (smoking, alcohol use, weight, and exercise). Please answer each question as accurately as possible.

1. Do you smoke currently?

   ☐ No
   ☐ Yes

   If yes, how many cigarettes do you smoke per day? (1 pack = 20 cigarettes)

   ☐ I smoke occasionally.
   ☐ 0 - 5 cigarettes a day
   ☐ 6 - 20 cigarettes a day
   ☐ 21 - 30 cigarettes a day
   ☐ 31 - 40 cigarettes a day
   ☐ more than 40 cigarettes a day

2. Do you currently drink alcoholic beverages?

   ☐ No
   ☐ Yes

   If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currently drink in an average month?

   ☐☐☐ Beverages per month

3. What is your current weight?

☐☐☐ pounds

The following questions are about your usual physical activity and exercise. This includes walking and sports.

4. Think about the walking you do outside the home. In the past month, how often did you walk outside the home for more than 10 minutes without stopping? **(Mark only one.)**

☐	Rarely or never	--->	(Go to Question 5)
☐	1-3 times each month	--->	(Go to Question 4a)
☐	1 time each week	--->	(Go to Question 4a)
☐	2-3 times each week	--->	(Go to Question 4a)
☐	4-6 times each week	--->	(Go to Question 4a)
☐	7 or more times each week	--->	(Go to Question 4a)

4a. When you walked outside the home for more than 10 minutes without stopping, how many minutes did you usually walk?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

4b. What was your usual speed?

- ☐ Casual strolling or walking (less than 2 miles an hour)
- ☐ Average or normal (2-3 miles an hour)
- ☐ Fairly fast (3-4 miles an hour)
- ☐ Very fast (more than 4 miles an hour)
- ☐ Don't Know

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___

Following are three categories of exercise, (strenuous, moderate, and mild). Not including walking outside the home, how often each week (7 days) do you usually do the following strenuous, moderate, and mild types of exercise?

5. **STRENUOUS OR VERY HARD EXERCISE.** (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

- ☐ None ---> (Go to Question 6)
- ☐ 1 day per week ---> (Go to Question 5a)
- ☐ 2 days per week ---> (Go to Question 5a)
- ☐ 3 days per week ---> (Go to Question 5a)
- ☐ 4 days per week ---> (Go to Question 5a)
- ☐ 5 or more days per week ---> (Go to question 5a)

5a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

6. **MODERATE EXERCISE** (Not exhausting). For example, biking outdoors, using an exercise machine (like a stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

- ☐ None ---> (Go to Question 7)
- ☐ 1 day per week ---> (Go to Question 6a)
- ☐ 2 days per week ---> (Go to Question 6a)
- ☐ 3 days per week ---> (Go to Question 6a)
- ☐ 4 days per week ---> (Go to Question 6a)
- ☐ 5 or more days per week ---> (Go to Question 6a)

6a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

7. **MILD EXERCISE**. For example, slow dancing, bowling, golf.

☐	None		
☐	1 day per week	--->	(Go to Question 7a)
☐	2 days per week	--->	(Go to Question 7a)
☐	3 days per week	--->	(Go to Question 7a)
☐	4 days per week	--->	(Go to Question 7a)
☐	5 or more days per week	--->	(Go to Question 7a)

7a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

CONTACT INFORMATION FORM

We would like you to update your contact information so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. **Has your address changed since our last mailing to you?**

   ☐ No ☐ **Yes → <u>If yes,</u> please provide current mailing address**

   Your Current Mailing Address?

   ____

   ____

   ____

2. Telephone Numbers: Home: Area Code (__ __ __) __ __ __ - __ __ __ __

   Work: Area Code (__ __ __) __ __ __ - __ __ __ __

   Other: Area Code (__ __ __) __ __ __ - __ __ __ __

3. When is the best time to contact you? Where is the best place to contact you?

   ______________ ______________
   Day of week time(s)

   ☐ At home
   ☐ At work
   ☐ Other

   ______________ ______________
   Day of week time(s)

   ☐ At home
   ☐ At work
   ☐ Other

4. In case we might ever need to contact you by telephone, may we leave a message for you on your answering machine, (if you have one), if we are unable to reach you directly?

- ☐ No
- ☐ Yes

5. What is your husband's or partner's legal name? (This information will help us keep in contact with you during the study. Please leave this blank if you are not currently married or with a long-term partner.)

____________________ ______ ____________________

First MI Last

6. Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we are unable to reach you.

Name: ____

Address: ____

____

Phone Number: Area Code (_ _ _) _ _ _ - _ _ _ _

Relationship to you:____

Name: ____

Address: ____

____

Phone Number: Area Code (_ _ _) _ _ _ - _ _ _ _

Relationship to you:____

Appendix B

MENSTRUAL CYCLE MAINTENANCE
AND
QUALITY OF LIFE

One-Year Follow-up Survey

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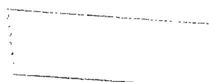
The U.S. Army Medical Research and Material Command:
Breast Cancer Research Program A



Patient I.D. ___ ___ - ___ ___ ___ ___
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DEMOGRAPHIC FOLLOW-UP FORM

YOUR BACKGROUND

The following questions are about your background. We would like to see if you have had any changes in your personal situation in the past year. Please mark the appropriate box for each question.

1. What is your marital status?

☐ Never married
☐ Presently married
☐ Living in a marriage-like relationship
☐ Divorced
☐ Separated
☐ Widowed

2. Which category below best describes the <u>highest</u> level of formal education you have completed? (*Choose the one best answer*).

☐ No formal education
☐ Grade school (1st through 8th grade)
☐ Some high school (9th through 11th grade)
☐ High school diploma or G.E.D.
☐ Business or vocational training school after high school graduation
☐ Some college (but a college degee was not obtained)
☐ Associate Degree (A.D. or A.A.)
☐ College graduate or Baccalaureate Degree (B.A. or B.S.)
☐ Some college or professional school after college graduation
☐ Master's Degree
☐ Doctoral Degree (Ph.D., M.D., J.D., D.D.S., etc.)

3. What was your total family income (before taxes) from all sources last year? (Check one box below. This information is important for describing the women in the study as a group and is kept strictly confidential).

- ☐ Less than $10,000
- ☐ $10,000 to $19,999
- ☐ $20,000 to $34,999
- ☐ $35,000 to $49,999
- ☐ $50,000 to $74,999
- ☐ $75,000 to $100,000
- ☐ More than $100,000

4. What type of health insurance do you have? (If you have more than one type of insurance, please mark the box for your primary source of insurance.*)*

- ☐ HMO
- ☐ Group Health Insurance
- ☐ V.A./Military Sponsored
- ☐ Individual Health Insurance (includes CHAMPUS)
- ☐ Medicaid
- ☐ Disability Insurance
- ☐ None
- ☐ Other (Please list: ______________________________)

5. What is your current employment status? (*Check the box that best describes you.)*

- ☐ Unemployed/Looking for work → (Go to question 8)
- ☐ Retired → (Go to question 8)
- ☐ Full-time Homemaker → (Go to question 8)
- ☐ Employed - full-time → (Go to question 6)
- ☐ Employed - part-time → (Go to question 6)
- ☐ Disabled, unable to work → (Go to question 8)
- ☐ Student → (Go to question 8)
- ☐ Other (Please list: ______________________________) → (Go to question 8)

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6. If you are employed, which category best describes your occupation?

- ☐ **Professional, Technical & Related Occupations** (such as teachers/professors, nurses, lawyers, physicians & engineers)
- ☐ **Managers, Administrators, or Proprietors** (such as sales managers, real estate agents, or postmasters)
- ☐ **Clerical & Related Occupations** (such as secretaries, clerks or mail carriers)
- ☐ **Sales Occupations** (such as salespersons, demonstrators, agents and brokers)
- ☐ **Service Occupations** (such as police, cooks, or hairdressers)
- ☐ **Skilled Crafts, Service Repair Persons, & Related Occupations** (such as carpenters, appliance repair, or telephone line workers)
- ☐ **Equipment or Vehicle Operators & Related Occupations** (such as drivers, railroad brakemen or sewer workers)
- ☐ **Laborers** (such as helpers, longshoremen, or warehouse workers)
- ☐ **Farmers** (owners, managers, operators or tenants)
- ☐ **Members of the military**
- ☐ **Other** (please describe): ____________________________

7. This following is a list of employment issues that a person might have. For each statement, indicate whether this has happened to you since your diagnosis. If it did occur, indicate whether you believe this situation was related to your diagnosis. (Check the box by the answers that are most true for you in each statement.)

Since your diagnosis have you:

a. believed you could not change jobs for fear of losing your health insurance?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

b. lost your health insurance due to sick leave?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

c. been fired or laid off?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

d. been demoted?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

e. been denied a promotion?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

f. been denied a wage increase?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

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g. had your work responsibilities limited unnecessarily?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

h. been promoted?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

8. This following is a list of insurance issues that a person might have. For each statement, indicate whether this has happened to you since your diagnosis. If it did occur, indicate whether you believe this situation was related to your diagnosis. (Check the box by the answers that are most true for you in each statement.)

Since your diagnosis have:

a. you been denied health insurance?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

b. you been denied life insurance?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

c. your health insurance rates increased?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

d. your life insurance rates increased?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

e. you had a health benefit payment denied?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

f. you had trouble changing from group health to individual health insurance?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

9. Please give the date you completed this form: ☐☐ / ☐☐ / ☐☐☐☐
   Month / Day / Year

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PART 1

MEDICAL & REPRODUCTIVE HISTORY
FOLLOW-UP QUESTIONNAIRE

The following questions ask about health professionals you may have seen in the past 6 months. This information will help us describe in general terms the kinds of services being used.

1. In the past six months, which of the following doctors or other health professionals have you seen? **(Please Check all that apply)**

- ☐ None
- ☐ Acupuncturist
- ☐ Allergist
- ☐ Cardiologist
- ☐ Chiropractor
- ☐ Dentist
- ☐ Dermatologist
- ☐ Ear/Nose/Throat Doctor
- ☐ Eye Doctor
- ☐ Marital Counselor
- ☐ Gastroenterologist
- ☐ General Practitioner
- ☐ Gynecologist
- ☐ Infertility Specialist
- ☐ Internist
- ☐ Massage Therapist
- ☐ Neurologist
- ☐ Sexual Therapist
- ☐ Family Therapist
- ☐ Nutritionist
- ☐ Obstetrician
- ☐ Medical Oncologist/Chemotherapist
- ☐ Orthopedic Surgeon
- ☐ Homeopathic/Herbalist/Naturopathic
- ☐ Pain Control Professional
- ☐ Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
- ☐ Physical Therapist
- ☐ Plastic Surgeon
- ☐ Psychiatrist
- ☐ Clinical Psychologist
- ☐ Radiologist
- ☐ Rheumatologist
- ☐ Social Worker
- ☐ Organized Support Group
- ☐ Surgeon
- ☐ Urologist
- ☐ Other:____________________

2. In the past 6 months, have you been seen at an emergency room?

☐ No

☐ Yes → For what reason: ____________________

____

3. In the past 6 months, have you been hospitalized or had surgery? Please mark <u>one</u> box for each line item (a) and (b).

	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			

4. Has anything else changed regarding either your mental or physical health status? Please mark <u>one</u> box for each line item (a) and (b).

	No	Yes	What has changed?
(a) Mental Health?			
(b) Physical Health?			

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5. Have you had any biopsies in the past 6 months?

☐ No

☐ Yes →If yes, what was biopsied?______________________________

Why was this biopsied?______________________________

____

6. In the past 6 months, have you had a re-occurrence of breast cancer?

☐ No

☐ Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?

____

7. Have you been diagnosed with any other cancer in the past 6 months?

☐ No

☐ Yes → If yes, what type?______________________________

How was this diagnosis made? (For example, biopsy, lab tests)?

____

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PART II **REPRODUCTIVE HISTORY**

The following questions ask about your menstrual cycles and reproductive history. We are very interested in this information so that we can understand more about women's health during their childbearing years. Some of the questions ask you to give dates or the number of times when certain things happened. If you are not sure about the exact date or number of times, please give your best estimate.

1. What was the date of the first day of your last menstrual period (your best guess)?

☐☐-☐☐-☐☐☐☐
Month Day Year

2. In the past 6 months, have you been sexually active with a male partner:

☐ No →Go to question 6
☐ Yes →Go to question 3

3. Which method of birth control are you and your partner using currently? **(Check all that apply.)**

☐ No method
☐ Condoms (rubbers)
☐ Birth control pills
☐ Foams/jellies/suppositories
☐ Sponge
☐ Withdrawal (pulling out)
☐ Diaphragm
☐ Safe periods (rhythm or counting days)
☐ Norplant
☐ Cervical cap
☐ Tubal ligation (tubes tied)
☐ Vasectomy
☐ Other (Please describe:___________)
☐ Don't know

4. In the past month, how many times have you had sexual intercourse without using contraception?

☐☐ Times

5. In the past 6 months, have you become pregnant?

☐ No
☐ Yes → If yes, are you pregnant now?

☐ No
☐ Yes

6. In the past month, have you had any hot flashes or night sweats (hot flashes that occur during sleep)?

☐ No
☐ Yes ----> If yes, how many have you had in the **past week**?

☐☐☐ hot flashes/night sweats

FAMILY HISTORY UPDATE

Please update the following grid about the **history of breast cancer** among your female relatives. If you do not have a full-blooded relative in one of the categories listed below, please leave that line blank. (MARK ONLY ONE BOX PER LINE.)

1. Did this relative have breast cancer?

	No	**Yes**			**Don't know if she had breast cancer**	**Does Not Apply**
		How old was she when her first breast cancer occurred?				
		Less than 45	45 or older	Don't know age		
a. Mother	☐	☐	☐	☐	☐	☐
b. Sister 1	☐	☐	☐	☐	☐	☐
c. Sister 2	☐	☐	☐	☐	☐	☐
d. Sister 3	☐	☐	☐	☐	☐	☐
e. Sister 4	☐	☐	☐	☐	☐	☐
f. Daughter 1	☐	☐	☐	☐	☐	☐
g. Daughter 2	☐	☐	☐	☐	☐	☐
h. Daughter 3	☐	☐	☐	☐	☐	☐
I. Daughter 4	☐	☐	☐	☐	☐	☐
j. Maternal grandmother (your mother's mother)	☐	☐	☐	☐	☐	☐
k. Paternal grandmother (your father's mother)	☐	☐	☐	☐	☐	☐

Please update the following grid about the **history of ovarian cancer** among your female relatives. If you do not have a full-blooded relative in one of the categories listed below, please leave that line blank. (MARK ONLY ONE BOX PER LINE.)

2. Did this relative have ovarian cancer?

	No	**Yes** — How old was she when her first ovarian cancer occurred? Less than 45	45 or older	Don't know age	**Don't know if she had ovarian cancer**	**Does Not Apply**
a. Mother	☐	☐	☐	☐	☐	☐
b. Sister 1	☐	☐	☐	☐	☐	☐
c. Sister 2	☐	☐	☐	☐	☐	☐
d. Sister 3	☐	☐	☐	☐	☐	☐
e. Sister 4	☐	☐	☐	☐	☐	☐
f. Daughter 1	☐	☐	☐	☐	☐	☐
g. Daughter 2	☐	☐	☐	☐	☐	☐
h. Daughter 3	☐	☐	☐	☐	☐	☐
I. Daughter 4	☐	☐	☐	☐	☐	☐
j. Maternal grandmother (your mother's mother)	☐	☐	☐	☐	☐	☐
k. Paternal grandmother (your father's mother)	☐	☐	☐	☐	☐	☐

Patient I.D. ___ ___ - ___ ___ ___ ___

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CURRENT MEDICATIONS

1. Please list below all of the **prescription medications** you are taking currently. (Write "none" if you are not taking any prescription medications at this time.)

Drug Name	Dosage

2. Please list below all of the **non-prescription medications or supplements** you are taking currently. (Write "none" if are not taking any non-prescription medications or supplements at this time.)

Drug Name	Dosage

Patient I.D. __ __ - __ __ __ __

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TREATMENT EXPECTATIONS

1. We are interested in your expectations regarding the treatments you received over the past year. For each of the treatments listed below, how did your expectations before treatment compare with the actual treatment you received? Better than expected, the same as you expected, or worse than you expected? (Mark one box for each line.)

	Not Applicable. (Did not have this treatment.)	**Worse Than Expected**	**Same As Expected**	**Better Than Expected**
Lumpectomy				
Mastectomy				
Reconstructive Surgery				
Radiation				
Chemotherapy				
Tamoxifen				
Bone Marrow Transplant				

Patient I.D. ___ ___ - ___ ___ ___ ___

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SWELLING FORM

The following questions concern swelling in your arm and/or hand. Please mark the appropriate box(es) for each question.

1. In the past 6 months, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

   ☐ No → (Go to question 8)
   ☐ Yes → (Continue to question 2)
   ☐ Don't know → (Go to question 8)

2. Do you believe the start of your swelling was related to any of the following?

Yes	No	Don't Know	
☐	☐	☐	Radiation treatment
☐	☐	☐	Breast reconstruction
☐	☐	☐	Infection or injury to arm / hand
☐	☐	☐	Weather changes
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Airplane travel
☐			Other: Please describe: ________________

2a. How soon after you had surgery and/or began treatment did this swelling occur?

- ☐ Less than 1 week
- ☐ 1 week to 4 weeks
- ☐ 1 month to 3 months
- ☐ 4 months to 6 months
- ☐ 7 months to 9 months
- ☐ 10 months to 12 months
- ☐ 13 months to 15 months

2b. Where does (did) the swelling occur? **(Check all that apply)**

- ☐ Hand
- ☐ Upper Arm
- ☐ Lower Arm

2c. Do (did) you consider the swelling to be mostly?

- ☐ Mild
- ☐ Moderate
- ☐ Severe

3. Does (did) the swelling interfere with any of the following?

Yes	No	
☐	☐	Clothing that you wear
☐	☐	Your ability to do routine activities, such as household chores or grooming.
☐	☐	Exercise
☐	☐	Your appearance
☐		Other, please describe: ______________________

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4. Does (did) swelling seem to get worse with any of the following?

Yes	No	Don't Know	
☐	☐	☐	Hot weather
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Sauna / Jacuzzi / Hot bath
☐	☐	☐	Airplane travel
☐	☐	☐	Specific foods
☐	☐	☐	Mental / emotional stress
☐			Other: Please describe: ______________________

5. Prior to your breast cancer diagnosis, did you notice swelling in your hand and/or arm with any of the following? **(Check all that apply)**

Yes	No	Don't Know	
☐	☐	☐	Exercise
☐	☐	☐	Household Chores
☐	☐	☐	Heat/Humidity
☐	☐	☐	Eating salty foods
☐	☐	☐	Drinking alcoholic beverages
☐			Other: Please describe: ______________________

6. Did you seek treatment for this swelling in the past 6 months?

☐ No → If no, why not?

____

____

☐ Yes → If yes, what type of treatment did you receive? **(Check all that apply)**

- ☐ Compression therapy by machine
- ☐ Glove / Sleeve Compression / Garment
- ☐ Physical therapy
- ☐ Manual lymphatic drainage
- ☐ Bandaging technique
- ☐ Other, please describe: ______________________________

____

7. Do you have swelling now?

☐ No → (Go to question 8)

☐ Yes → (Continue to question 7a)

7a. If yes, how long have you had swelling?

- ☐ Less than 1 week
- ☐ 2 - 4 weeks
- ☐ 1 - 3 months
- ☐ 4 - 6 months
- ☐ 7 - 9 months
- ☐ 10 - 12 months

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8. In the past 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin injuries in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No→ (Go to question 9)

☐ Yes → (Continue to question 8a)

☐ Don't Know → (Continue to question 9)

8a. If yes, did you receive antibiotics?

☐ Yes

☐ No

☐ Don't know

9. In the past 6 months, did you have any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No→ (Go to question 10)

☐ Yes → (Continue to question 9a)

☐ Don't Know → (Continue to question 10)

If yes, did you:

9a. receive antibiotics by mouth?

☐ No

☐ Yes → (Continue to question 9b)

☐ Don't know

If yes, did you:

9b. receive antibiotics by injection?

☐ No
☐ Yes
☐ Don't know

10. Do you have pain in the affected arm and/or hand? **(Check one box for each site)**

	Yes	No
hand		
arm		

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SYMPTOMS QUESTIONNAIRE

Below are statements about symptoms some people may experience. For each statement, check the appropriate box for the response that best describes how bothersome the symptom was for you **during the past month**. If you did not have the problem, check the box under the column titled "symptom did not occur". Please do not skip any questions. **Mark only one box on each line.**

If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = **symptom did not interfere with usual activities.**
Moderate = **symptom interfered somewhat with usual activities.**
Severe = **symptom was so bothersome that usual activities could not be performed.**

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
1. Fatigue or low energy level				
2. Mouth ulcers				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Lightheadedness when standing up				
9. Faintness or dizziness at rest				
10. Headaches				
11. Swelling of ankles or feet				
12. Diarrhea				

Symptom	Symptom did not occur	Symptom Occurred and Was: Mild	Moderate	Severe
13. Constipation				
14. Abdominal pain/cramps				
15. Vaginal dryness				
16. Muscle pain/ache/or cramp				
17. Weight gain				
18. Weight loss				
19. General aches and pains				
20. Hot flashes				
21. Joint pains				
22. Night sweats				
23. Aches in back of neck and skull				
24. Forgetfulness				
25. Difficulty concentrating				
26. Increased appetite				
27. Short temper				
28. Decreased efficiency				
29. Loss of interest in work/activities				
30. Lowered work performance				
31. Blind spots, fuzzy vision				
32. Breast sensitivity/tenderness				
33. Avoidance of social affairs				
34. Cold sweats				
35. Decreased appetite				
36. Feelings of suffocation				
37. Difficulty healing				
38. Bloating				

Patient I.D. __ __ - __ __ __ __ __

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QUALITY OF LIFE FORM

1. In general, would you say your health is: **(Check one)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

3. Climbing several flights of stairs.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like.	☐	☐
5. Had difficulty performing the work or other activities, for example, it took extra effort.	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like.	☐	☐
7. Didn't do work or other activities as carefully as usual.	☐	☐

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework and family activities)? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

10. Have you felt calm and peaceful? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

11. Did you have a lot of energy? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

12. Have you felt downhearted and blue? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

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Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you *during the past 7 days*.

Physical Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
13. I had a lack of energy.	1	2	3	4	5
14. I had nausea.	1	2	3	4	5
15. I had trouble meeting the needs of my family.	1	2	3	4	5
16. I had pain.	1	2	3	4	5
17. I was bothered by side effects of treatment.	1	2	3	4	5
18. In general, I felt sick.	1	2	3	4	5
19. I was forced to spend time in bed.	1	2	3	4	5

20. How much does your Physical Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Social/Family Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
21. I felt distant from my friends	1	2	3	4	5
22. I got emotional support from my family.	1	2	3	4	5
23. I got support from my friends and neighbors.	1	2	3	4	5
24. My family had accepted my illness.	1	2	3	4	5
25. Family communication about my illness was poor.	1	2	3	4	5

If you have a spouse/partner, or are sexually active, please answer questions 26-27. Otherwise, go to question 28.

26. I felt close to my partner (or main support).	1	2	3	4	5
27. I was satisfied with my sex life.	1	2	3	4	5

28. How much does your Social/Family Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Relationship With Doctor	Not At All	A Little Bit	Some-What	Quite a bit	Very Much
29. I had confidence in my doctor(s).	1	2	3	4	5
30. My doctor was available to answer my questions.	1	2	3	4	5

31. How much does your Relationship with your Doctor affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Emotional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
32. I felt sad.	1	2	3	4	5
33. I was proud of how I'm coping with my illness.	1	2	3	4	5
34. I was losing hope in the fight against my illness.	1	2	3	4	5
35. I felt nervous.	1	2	3	4	5
36. I worried about dying.	1	2	3	4	5

37. How much does your Emotional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Functional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
38. I was able to work (include work in home).	1	2	3	4	5
39. My work (include work in home) was fulfilling.	1	2	3	4	5
40. I was able to enjoy life "in the moment."	1	2	3	4	5
41. I had accepted my illness.	1	2	3	4	5
42. I was sleeping well.	1	2	3	4	5
43. I enjoyed my usual leisure pursuits.	1	2	3	4	5
44. I was content with the quality of my life right now.	1	2	3	4	5

45. How much does your Functional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
46. I was short of breath.	1	2	3	4	5
47. I was self-conscious about the way I dressed.	1	2	3	4	5
48. My arms were swollen or tender.	1	2	3	4	5
49. I felt sexually attractive.	1	2	3	4	5
50. I was bothered by hair loss.	1	2	3	4	5
51. I worried about the risk of cancer in other family members.	1	2	3	4	5
52. I worried about the effect of stress on my illness.	1	2	3	4	5
53. I was bothered by a change in weight.	1	2	3	4	5
54. I was able to feel like a woman.	1	2	3	4	5

55. How much do these Additional Concerns affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

YOUR APPEARANCE

This section asks you about your general perceptions regarding your body. Right now, how satisfied are you with these parts of your body? Please check the appropriate box for the response that best describes your satisfaction with each body part.

	Very dissatisfied	Somewhat dissatisfied	Neutral	Somewhat satisfied	Very satisfied
56. Hair					
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How much do you agree or disagree with the following statement? (Check the appropriate box.)

64. The appearance of my breast area is important to me.

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

65. I view myself as a:

☐ Very overweight person
☐ Moderately overweight person
☐ Normal weight person
☐ Moderately thin person
☐ Very thin person

PART III. SEXUALITY

These next questions are about the way health problems may interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems may affect women's sexuality.

66. Have you been sexually active with a partner during the last 6 months?

☐ No ----> (If no, skip to Question 79).
☐ Yes ----> (If yes, continue to Question 67).

67. How many times have you had sexual intercourse in the past month?

☐ 0 times
☐ 1 - 4 times
☐ 5 - 10 times
☐ 11 or more

Patient I.D. __ __ - __ __ __ __ __
Patient Acrostic: __ __ __ __ __ __

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Never	Almost Never	Sometimes	Almost Always	Always
68. How often were you aware of wetness in your vagina as you became sexually excited?					
69. How often did it take a long time for your vagina to become wet or slippery as you became sexually excited?					
70. During sexual relations, how frequently did you notice dryness of your vagina?					
71. How often did you feel pain or discomfort during vaginal penetration?					
72. How often did you feel satisfied after sexual activity?					
73. How often were you satisfied with the frequency of sexual activity?					
74. How frequently did you feel tense or nervous after a sexual experience?					

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
75. I avoided having my breast area fondled or kissed.					
76. My partner avoided fondling or kissing my breast area.					
77. I notice I didn't hug or kiss my partner much.					
78. I notice my partner didn't hug and kiss me much.					

PART IV. SLEEP HABITS

The next group of questions ask about your sleep habits. Please check the appropriate box for the one response that best describes how often you experienced these situations in **THE PAST 4 WEEKS**.

79. Did you have trouble falling asleep?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

80. Did you wake up several times a night?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

81. Did you wake up earlier than you planned to?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

82. Did you have trouble getting back to sleep after you woke up too early?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

Patient I.D. ___ ___ - ___ ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

83. Overall, how was your typical night's sleep during the past 4 weeks?

- ☐ Very sound or restful
- ☐ Sound or restful
- ☐ Average quality
- ☐ Restless
- ☐ Very restless

84. About how many hours of sleep did you get on a typical night during the past 4 weeks?

- ☐ 5 or less hours
- ☐ 6 hours
- ☐ 7 hours
- ☐ 8 hours
- ☐ 9 hours
- ☐ 10 or more hours

PART V. SPIRITUAL BELIEFS

The following questions are about spiritual beliefs. Please check the appropriate box indicating how true the statement has been for you during **THE PAST WEEK.**

	Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
85. I felt peaceful.					
86. I had a reason for living.					
87. I felt a sense of purpose in my life.					
88. I was able to reach down deep into myself for comfort.					
89. I felt a sense of harmony within myself.					
90. I found comfort in my faith.					
91. I found strength in my faith.					

92. Where would you place yourself on the following scale, if "0" means that your life is just the way it was before your breast cancer, "+5" means that everything is totally different but better, and "-5" means that everything is totally different but worse. ***(Please circle ONE number).***

-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
Worse					Same as before					Better

PART VI. EMOTIONAL FEELINGS

The following questions consist of groups of statements. After reading each group of statements carefully, check the box next to the one statement in each group which **best** describes the way you have been feeling **the past week, including today**. If several statements within a group seem to apply equally, check each one. **Be sure to read all the statements in each group before making your choice.**

93. ☐ I do not feel sad.
    ☐ I feel sad.
    ☐ I am sad all the time and I can't snap out of it.
    ☐ I am so sad or unhappy that I can't stand it.

94. ☐ I am not particularly discouraged about the future.
    ☐ I feel discouraged about the future.
    ☐ I feel I have nothing to look forward to.
    ☐ I feel that the future is hopeless and that things cannot improve.

95. ☐ I do not feel like a failure.
    ☐ I feel I have failed more than the average person.
    ☐ As I look back on my life, all I can see is a lot of failures.
    ☐ I feel I am a complete failure as a person.

96. ☐ I get as much satisfaction out of things as I used to.
    ☐ I don't enjoy things the way I used to.
    ☐ I don't get real satisfaction out of anything anymore.
    ☐ I am dissatisfied or bored with everything.

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

97. ☐ I don't feel particularly guilty.
 ☐ I feel guilty a good part of the time.
 ☐ I feel quite guilty most of the time.
 ☐ I feel guilty all of the time.

98. ☐ I don't feel I am being punished.
 ☐ I feel I may be punished.
 ☐ I expect to be punished.
 ☐ I feel I am being punished.

99. ☐ I don't feel disappointed in myself.
 ☐ I am disappointed in myself.
 ☐ I am disgusted with myself.
 ☐ I hate myself.

100. ☐ I don't feel I am any worse than anybody else.
 ☐ I am critical of myself for my weaknesses or mistakes.
 ☐ I blame myself all the time for my faults.
 ☐ I blame myself for everything bad that happens.

101. ☐ I don't have any thoughts of killing myself.
 ☐ I have thoughts of killing myself, but I would not carry them out.
 ☐ I would like to kill myself.
 ☐ I would kill myself if I had the chance.

102. ☐ I don't cry anymore than usual.
 ☐ I cry more now than I used to.
 ☐ I cry all the time now.
 ☐ I used to be able to cry, but now I can't cry even though I want to.

103. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

104. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

105. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all anymore.

106. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

107. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

108. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

109. ☐ I don't get more tired than usual.
☐ I get tired more easily than I used to.
☐ I get tired from doing almost anything.
☐ I am too tired to do anything.

110. ☐ My appetite is no worse than usual.
☐ My appetite is not as good as it used to be.
☐ My appetite is much worse now.
☐ I have no appetite at all anymore.

111. ☐ I haven't lost much weight, if any, lately.
☐ I have lost more than five (5) pounds.
☐ I have lost more than ten (10) pounds.
☐ I have lost more than fifteen (15) pounds.

112. ☐ I am no more worried about my health than usual.
☐ I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
☐ I am very worried about physical problems and it's hard to think of much else.
☐ I am so worried about my physical problems that I cannot think about anything else.

113. ☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

Patient I.D. __ __ - __ __ __ __ __

Patient Acrostic: __ __ __ __ __ __

SOCIAL SUPPORT FORM

The following are questions about the support that is available to you.

1. At the present time, about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)? **(Please write the number in the boxes below.)**

☐☐ Number of close friends and close relatives

People sometimes look to others for companionship, assistance, or other types of support. Currently, how often is each of the following kinds of support available to you if you need it? (Check one box for each statement.)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Someone to help you if you were confined to bed.					
3. Someone you can count on to listen to you when you need to talk.					
4. Someone to give you good advice about a crisis.					
5. Someone to take you to the doctor if you needed it.					
6. Someone who shows you love and affection.					
7. Someone to have a good time with.					
8. Someone to give you information to help you understand a situation.					
9. Someone to confide in or talk to about yourself or your problems.					

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
10. Someone who hugs you.					
11. Someone to get together with for relaxation.					
12. Someone to prepare your meals if you were unable to do it yourself.					
13. Someone whose advice you really want.					
14. Someone to do things with to help you get your mind off things.					
15 Someone to help with daily chores if you were sick.					
16. Someone to share your most private worries and fears with.					
17. Someone to turn to for suggestions about how to deal with a personal problem.					
18. Someone to do something enjoyable with.					
19. Someone who understands your problems.					
20. Someone to love you and make you feel wanted.					

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

For the following questions, please check the box that is the most true for you at the present time. (Check only one box for each statement.)

Of the people who are important to you, how many:

	None	**One**	**Some**	**Most**	**All**
21. Don't understand you.					
22. Get on your nerves.					
23. Ask too much of you.					
24. Argue with you.					
25. Don't include you.					
26. Show that they don't like you.					
27. Boss you.					
28. Try to get you to do things you don't want to do.					

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

PERSONAL HABITS FORM

These questions are about habits that may affect your health (smoking, alcohol use, weight, and exercise). Please answer each question as accurately as possible.

1. Do you smoke currently?

   ☐ No
   ☐ Yes

   If yes, how many cigarettes do you smoke per day? (1 pack = 20 cigarettes)

   ☐ I smoke occasionally.
   ☐ 0 - 5 cigarettes a day
   ☐ 6 - 20 cigarettes a day
   ☐ 21 - 30 cigarettes a day
   ☐ 31 - 40 cigarettes a day
   ☐ more than 40 cigarettes a day

2. Do you currently drink alcoholic beverages?

   ☐ No
   ☐ Yes

   If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currently drink in an average month?

   ☐☐☐ Beverages per month

3. What is your current weight?

☐☐☐ pounds

The following questions are about your usual physical activity and exercise. This includes walking and sports.

4. Think about the walking you do outside the home. In the past month, how often did you walk outside the home for more than 10 minutes without stopping? **(Mark only one.)**

☐	Rarely or never	--->	(Go to Question 5)
☐	1-3 times each month	--->	(Go to Question 4a)
☐	1 time each week	--->	(Go to Question 4a)
☐	2-3 times each week	--->	(Go to Question 4a)
☐	4-6 times each week	--->	(Go to Question 4a)
☐	7 or more times each week	--->	(Go to Question 4a)

4a. When you walked outside the home for more than 10 minutes without stopping, how many minutes did you usually walk?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

4b. What was your usual speed?

- ☐ Casual strolling or walking (less than 2 miles an hour)
- ☐ Average or normal (2-3 miles an hour)
- ☐ Fairly fast (3-4 miles an hour)
- ☐ Very fast (more than 4 miles an hour)
- ☐ Don't Know

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

Following are three categories of exercise, (strenuous, moderate, and mild). Not including walking outside the home, how often each week (7 days) do you usually do the following strenuous, moderate, and mild types of exercise?

5. **STRENUOUS OR VERY HARD EXERCISE.** (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

☐	None	--->	(Go to Question 6)
☐	1 day per week	--->	(Go to Question 5a)
☐	2 days per week	--->	(Go to Question 5a)
☐	3 days per week	--->	(Go to Question 5a)
☐	4 days per week	--->	(Go to Question 5a)
☐	5 or more days per week	--->	(Go to question 5a)

5a. How long do you usually exercise like this at one time?

☐ Less than 20 minutes

☐ 20-39 minutes

☐ 40-59 minutes

☐ 1 hour or more

6. **MODERATE EXERCISE** (Not exhausting). For example, biking outdoors, using an exercise machine (like a stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

☐	None	--->	(Go to Question 7)
☐	1 day per week	--->	(Go to Question 6a)
☐	2 days per week	--->	(Go to Question 6a)
☐	3 days per week	--->	(Go to Question 6a)
☐	4 days per week	--->	(Go to Question 6a)
☐	5 or more days per week	--->	(Go to Question 6a)

6a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

7. **MILD EXERCISE**. For example, slow dancing, bowling, golf.

- ☐ None
- ☐ 1 day per week ---> (Go to Question 7a)
- ☐ 2 days per week ---> (Go to Question 7a)
- ☐ 3 days per week ---> (Go to Question 7a)
- ☐ 4 days per week ---> (Go to Question 7a)
- ☐ 5 or more days per week ---> (Go to Question 7a)

7a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

We are interested in how your life, in general, has been since your diagnosis.

1. What major challenges have you faced since your diagnosis?

2. What positive experiences have you had? (For example, things you learned about yourself, how you interact with your family, etc.)

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

LIFE EVENTS

Below are things that sometimes happen to people. Please try to think back over the **past year** to remember if any of these things happened. (**Mark only one box on each line.**)

Over the past year:	**NO**	**YES, and it upset me:** Not too much	Moderately (Medium)	Very Much
1. Did you have any major problems with money.				
2. Did you or a family member or close friend lose their jobs or retire?				
3. Did you have a major conflict with children?				
4. Did you have a divorce or break-up with a spouse or partner?				
5. Did a family member or close friend have a divorce or breakup?				
6. Did a close friend or family member die or have a serious illness (other than your spouse or partner.)				
7. Did you have any major accidents, disasters, muggings, unwanted sexual experiences, robberies, or similar events?				
8. Did your spouse or partner die or have a serious illness?				
9. Were you physically abused by a family member or close friend?				
10. Were you verbally abused by a family member or close friend?				
11. Did a pet die?				

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

CONTACT INFORMATION FORM

We would like you to update your contact information so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. **Has your address changed since our last mailing to you?**

☐ No ☐ **Yes → <u>If yes,</u> please provide current mailing address**

Your Current Mailing Address?

____

____

____

2. Telephone Numbers:

Home:	Area Code (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___
Work:	Area Code (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___
Other:	Area Code (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

3. When is the best time to contact you?

Day of week	time(s)	Where is the best place to contact you?
______________	______________	☐ At home ☐ At work ☐ Other
______________	______________	☐ At home ☐ At work ☐ Other

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

4. In case we might ever need to contact you by telephone, may we leave a message for you on your answering machine, (if you have one), if we are unable to reach you directly?

   ☐ No
   ☐ Yes

5. What is your husband's or partner's legal name? (This information will help us keep in contact with you during the study. Please leave this blank if you are not currently married or with a long-term partner.)

   ______________________ ______ ______________________

   First MI Last

6. Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we are unable to reach you.

   Name: ______________________

   Address: ______________________

   ____

   Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

   Relationship to you:______________________

   Name: ______________________

   Address: ______________________

   ____

   Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

   Relationship to you:______________________

Appendix C

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE

18-Month Follow-up Survey

Clinical Coordinating Center

Wake Forest University School of Medicine
Department of Public Health Sciences
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Funded by
The U.S. Army Medical Research and Material Command:
Breast Cancer Research Program A

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

PART I

MEDICAL and REPRODUCTIVE HISTORY FOLLOW-UP QUESTIONNAIRE

The following questions ask about health professionals you may have seen in the past 6 months. This information will help us describe in general terms the kinds of services being used.

1. In the past six months, which of the following doctors or other health professionals have you seen? **(Please Check all that apply)**

- ☐ None
- ☐ Acupuncturist
- ☐ Allergist
- ☐ Cardiologist
- ☐ Chiropractor
- ☐ Dentist
- ☐ Dermatologist
- ☐ Ear/Nose/Throat Doctor
- ☐ Eye Doctor
- ☐ Marital Counselor
- ☐ Gastroenterologist
- ☐ General Practitioner
- ☐ Gynecologist
- ☐ Infertility Specialist
- ☐ Internist
- ☐ Massage Therapist
- ☐ Neurologist
- ☐ Sexual Therapist
- ☐ Family Therapist
- ☐ Nutritionist
- ☐ Obstetrician
- ☐ Medical Oncologist/Chemotherapist
- ☐ Orthopedic Surgeon
- ☐ Homeopathic/Herbalist/Naturopathic
- ☐ Pain Control Professional
- ☐ Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
- ☐ Physical Therapist
- ☐ Plastic Surgeon
- ☐ Psychiatrist
- ☐ Clinical Psychologist
- ☐ Radiologist
- ☐ Rheumatologist
- ☐ Social Worker
- ☐ Organized Support Group
- ☐ Surgeon
- ☐ Urologist
- ☐ Other: ____________________

2. In the past 6 months, have you been seen at an emergency room?

☐ No

☐ Yes → For what reason: ____

____

3. In the past 6 months, have you been hospitalized or had surgery? Please mark one box for each line item (a) and (b).

	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			

4. Has anything else changed regarding either your mental or physical health status? Please mark one box for each line item (a) and (b).

	No	Yes	What has changed?
(a) Mental Health?			
(b) Physical Health?			

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

5. Have you had any biopsies in the past 6 months?

- ☐ No
- ☐ Yes → If yes, what was biopsied? ____________________

  Why was this biopsied? ____________________

  ____

6. In the past 6 months, have you had a recurrence of breast cancer?

- ☐ No
- ☐ Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?

  ____

7. Have you been diagnosed with any other cancer in the past 6 months?

- ☐ No
- ☐ Yes → If yes, what type? ____________________

  How was this diagnosis made? (For example, biopsy, lab tests)?

  ____

8. Today's date is: ☐☐ / ☐☐ / ☐☐☐☐
   Month / Day / Year

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

PART II **REPRODUCTIVE HISTORY**

The following questions ask about your menstrual cycles and reproductive history. We are very interested in this information so that we can understand more about women's health during their childbearing years. Some of the questions ask you to give dates or the number of times when certain things happened. If you are not sure about the exact date or number of times, please give your best estimate.

1. What was the date of the first day of your last menstrual period (your best guess)?

☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

2. In the past 6 months, have you been sexually active with a male partner:

☐ No →Go to question 6
☐ Yes →Go to question 3

3. Which method of birth control are you and your partner using currently? **(Check all that apply.)**

☐ No method
☐ Condoms (rubbers)
☐ Birth control pills
☐ Foams/jellies/suppositories
☐ Sponge
☐ Withdrawal (pulling out)
☐ Diaphragm
☐ Safe periods (rhythm or counting days)
☐ Norplant
☐ Cervical cap
☐ Tubal ligation (tubes tied)
☐ Vasectomy
☐ Other (Please describe: ___________)
☐ Don't know

4. In the past month, how many times have you had sexual intercourse without using contraception?

☐☐ Times

5. In the past 6 months, have you become pregnant?

☐ No
☐ Yes → If yes, are you pregnant now?

☐ No
☐ Yes

6. In the past month, have you had any hot flashes or night sweats (hot flashes that occur during sleep)?

☐ No
☐ Yes ----> If yes, how many have you had in the **past week**?

☐☐☐ hot flashes/night sweats

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

PART III **CURRENT MEDICATIONS**

1. Please list below all of the **prescription medications** you are taking currently. (Write "none" if you are not taking any prescription medications at this time.)

Drug Name	Dosage

2. Please list below all of the **non-prescription medications or supplements** you are taking currently. (Write "none" if are not taking any non-prescription medications or supplements at this time.)

Drug Name	Dosage

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

SWELLING FORM

The following questions concern swelling in your arm and/or hand. Please mark the appropriate box(es) for each question.

1. In the past 6 months, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

   ☐ No → (Go to question 8)
   ☐ Yes → (Continue to question 2)
   ☐ Don't know → (Go to question 8)

2. Do you believe the start of your swelling was related to any of the following?

Yes	No	Don't Know	
☐	☐	☐	Radiation treatment
☐	☐	☐	Breast reconstruction
☐	☐	☐	Infection or injury to arm / hand
☐	☐	☐	Weather changes
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Airplane travel
☐			Other: Please describe: ________________________________

____

2a. How soon after you had surgery and/or began treatment did this swelling occur?

☐ Less than 1 week
☐ 1 week to 4 weeks
☐ 1 month to 3 months
☐ 4 months to 6 months
☐ 7 months to 9 months
☐ 10 months to 12 months
☐ 13 months to 15 months

2b. Where does (did) the swelling occur? **(Check all that apply)**

☐ Hand
☐ Upper Arm
☐ Lower Arm

2c. Do (did) you consider the swelling to be mostly?

☐ Mild
☐ Moderate
☐ Severe

3. Does (did) the swelling interfere with any of the following?

Yes	No	
☐	☐	Clothing that you wear
☐	☐	Your ability to do routine activities, such as household chores or grooming.
☐	☐	Exercise
☐	☐	Your appearance
☐		Other, please describe: ______________________________

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

4. Does (did) swelling seem to get worse with any of the following?

Yes	No	Don't Know	
☐	☐	☐	Hot weather
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Sauna / Jacuzzi / Hot bath
☐	☐	☐	Airplane travel
☐	☐	☐	Specific foods
☐	☐	☐	Mental / emotional stress
☐			Other: Please describe: ______________________

____

5. Prior to your breast cancer diagnosis, did you notice swelling in your hand and/or arm with any of the following? **(Check all that apply)**

Yes	No	Don't Know	
☐	☐	☐	Exercise
☐	☐	☐	Household Chores
☐	☐	☐	Heat/Humidity
☐	☐	☐	Eating salty foods
☐	☐	☐	Drinking alcoholic beverages
☐			Other: Please describe: ______________________

____

6. Did you seek treatment for this swelling in the past 6 months?

☐ No → If no, why not?

____

____

☐ Yes → If yes, what type of treatment did you receive? **(Check all that apply)**

- ☐ Compression therapy by machine
- ☐ Glove / Sleeve Compression / Garment
- ☐ Physical therapy
- ☐ Manual lymphatic drainage
- ☐ Bandaging technique
- ☐ Other, please describe: ______________________________

____

7. Do you have swelling now?

☐ No → (Go to question 8)

☐ Yes → (Continue to question 7a)

7a. If yes, how long have you had swelling?

- ☐ Less than 1 week
- ☐ 2 - 4 weeks
- ☐ 1 - 3 months
- ☐ 4 - 6 months
- ☐ 7 - 9 months
- ☐ 10 - 12 months

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

8. In the past 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin injuries in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 9)
☐ Yes → (Continue to question 8a)
☐ Don't Know → (Continue to question 9)

8a. If yes, did you receive antibiotics?

☐ Yes
☐ No
☐ Don't know

9. In the past 6 months, did you have any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 10)
☐ Yes → (Continue to question 9a)
☐ Don't Know → (Continue to question 10)

If yes, did you:

9a. receive antibiotics by mouth?

☐ No
☐ Yes
☐ Don't know

If yes, did you:

9b. receive antibiotics by injection?

☐ No
☐ Yes
☐ Don't know

10. Do you have pain in the affected arm and/or hand? **(Check one box for each site)**

	Yes	No
hand		
arm		
hand and arm		

Patient I.D. ___ ___ - ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

SYMPTOMS QUESTIONNAIRE

Below are statements about symptoms some people may experience. For each statement, check the appropriate box for the response that best describes how bothersome the symptom was for you **during the past month**. If you did not have the problem, check the box under the column titled "symptom did not occur". Please do not skip any questions. **Mark only one box on each line.**

If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = **symptom did not interfere with usual activities.**
Moderate = **symptom interfered somewhat with usual activities.**
Severe = **symptom was so bothersome that usual activities could not be performed.**

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
1. Fatigue or low energy level				
2. Mouth ulcers				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Lightheadedness when standing up				
9. Faintness or dizziness at rest				
10. Headaches				
11. Swelling of ankles or feet				
12. Diarrhea				

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
13. Constipation				
14. Abdominal pain/cramps				
15. Vaginal dryness				
16. Muscle pain/ache/or cramp				
17. Weight gain				
18. Weight loss				
19. General aches and pains				
20. Hot flashes				
21. Joint pains				
22. Night sweats				
23. Aches in back of neck and skull				
24. Forgetfulness				
25. Difficulty concentrating				
26. Increased appetite				
27. Short temper				
28. Decreased efficiency				
29. Loss of interest in work/activities				
30. Lowered work performance				
31. Blind spots, fuzzy vision				
32. Breast sensitivity/tenderness				
33. Avoidance of social affairs				
34. Cold sweats				
35. Decreased appetite				
36. Feelings of suffocation				
37. Difficulty healing				
38. Bloating				

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

QUALITY OF LIFE FORM

1. In general, would you say your health is: **(Check one)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

3. Climbing several flights of stairs.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		Yes	No
4.	Accomplished less than you would like.	☐	☐
5.	Had difficulty performing the work or other activities, for example, it took extra effort.	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

		Yes	No
6.	Accomplished less than you would like.	☐	☐
7.	Didn't do work or other activities as carefully as usual.	☐	☐

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework and family activities)? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

10. Have you felt calm and peaceful? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

11. Did you have a lot of energy? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

12. Have you felt downhearted and blue? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___

Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you *during the past 7 days*.

Physical Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
13. I had a lack of energy.	1	2	3	4	5
14. I had nausea.	1	2	3	4	5
15. I had trouble meeting the needs of my family.	1	2	3	4	5
16. I had pain.	1	2	3	4	5
17. I was bothered by side effects of treatment.	1	2	3	4	5
18. In general, I felt sick.	1	2	3	4	5
19. I was forced to spend time in bed.	1	2	3	4	5

20. How much does your Physical Well-Being affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all ... Very Much So

Social/Family Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
21. I felt distant from my friends	1	2	3	4	5
22. I got emotional support from my family.	1	2	3	4	5
23. I got support from my friends and neighbors.	1	2	3	4	5
24. My family had accepted my illness.	1	2	3	4	5
25. Family communication about my illness was poor.	1	2	3	4	5

If you have a spouse/partner, or are sexually active, please answer questions 26-27. Otherwise, go to question 28.

26. I felt close to my partner (or main support).	1	2	3	4	5
27. I was satisfied with my sex life.	1	2	3	4	5

28. How much does your Social/Family Well-Being affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all ... Very Much So

Relationship With Doctor	Not At All	A Little Bit	Some-What	Quite a bit	Very Much
29. I had confidence in my doctor(s).	1	2	3	4	5
30. My doctor was available to answer my questions.	1	2	3	4	5

31. How much does your Relationship with your Doctor affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Emotional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
32. I felt sad.	1	2	3	4	5
33. I was proud of how I'm coping with my illness.	1	2	3	4	5
34. I was losing hope in the fight against my illness.	1	2	3	4	5
35. I felt nervous.	1	2	3	4	5
36. I worried about dying.	1	2	3	4	5

37. How much does your Emotional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Functional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
38. I was able to work (include work in home).	1	2	3	4	5
39. My work (include work in home) was fulfilling.	1	2	3	4	5
40. I was able to enjoy life "in the moment."	1	2	3	4	5
41. I had accepted my illness.	1	2	3	4	5
42. I was sleeping well.	1	2	3	4	5
43. I enjoyed my usual leisure pursuits.	1	2	3	4	5
44. I was content with the quality of my life right now.	1	2	3	4	5

45. How much does your Functional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
46. I was short of breath.	1	2	3	4	5
47. I was self-conscious about the way I dressed.	1	2	3	4	5
48. My arms were swollen or tender.	1	2	3	4	5
49. I felt sexually attractive.	1	2	3	4	5
50. I was bothered by hair loss.	1	2	3	4	5
51. I worried about the risk of cancer in other family members.	1	2	3	4	5
52. I worried about the effect of stress on my illness.	1	2	3	4	5
53. I was bothered by a change in weight.	1	2	3	4	5
54. I was able to feel like a woman.	1	2	3	4	5

55. How much do these Additional Concerns affect your quality of life? **(Circle one number.)**

0 1 2 3 4 5 6 7 8 9 10

Not at all ... Very Much So

YOUR APPEARANCE

This section asks you about your general perceptions regarding your body. Right now, how satisfied are you with these parts of your body? Please check the appropriate box for the response that best describes your satisfaction with each body part.

	Very dissatisfied	Somewhat dissatisfied	Neutral	Somewhat satisfied	Very satisfied
56. Hair					
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How much do you agree or disagree with the following statement? (Check the appropriate box.)

64. The appearance of my breast area is important to me.

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

65. I view myself as a:

☐ Very overweight person
☐ Moderately overweight person
☐ Normal weight person
☐ Moderately thin person
☐ Very thin person

PART III. SEXUALITY

These next questions are about the way health problems may interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems may affect women's sexuality.

66. Have you been sexually active with a partner during the last 6 months?

☐ No ----> (If no, skip to Question 79).
☐ Yes ----> (If yes, continue to Question 67).

67. How many times have you had sexual intercourse in the past month?

☐ 0 times
☐ 1 - 4 times
☐ 5 - 10 times
☐ 11 or more

Patient I.D.	___ ___ - ___ ___ ___ ___
Patient Acrostic:	___ ___ ___ ___ ___ ___

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Never	Almost Never	Sometimes	Almost Always	Always
68. How often were you aware of wetness in your vagina as you became sexually excited?					
69. How often did it take a long time for your vagina to become wet or slippery as you became sexually excited?					
70. During sexual relations, how frequently did you notice dryness of your vagina?					
71. How often did you feel pain or discomfort during vaginal penetration?					
72. How often did you feel satisfied after sexual activity?					
73. How often were you satisfied with the frequency of sexual activity?					
74. How frequently did you feel tense or nervous after a sexual experience?					

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
75. I avoided having my breast area fondled or kissed.					
76. My partner avoided fondling or kissing my breast area.					
77. I notice I didn't hug or kiss my partner much.					
78. I notice my partner didn't hug and kiss me much.					

PART IV. SLEEP HABITS

The next group of questions ask about your sleep habits. Please check the appropriate box for the one response that best describes how often you experienced these situations in **THE PAST 4 WEEKS**.

79. Did you have trouble falling asleep?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

80. Did you wake up several times a night?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

81. Did you wake up earlier than you planned to?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

82. Did you have trouble getting back to sleep after you woke up too early?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

83. Overall, how was your typical night's sleep during the past 4 weeks?

- ☐ Very sound or restful
- ☐ Sound or restful
- ☐ Average quality
- ☐ Restless
- ☐ Very restless

84. About how many hours of sleep did you get on a typical night during the past 4 weeks?

- ☐ 5 or less hours
- ☐ 6 hours
- ☐ 7 hours
- ☐ 8 hours
- ☐ 9 hours
- ☐ 10 or more hours

PART V. SPIRITUAL BELIEFS

The following questions are about spiritual beliefs. Please check the appropriate box indicating how true the statement has been for you during **THE PAST WEEK.**

	Not at all	A little bit	Somewhat	Quite a bit	Very much
85. I felt peaceful.					
86. I had a reason for living.					
87. I felt a sense of purpose in my life.					
88. I was able to reach down deep into myself for comfort.					
89. I felt a sense of harmony within myself.					
90. I found comfort in my faith.					
91. I found strength in my faith.					

92. Where would you place yourself on the following scale, if "0" means that your life is just the way it was before your breast cancer, "+5" means that everything is totally different but better, and "-5" means that everything is totally different but worse. ***(Please circle ONE number).***

-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
Worse					Same as before					Better

PART VI. EMOTIONAL FEELINGS

The following questions consist of groups of statements. After reading each group of statements carefully, check the box next to the one statement in each group which **best** describes the way you have been feeling **the past week, including today**. If several statements within a group seem to apply equally, check each one. **Be sure to read all the statements in each group before making your choice.**

93. ☐ I do not feel sad.
    ☐ I feel sad.
    ☐ I am sad all the time and I can't snap out of it.
    ☐ I am so sad or unhappy that I can't stand it.

94. ☐ I am not particularly discouraged about the future.
    ☐ I feel discouraged about the future.
    ☐ I feel I have nothing to look forward to.
    ☐ I feel that the future is hopeless and that things cannot improve.

95. ☐ I do not feel like a failure.
    ☐ I feel I have failed more than the average person.
    ☐ As I look back on my life, all I can see is a lot of failures.
    ☐ I feel I am a complete failure as a person.

96. ☐ I get as much satisfaction out of things as I used to.
    ☐ I don't enjoy things the way I used to.
    ☐ I don't get real satisfaction out of anything anymore.
    ☐ I am dissatisfied or bored with everything.

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

97. ☐ I don't feel particularly guilty.
    ☐ I feel guilty a good part of the time.
    ☐ I feel quite guilty most of the time.
    ☐ I feel guilty all of the time.

98. ☐ I don't feel I am being punished.
    ☐ I feel I may be punished.
    ☐ I expect to be punished.
    ☐ I feel I am being punished.

99. ☐ I don't feel disappointed in myself.
    ☐ I am disappointed in myself.
    ☐ I am disgusted with myself.
    ☐ I hate myself.

100. ☐ I don't feel I am any worse than anybody else.
     ☐ I am critical of myself for my weaknesses or mistakes.
     ☐ I blame myself all the time for my faults.
     ☐ I blame myself for everything bad that happens.

101. ☐ I don't have any thoughts of killing myself.
     ☐ I have thoughts of killing myself, but I would not carry them out.
     ☐ I would like to kill myself.
     ☐ I would kill myself if I had the chance.

102. ☐ I don't cry anymore than usual.
     ☐ I cry more now than I used to.
     ☐ I cry all the time now.
     ☐ I used to be able to cry, but now I can't cry even though I want to.

103. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

104. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

105. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all anymore.

106. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

107. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

108. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __ __

109. ☐ I don't get more tired than usual.
☐ I get tired more easily than I used to.
☐ I get tired from doing almost anything.
☐ I am too tired to do anything.

110. ☐ My appetite is no worse than usual.
☐ My appetite is not as good as it used to be.
☐ My appetite is much worse now.
☐ I have no appetite at all anymore.

111. ☐ I haven't lost much weight, if any, lately.
☐ I have lost more than five (5) pounds.
☐ I have lost more than ten (10) pounds.
☐ I have lost more than fifteen (15) pounds.

112. ☐ I am no more worried about my health than usual.
☐ I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
☐ I am very worried about physical problems and it's hard to think of much else.
☐ I am so worried about my physical problems that I cannot think about anything else.

113. ☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

SOCIAL SUPPORT FORM

The following are questions about the support that is available to you.

1. At the present time, about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)? **(Please write the number in the boxes below.)**

   ☐☐ Number of close friends and close relatives

People sometimes look to others for companionship, assistance, or other types of support. Currently, how often is each of the following kinds of support available to you if you need it? (Check one box for each statement.)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Someone to help you if you were confined to bed.					
3. Someone you can count on to listen to you when you need to talk.					
4. Someone to give you good advice about a crisis.					
5. Someone to take you to the doctor if you needed it.					
6. Someone who shows you love and affection.					
7. Someone to have a good time with.					
8. Someone to give you information to help you understand a situation.					
9. Someone to confide in or talk to about yourself or your problems.					

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
10. Someone who hugs you.					
11. Someone to get together with for relaxation.					
12. Someone to prepare your meals if you were unable to do it yourself.					
13. Someone whose advice you really want.					
14. Someone to do things with to help you get your mind off things.					
15 Someone to help with daily chores if you were sick.					
16. Someone to share your most private worries and fears with.					
17. Someone to turn to for suggestions about how to deal with a personal problem.					
18. Someone to do something enjoyable with.					
19. Someone who understands your problems.					
20. Someone to love you and make you feel wanted.					

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

For the following questions, please check the box that is the most true for you at the present time. (Check only one box for each statement.)

Of the people who are important to you, how many:

	None	**One**	**Some**	**Most**	**All**
21. Don't understand you.					
22. Get on your nerves.					
23. Ask too much of you.					
24. Argue with you.					
25. Don't include you.					
26. Show that they don't like you.					
27. Boss you.					
28. Try to get you to do things you don't want to do.					

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

PERSONAL HABITS FORM

These questions are about habits that may affect your health (smoking, alcohol use, weight, and exercise). Please answer each question as accurately as possible.

1. Do you smoke currently?

☐ No
☐ Yes

If yes, how many cigarettes do you smoke per day? (1 pack = 20 cigarettes)

☐ I smoke occasionally.
☐ 0 - 5 cigarettes a day
☐ 6 - 20 cigarettes a day
☐ 21 - 30 cigarettes a day
☐ 31 - 40 cigarettes a day
☐ more than 40 cigarettes a day

2. Do you currently drink alcoholic beverages?

☐ No
☐ Yes

If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currently drink in an average month?

☐☐☐ Beverages per month

3. What is your current weight?

☐☐☐ pounds

The following questions are about your usual physical activity and exercise. This includes walking and sports.

4. Think about the walking you do outside the home. In the past month, how often did you walk outside the home for more than 10 minutes without stopping? **(Mark only one.)**

- ☐ Rarely or never ---> (Go to Question 5)
- ☐ 1-3 times each month ---> (Go to Question 4a)
- ☐ 1 time each week ---> (Go to Question 4a)
- ☐ 2-3 times each week ---> (Go to Question 4a)
- ☐ 4-6 times each week ---> (Go to Question 4a)
- ☐ 7 or more times each week ---> (Go to Question 4a)

4a. When you walked outside the home for more than 10 minutes without stopping, how many minutes did you usually walk?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

4b. What was your usual speed?

- ☐ Casual strolling or walking (less than 2 miles an hour)
- ☐ Average or normal (2-3 miles an hour)
- ☐ Fairly fast (3-4 miles an hour)
- ☐ Very fast (more than 4 miles an hour)
- ☐ Don't Know

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___

Following are three categories of exercise, (strenuous, moderate, and mild). Not including walking outside the home, <u>how often each week (7 days</u>) do you usually do the following strenuous, moderate, and mild types of exercise?

5. **STRENUOUS OR VERY HARD EXERCISE**. (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

- ☐ None ---> (Go to Question 6)
- ☐ 1 day per week ---> (Go to Question 5a)
- ☐ 2 days per week ---> (Go to Question 5a)
- ☐ 3 days per week ---> (Go to Question 5a)
- ☐ 4 days per week ---> (Go to Question 5a)
- ☐ 5 or more days per week ---> (Go to question 5a)

5a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

6. **MODERATE EXERCISE** (Not exhausting). For example, biking outdoors, using an exercise machine (like a stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

- ☐ None ---> (Go to Question 7)
- ☐ 1 day per week ---> (Go to Question 6a)
- ☐ 2 days per week ---> (Go to Question 6a)
- ☐ 3 days per week ---> (Go to Question 6a)
- ☐ 4 days per week ---> (Go to Question 6a)
- ☐ 5 or more days per week ---> (Go to Question 6a)

6a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

7. **MILD EXERCISE**. For example, slow dancing, bowling, golf.

☐	None		
☐	1 day per week	--->	(Go to Question 7a)
☐	2 days per week	--->	(Go to Question 7a)
☐	3 days per week	--->	(Go to Question 7a)
☐	4 days per week	--->	(Go to Question 7a)
☐	5 or more days per week	--->	(Go to Question 7a)

7a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

CONTACT INFORMATION FORM

We would like you to update your contact information so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. **Has your address changed since our last mailing to you?**

☐ No ☐ **Yes → <u>If yes,</u> please provide current mailing address**

Your Current Mailing Address?

____

____

____

2. Telephone Numbers:

Home:	Area Code	(__ __ __) __ __ __ - __ __ __ __
Work:	Area Code	(__ __ __) __ __ __ - __ __ __ __
Other:	Area Code	(__ __ __) __ __ __ - __ __ __ __

3. When is the best time to contact you? / Where is the best place to contact you?

Day of week	time(s)	
____________	____________	☐ At home ☐ At work ☐ Other
____________	____________	☐ At home ☐ At work ☐ Other

4. In case we might ever need to contact you by telephone, may we leave a message for you on your answering machine, (if you have one), if we are unable to reach you directly?

☐ No
☐ Yes

5. What is your husband's or partner's legal name? (This information will help us keep in contact with you during the study. Please leave this blank if you are not currently married or with a long-term partner.)

______________________________ _______ _________________________________

First MI Last

6. Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we are unable to reach you.

Name: ____

Address: ____

____

Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

Relationship to you:____

Name: ____

Address: ____

____

Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

Relationship to you:____

Appendix D

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE

Two-Year Follow-up Survey

Clinical Coordinating Center

Wake Forest University School of Medicine
Department of Public Health Sciences
Winston-Salem, North Carolina 27157-1063
(336) 716-2116

Funded by
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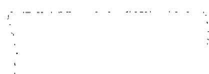
Breast Cancer Research Program A



Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

DEMOGRAPHIC FOLLOW-UP FORM

YOUR BACKGROUND

The following questions are about your background. We would like to see if you have had any changes in your personal situation in the past year. Please mark the appropriate box for each question.

1. What is your marital status?

   - ☐ Never married
   - ☐ Presently married
   - ☐ Living in a marriage-like relationship
   - ☐ Divorced
   - ☐ Separated
   - ☐ Widowed

2. Which category below best describes the highest level of formal education you have completed? (*Choose the one best answer*).

   - ☐ No formal education
   - ☐ Grade school (1st through 8th grade)
   - ☐ Some high school (9th through 11th grade)
   - ☐ High school diploma or G.E.D.
   - ☐ Business or vocational training school after high school graduation
   - ☐ Some college (but a college degee was not obtained)
   - ☐ Associate Degree (A.D. or A.A.)
   - ☐ College graduate or Baccalaureate Degree (B.A. or B.S.)
   - ☐ Some college or professional school after college graduation
   - ☐ Master's Degree
   - ☐ Doctoral Degree (Ph.D., M.D., J.D., D.D.S., etc.)

3. What was your total family income (before taxes) from all sources last year? (Check one box below. This information is important for describing the women in the study as a group and is kept strictly confidential).

☐ Less than $10,000
☐ $10,000 to $19,999
☐ $20,000 to $34,999
☐ $35,000 to $49,999
☐ $50,000 to $74,999
☐ $75,000 to $100,000
☐ More than $100,000

4. What type of health insurance do you have? (If you have more than one type of insurance, please mark the box for your primary source of insurance.*)*

☐ HMO
☐ Group Health Insurance
☐ V.A./Military Sponsored
☐ Individual Health Insurance (includes CHAMPUS)
☐ Medicaid
☐ Disability Insurance
☐ None
☐ Other (Please list: ______________________________)

5. What is your <u>current</u> employment status? *(Check the box that best describes you.)*

☐ Unemployed/Looking for work → (Go to question 8)
☐ Retired → (Go to question 8)
☐ Full-time Homemaker → (Go to question 8)
☐ Employed - full-time → (Go to question 6)
☐ Employed - part-time → (Go to question 6)
☐ Disabled, unable to work → (Go to question 8)
☐ Student → (Go to question 8)
☐ Other (Please list: ______________________________) → (Go to question 8)

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

6. If you are employed, which category best describes your occupation?

- ☐ **Professional, Technical & Related Occupations** (such as teachers/professors, nurses, lawyers, physicians & engineers)
- ☐ **Managers, Administrators, or Proprietors** (such as sales managers, real estate agents, or postmasters)
- ☐ **Clerical & Related Occupations** (such as secretaries, clerks or mail carriers)
- ☐ **Sales Occupations** (such as salespersons, demonstrators, agents and brokers)
- ☐ **Service Occupations** (such as police, cooks, or hairdressers)
- ☐ **Skilled Crafts, Service Repair Persons, & Related Occupations** (such as carpenters, appliance repair, or telephone line workers)
- ☐ **Equipment or Vehicle Operators & Related Occupations** (such as drivers, railroad brakemen or sewer workers)
- ☐ **Laborers** (such as helpers, longshoremen, or warehouse workers)
- ☐ **Farmers** (owners, managers, operators or tenants)
- ☐ **Members of the military**
- ☐ **Other** (please describe):____________________

7. This following is a list of employment issues that a person might have. For each statement, indicate whether this has happened to you since your diagnosis. If it did occur, indicate whether you believe this situation was related to your diagnosis. (Circle the answers that are most true for you on each line.)

Since your diagnosis have you:

a. believed you could not change jobs for fear of losing your health insurance?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

b. lost your health insurance due to sick leave?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

c. been fired or laid off?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

d. been demoted?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

e. been denied a promotion?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

f. been denied a wage increase?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

  ☐ No

  ☐ Yes

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

g. had your work responsibilities limited unnecessarily?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

☐ No

☐ Yes

h. been promoted?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

☐ No

☐ Yes

8. This following is a list of insurance issues that a person might have. For each statement, indicate whether this has happened to you since your diagnosis. If it did occur, indicate whether you believe this situation was related to your diagnosis. (Circle the answers that are most true for you on each line.)

Since your diagnosis have:

a. you been denied health insurance?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

☐ No

☐ Yes

b. you been denied life insurance?

☐ No

☐ Yes (If yes, was it related to your diagnosis?)

☐ No

☐ Yes

c. your health insurance rates increased?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

d. your life insurance rates increased?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

e. you had a health benefit payment denied?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

f. you had trouble changing from group health to individual health insurance?

- ☐ No
- ☐ Yes (If yes, was it related to your diagnosis?)
  - ☐ No
  - ☐ Yes

9. Please give the date you completed this form: ☐☐ / ☐☐ / ☐☐☐☐
   Month Day Year

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

PART 1

MEDICAL & REPRODUCTIVE HISTORY FOLLOW-UP QUESTIONNAIRE

The following questions ask about health professionals you may have seen in the past 6 months. This information will help us describe in general terms the kinds of services being used.

1. In the past six months, which of the following doctors or other health professionals have you seen? **(Please Check all that apply)**

- ☐ None
- ☐ Acupuncturist
- ☐ Allergist
- ☐ Cardiologist
- ☐ Chiropractor
- ☐ Dentist
- ☐ Dermatologist
- ☐ Ear/Nose/Throat Doctor
- ☐ Eye Doctor
- ☐ Marital Counselor
- ☐ Gastroenterologist
- ☐ General Practitioner
- ☐ Gynecologist
- ☐ Infertility Specialist
- ☐ Internist
- ☐ Massage Therapist
- ☐ Neurologist
- ☐ Sexual Therapist
- ☐ Family Therapist
- ☐ Nutritionist
- ☐ Obstetrician
- ☐ Medical Oncologist/Chemotherapist
- ☐ Orthopedic Surgeon
- ☐ Homeopathic/Herbalist/Naturopathic
- ☐ Pain Control Professional
- ☐ Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
- ☐ Physical Therapist
- ☐ Plastic Surgeon
- ☐ Psychiatrist
- ☐ Clinical Psychologist
- ☐ Radiologist
- ☐ Rheumatologist
- ☐ Social Worker
- ☐ Organized Support Group
- ☐ Surgeon
- ☐ Urologist
- ☐ Other:__________________

2. In the past 6 months, have you been seen at an emergency room?

☐ No

☐ Yes → For what reason: ______________________________

____

3. In the past 6 months, have you been hospitalized or had surgery? Please mark one box for each line item (a) and (b).

	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			

4. Has anything else changed regarding either your mental or physical health status? Please mark one box for each line item (a) and (b).

	No	Yes	What has changed?
(a) Mental Health?			
(b) Physical Health?			

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

5. Have you had any biopsies in the past 6 months?

☐ No
☐ Yes → If yes, what was biopsied? ______________________

Why was this biopsied? ______________________

____

6. In the past 6 months, have you had a re-occurrence of breast cancer?

☐ No
☐ Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?

____

7. Have you been diagnosed with any other cancer in the past 6 months?

☐ No
☐ Yes → If yes, what type? ______________________

How was this diagnosis made? (For example, biopsy, lab tests)?

____

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

PART II

REPRODUCTIVE HISTORY

The following questions ask about your menstrual cycles and reproductive history. We are very interested in this information so that we can understand more about women's health during their childbearing years. Some of the questions ask you to give dates or the number of times when certain things happened. If you are not sure about the exact date or number of times, please give your best estimate.

1. What was the date of the first day of your last menstrual period (your best guess)?

☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

2. In the past 6 months, have you been sexually active with a male partner:

☐ No → Go to question 6

☐ Yes → Go to question 3

3. Which method of birth control are you and your partner using currently? **(Check all that apply.)**

☐ No method
☐ Condoms (rubbers)
☐ Birth control pills
☐ Foams/jellies/suppositories
☐ Sponge
☐ Withdrawal (pulling out)
☐ Diaphragm
☐ Safe periods (rhythm or counting days)
☐ Norplant
☐ Cervical cap
☐ Tubal ligation (tubes tied)
☐ Vasectomy
☐ Other (Please describe: ____________)
☐ Don't know

4. In the past month, how many times have you had sexual intercourse without using contraception?

☐☐ Times

5. In the past 6 months, have you become pregnant?

☐ No
☐ Yes → If yes, are you pregnant now?

☐ No
☐ Yes

6. In the past month, have you had any hot flashes or night sweats (hot flashes that occur during sleep)?

☐ No
☐ Yes ----> If yes, how many have you had in the **past week**?

☐☐☐ hot flashes/night sweats

FAMILY HISTORY UPDATE

Please update the following grid about the **history of breast cancer** among your female relatives. If you do not have a full-blooded relative in one of the categories listed below, please leave that line blank. (MARK ONLY ONE BOX PER LINE.)

1. Did this relative have breast cancer?

	No	Yes — How old was she when her first breast cancer occurred? Less than 45	45 or older	Don't know age	Don't know if she had breast cancer	Does Not Apply
a. Mother	☐	☐	☐	☐	☐	☐
b. Sister 1	☐	☐	☐	☐	☐	☐
c. Sister 2	☐	☐	☐	☐	☐	☐
d. Sister 3	☐	☐	☐	☐	☐	☐
e. Sister 4	☐	☐	☐	☐	☐	☐
f. Daughter 1	☐	☐	☐	☐	☐	☐
g. Daughter 2	☐	☐	☐	☐	☐	☐
h. Daughter 3	☐	☐	☐	☐	☐	☐
I. Daughter 4	☐	☐	☐	☐	☐	☐
j. Maternal grandmother (your mother's mother)	☐	☐	☐	☐	☐	☐
k. Paternal grandmother (your father's mother)	☐	☐	☐	☐	☐	☐

Please update the following grid about the **history of ovarian cancer** among your female relatives. If you do not have a full-blooded relative in one of the categories listed below, please leave that line blank. (MARK ONLY ONE BOX PER LINE.)

2. Did this relative have ovarian cancer?

	No	Yes — How old was she when her first ovarian cancer occurred?			Don't know if she had ovarian cancer	Does Not Apply
		Less than 45	45 or older	Don't know age		
a. Mother	☐	☐	☐	☐	☐	☐
b. Sister 1	☐	☐	☐	☐	☐	☐
c. Sister 2	☐	☐	☐	☐	☐	☐
d. Sister 3	☐	☐	☐	☐	☐	☐
e. Sister 4	☐	☐	☐	☐	☐	☐
f. Daughter 1	☐	☐	☐	☐	☐	☐
g. Daughter 2	☐	☐	☐	☐	☐	☐
h. Daughter 3	☐	☐	☐	☐	☐	☐
I. Daughter 4	☐	☐	☐	☐	☐	☐
j. Maternal grandmother (your mother's mother)	☐	☐	☐	☐	☐	☐
k. Paternal grandmother (your father's mother)	☐	☐	☐	☐	☐	☐

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

CURRENT MEDICATIONS

1. Please list below all of the **prescription medications** you are taking currently. (Write "none" if you are not taking any prescription medications at this time.)

Drug Name	Dosage

2. Please list below all of the **non-prescription medications or supplements** you are taking currently. (Write "none" if are not taking any non-prescription medications or supplements at this time.)

Drug Name	Dosage

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

TREATMENT EXPECTATIONS

1. We are interested in your expectations regarding the treatments you received over the past year. For each of the treatments listed below, how did your expectations before treatment compare with the actual treatment you received? Better than expected, the same as you expected, or worse than you expected? (Mark one box for each line.)

	Not Applicable. (Did not have this treatment.)	**Worse Than Expected**	**Same As Expected**	**Better Than Expected**
Lumpectomy				
Mastectomy				
Reconstructive Surgery				
Radiation				
Chemotherapy				
Tamoxifen				
Bone Marrow Transplant				

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

SWELLING FORM

The following questions concern swelling in your arm and/or hand. Please mark the appropriate box(es) for each question.

1. In the past 6 months, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 2)
☐ Don't know → (Go to question 8)

2. Do you believe the start of your swelling was related to any of the following?

Yes	No	Don't Know	
☐	☐	☐	Radiation treatment
☐	☐	☐	Breast reconstruction
☐	☐	☐	Infection or injury to arm / hand
☐	☐	☐	Weather changes
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Airplane travel
☐			Other: Please describe: ________________________________

____

2a. How soon after you had surgery and/or began treatment did this swelling occur?

- ☐ Less than 1 week
- ☐ 1 week to 4 weeks
- ☐ 1 month to 3 months
- ☐ 4 months to 6 months
- ☐ 7 months to 9 months
- ☐ 10 months to 12 months
- ☐ 13 months to 15 months

2b. Where does (did) the swelling occur? **(Check all that apply)**

- ☐ Hand
- ☐ Upper Arm
- ☐ Lower Arm

2c. Do (did) you consider the swelling to be mostly?

- ☐ Mild
- ☐ Moderate
- ☐ Severe

3. Does (did) the swelling interfere with any of the following?

Yes	No	
☐	☐	Clothing that you wear
☐	☐	Your ability to do routine activities, such as household chores or grooming.
☐	☐	Exercise
☐	☐	Your appearance
☐		Other, please describe: ______________________

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

4. Does (did) swelling seem to get worse with any of the following?

Yes	No	Don't Know	
☐	☐	☐	Hot weather
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Sauna / Jacuzzi / Hot bath
☐	☐	☐	Airplane travel
☐	☐	☐	Specific foods
☐	☐	☐	Mental / emotional stress
☐			Other: Please describe: ______________________

____

5. Prior to your breast cancer diagnosis, did you notice swelling in your hand and/or arm with any of the following? **(Check all that apply)**

Yes	No	Don't Know	
☐	☐	☐	Exercise
☐	☐	☐	Household Chores
☐	☐	☐	Heat/Humidity
☐	☐	☐	Eating salty foods
☐	☐	☐	Drinking alcoholic beverages
☐			Other: Please describe: ______________________

____

6. Did you seek treatment for this swelling in the past 6 months?

☐ No → If no, why not?

____

____

☐ Yes → If yes, what type of treatment did you receive? **(Check all that apply)**

- ☐ Compression therapy by machine
- ☐ Glove / Sleeve Compression / Garment
- ☐ Physical therapy
- ☐ Manual lymphatic drainage
- ☐ Bandaging technique
- ☐ Other, please describe: ______________________________

____

7. Do you have swelling now?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 7a)

7a. If yes, how long have you had swelling?

- ☐ Less than 1 week
- ☐ 2 - 4 weeks
- ☐ 1 - 3 months
- ☐ 4 - 6 months
- ☐ 7 - 9 months
- ☐ 10 - 12 months

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

8. In the past 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin injuries in your arm or hand on the same side that you had your lumpectomy or mastectomy?

- ☐ No → (Go to question 9)
- ☐ Yes → (Continue to question 8a)
- ☐ Don't Know → (Continue to question 9)

8a. <u>If yes</u>, did you receive antibiotics?

- ☐ Yes
- ☐ No
- ☐ Don't know

9. In the past 6 months, did you have any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

- ☐ No → (Go to question 10)
- ☐ Yes → (Continue to question 9a)
- ☐ Don't Know → (Continue to question 10)

9a. <u>If yes</u>, did you receive antibiotics by mouth?

- ☐ No
- ☐ Yes
- ☐ Don't know

9b. If yes, did you receive antibiotics by injection?

☐ No
☐ Yes
☐ Don't know

10. Do you have pain in the affected arm and/or hand? **(Check one box for each site)**

	Yes	No
hand		
arm		

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

SYMPTOMS QUESTIONNAIRE

Below are statements about symptoms some people may experience. For each statement, check the appropriate box for the response that best describes how bothersome the symptom was for you **during the past month**. If you did not have the problem, check the box under the column titled "symptom did not occur". Please do not skip any questions. **Mark only one box on each line.**

If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild	=	**symptom did not interfere with usual activities.**
Moderate	=	**symptom interfered somewhat with usual activities.**
Severe	=	**symptom was so bothersome that usual activities could not be performed.**

Symptom	**Symptom did not occur**	**Symptom Occurred and Was:**		
		Mild	**Moderate**	**Severe**
1. Fatigue or low energy level				
2. Mouth ulcers				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Lightheadedness when standing up				
9. Faintness or dizziness at rest				
10. Headaches				
11. Swelling of ankles or feet				
12. Diarrhea				

Symptom	Symptom did not occur	Symptom Occurred and Was: Mild	Moderate	Severe
13. Constipation				
14. Abdominal pain/cramps				
15. Vaginal dryness				
16. Muscle pain/ache/or cramp				
17. Weight gain				
18. Weight loss				
19. General aches and pains				
20. Hot flashes				
21. Joint pains				
22. Night sweats				
23. Aches in back of neck and skull				
24. Forgetfulness				
25. Difficulty concentrating				
26. Increased appetite				
27. Short temper				
28. Decreased efficiency				
29. Loss of interest in work/activities				
30. Lowered work performance				
31. Blind spots, fuzzy vision				
32. Breast sensitivity/tenderness				
33. Avoidance of social affairs				
34. Cold sweats				
35. Decreased appetite				
36. Feelings of suffocation				
37. Difficulty healing				
38. Bloating				

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __

QUALITY OF LIFE FORM

PART I. ACTIVITIES

1. In general, would you say your health is: **(Check one)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

3. Climbing several flights of stairs.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like.	☐	☐
5. Had difficulty performing the work or other activities, for example, it took extra effort.	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

		Yes	No
6.	Accomplished less than you would like.	☐	☐
7.	Didn't do work or other activities as carefully as usual.	☐	☐

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework and family activities)? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

10. Have you felt calm and peaceful? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

11. Did you have a lot of energy? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

12. Have you felt downhearted and blue? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

Patient I.D.	__ __ - __ __ __ __
Patient Acrostic:	__ __ __ __ __ __

Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you *during the past 7 days*.

Physical Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
13. I had a lack of energy.	1	2	3	4	5
14. I had nausea.	1	2	3	4	5
15. I had trouble meeting the needs of my family.	1	2	3	4	5
16. I had pain.	1	2	3	4	5
17. I was bothered by side effects of treatment.	1	2	3	4	5
18. In general, I felt sick.	1	2	3	4	5
19. I was forced to spend time in bed.	1	2	3	4	5

20. How much does your Physical Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Social/Family Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
21. I felt distant from my friends	1	2	3	4	5
22. I got emotional support from my family.	1	2	3	4	5
23. I got support from my friends and neighbors.	1	2	3	4	5
24. My family had accepted my illness.	1	2	3	4	5
25. Family communication about my illness was poor.	1	2	3	4	5

If you have a spouse/partner, or are sexually active, please answer questions 26-27. Otherwise, go to question 28.

26. I felt close to my partner (or main support).	1	2	3	4	5
27. I was satisfied with my sex life.	1	2	3	4	5

28. How much does your Social/Family Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Relationship With Doctor	Not At All	A Little Bit	Some-What	Quite a bit	Very Much
29. I had confidence in my doctor(s).	1	2	3	4	5
30. My doctor was available to answer my questions.	1	2	3	4	5

31. How much does your Relationship with your Doctor affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Emotional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
32. I felt sad.	1	2	3	4	5
33. I was proud of how I'm coping with my illness.	1	2	3	4	5
34. I was losing hope in the fight against my illness.	1	2	3	4	5
35. I felt nervous.	1	2	3	4	5
36. I worried about dying.	1	2	3	4	5

37. How much does your Emotional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Functional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
38. I was able to work (include work in home).	1	2	3	4	5
39. My work (include work in home) was fulfilling.	1	2	3	4	5
40. I was able to enjoy life "in the moment."	1	2	3	4	5
41. I had accepted my illness.	1	2	3	4	5
42. I was sleeping well.	1	2	3	4	5
43. I enjoyed my usual leisure pursuits.	1	2	3	4	5
44. I was content with the quality of my life right now.	1	2	3	4	5

45. How much does your Functional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
46. I was short of breath.	1	2	3	4	5
47. I was self-conscious about the way I dressed.	1	2	3	4	5
48. My arms were swollen or tender.	1	2	3	4	5
49. I felt sexually attractive.	1	2	3	4	5
50. I was bothered by hair loss.	1	2	3	4	5
51. I worried about the risk of cancer in other family members.	1	2	3	4	5
52. I worried about the effect of stress on my illness.	1	2	3	4	5
53. I was bothered by a change in weight.	1	2	3	4	5
54. I was able to feel like a woman.	1	2	3	4	5

55. How much do these Additional Concerns affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

PART II. YOUR APPEARANCE

This section asks you about your general perceptions regarding your body. Right now, how satisfied are you with these parts of your body? Please check the appropriate box for the response that best describes your satisfaction with each body part.

	Very dissatisfied	Somewhat dissatisfied	Neutral	Somewhat satisfied	Very satisfied
56. Hair					
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How much do you agree or disagree with the following statement? (Check the appropriate box.)

64. The appearance of my breast area is important to me.

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

65. I view myself as a:

- ☐ Very overweight person
- ☐ Moderately overweight person
- ☐ Normal weight person
- ☐ Moderately thin person
- ☐ Very thin person

PART III. SEXUALITY

These next questions are about the way health problems may interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems may affect women's sexuality.

66. Have you been sexually active with a partner <u>during the last 6 months</u>?

- ☐ No ----> (If no, skip to Question 79).
- ☐ Yes ----> (If yes, continue to Question 67).

67. How many times have you had sexual intercourse <u>in the past month</u>?

- ☐ 0 times
- ☐ 1 - 4 times
- ☐ 5 - 10 times
- ☐ 11 or more

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Never	Almost Never	Sometimes	Almost Always	Always
68. How often were you aware of wetness in your vagina as you became sexually excited?					
69. How often did it take a long time for your vagina to become wet or slippery as you became sexually excited?					
70. During sexual relations, how frequently did you notice dryness of your vagina?					
71. How often did you feel pain or discomfort during vaginal penetration?					
72. How often did you feel satisfied after sexual activity?					
73. How often were you satisfied with the frequency of sexual activity?					
74. How frequently did you feel tense or nervous after a sexual experience?					

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
75. I avoided having my breast area fondled or kissed.					
76. My partner avoided fondling or kissing my breast area.					
77. I notice I didn't hug or kiss my partner much.					
78. I notice my partner didn't hug and kiss me much.					

PART IV. SLEEP HABITS

The next group of questions ask about your sleep habits. Please check the appropriate box for the one response that best describes how often you experienced these situations in **THE PAST 4 WEEKS**.

79. Did you have trouble falling asleep?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

80. Did you wake up several times a night?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

81. Did you wake up earlier than you planned to?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

82. Did you have trouble getting back to sleep after you woke up too early?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

83. Overall, how was your typical night's sleep during the past 4 weeks?

- ☐ Very sound or restful
- ☐ Sound or restful
- ☐ Average quality
- ☐ Restless
- ☐ Very restless

84. About how many hours of sleep did you get on a typical night during the past 4 weeks?

- ☐ 5 or less hours
- ☐ 6 hours
- ☐ 7 hours
- ☐ 8 hours
- ☐ 9 hours
- ☐ 10 or more hours

PART V. SPIRITUAL BELIEFS

The following questions are about spiritual beliefs. Please check the appropriate box indicating how true the statement has been for you during **THE PAST WEEK.**

	Not at all	A little bit	Somewhat	Quite a bit	Very much
85. I felt peaceful.					
86. I had a reason for living.					
87. I felt a sense of purpose in my life.					
88. I was able to reach down deep into myself for comfort.					
89. I felt a sense of harmony within myself.					
90. I found comfort in my faith.					
91. I found strength in my faith.					

92. Where would you place yourself on the following scale, if "0" means that your life is just the way it was before your breast cancer, "+5" means that everything is totally different but better, and "-5" means that everything is totally different but worse. ***(Please circle ONE number).***

-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
Worse					Same as before					Better

PART VI. EMOTIONAL FEELINGS

The following questions consist of groups of statements. After reading each group of statements carefully, check the box next to the one statement in each group which **best** describes the way you have been feeling **the past week, including today**. If several statements within a group seem to apply equally, check each one. **Be sure to read all the statements in each group before making your choice.**

93. ☐ I do not feel sad.
    ☐ I feel sad.
    ☐ I am sad all the time and I can't snap out of it.
    ☐ I am so sad or unhappy that I can't stand it.

94. ☐ I am not particularly discouraged about the future.
    ☐ I feel discouraged about the future.
    ☐ I feel I have nothing to look forward to.
    ☐ I feel that the future is hopeless and that things cannot improve.

95. ☐ I do not feel like a failure.
    ☐ I feel I have failed more than the average person.
    ☐ As I look back on my life, all I can see is a lot of failures.
    ☐ I feel I am a complete failure as a person.

96. ☐ I get as much satisfaction out of things as I used to.
    ☐ I don't enjoy things the way I used to.
    ☐ I don't get real satisfaction out of anything anymore.
    ☐ I am dissatisfied or bored with everything.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

97. ☐ I don't feel particularly guilty.
☐ I feel guilty a good part of the time.
☐ I feel quite guilty most of the time.
☐ I feel guilty all of the time.

98. ☐ I don't feel I am being punished.
☐ I feel I may be punished.
☐ I expect to be punished.
☐ I feel I am being punished.

99. ☐ I don't feel disappointed in myself.
☐ I am disappointed in myself.
☐ I am disgusted with myself.
☐ I hate myself.

100. ☐ I don't feel I am any worse than anybody else.
☐ I am critical of myself for my weaknesses or mistakes.
☐ I blame myself all the time for my faults.
☐ I blame myself for everything bad that happens.

101. ☐ I don't have any thoughts of killing myself.
☐ I have thoughts of killing myself, but I would not carry them out.
☐ I would like to kill myself.
☐ I would kill myself if I had the chance.

102. ☐ I don't cry anymore than usual.
☐ I cry more now than I used to.
☐ I cry all the time now.
☐ I used to be able to cry, but now I can't cry even though I want to.

103. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

104. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

105. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all anymore.

106. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

107. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

108. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

109. ☐ I don't get more tired than usual.
☐ I get tired more easily than I used to.
☐ I get tired from doing almost anything.
☐ I am too tired to do anything.

110. ☐ My appetite is no worse than usual.
☐ My appetite is not as good as it used to be.
☐ My appetite is much worse now.
☐ I have no appetite at all anymore.

111. ☐ I haven't lost much weight, if any, lately.
☐ I have lost more than five (5) pounds.
☐ I have lost more than ten (10) pounds.
☐ I have lost more than fifteen (15) pounds.

112. ☐ I am no more worried about my health than usual.
☐ I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
☐ I am very worried about physical problems and it's hard to think of much else.
☐ I am so worried about my physical problems that I cannot think about anything else.

113. ☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

SOCIAL SUPPORT FORM

The following are questions about the <u>support</u> that is available to you.

1. At the present time, about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)? **(Please write the number in the boxes below.)**

   [ ][ ] Number of close friends and close relatives

People sometimes look to others for companionship, assistance, or other types of support. Currently, how often is each of the following kinds of support available to you if you need it? (Check one box for each statement.)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Someone to help you if you were confined to bed.					
3. Someone you can count on to listen to you when you need to talk.					
4. Someone to give you good advice about a crisis.					
5. Someone to take you to the doctor if you needed it.					
6. Someone who shows you love and affection.					
7. Someone to have a good time with.					
8. Someone to give you information to help you understand a situation.					
9. Someone to confide in or talk to about yourself or your problems.					

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
10. Someone who hugs you.					
11. Someone to get together with for relaxation.					
12. Someone to prepare your meals if you were unable to do it yourself.					
13. Someone whose advice you really want.					
14. Someone to do things with to help you get your mind off things.					
15 Someone to help with daily chores if you were sick.					
16. Someone to share your most private worries and fears with.					
17. Someone to turn to for suggestions about how to deal with a personal problem.					
18. Someone to do something enjoyable with.					
19. Someone who understands your problems.					
20. Someone to love you and make you feel wanted.					

Patient I.D.	__ __ - __ __ __ __
Patient Acrostic:	__ __ __ __ __ __

For the following questions, please check the box that is the most true for you at the present time. (Check only one box for each statement.)

Of the people who are important to you, how many:

	None	One	Some	Most	All
21. Don't understand you.					
22. Get on your nerves.					
23. Ask too much of you.					
24. Argue with you.					
25. Don't include you.					
26. Show that they don't like you.					
27. Boss you.					
28. Try to get you to do things you don't want to do.					

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

PERSONAL HABITS FORM

These questions are about habits that may affect your health (smoking, alcohol use, weight, and exercise). Please answer each question as accurately as possible.

1. Do you smoke currently?

☐ No

☐ Yes

If yes, how many cigarettes do you smoke per day? (1 pack = 20 cigarettes)

☐ I smoke occasionally.

☐ 0 - 5 cigarettes a day

☐ 6 - 20 cigarettes a day

☐ 21 - 30 cigarettes a day

☐ 31 - 40 cigarettes a day

☐ more than 40 cigarettes a day

2. Do you currently drink alcoholic beverages?

☐ No

☐ Yes

If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currently drink in an average month?

☐☐☐ Beverages per month

3. What is your current weight?

☐☐☐ pounds

The following questions are about your usual physical activity and exercise. This includes walking and sports.

4. Think about the walking you do outside the home. In the past month, how often did you walk outside the home for more than 10 minutes without stopping? **(Mark only one.)**

☐	Rarely or never	--->	(Go to Question 5)
☐	1-3 times each month	--->	(Go to Question 4a)
☐	1 time each week	--->	(Go to Question 4a)
☐	2-3 times each week	--->	(Go to Question 4a)
☐	4-6 times each week	--->	(Go to Question 4a)
☐	7 or more times each week	--->	(Go to Question 4a)

4a. When you walked outside the home for more than 10 minutes without stopping, how many minutes did you usually walk?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

4b. What was your usual speed?

- ☐ Casual strolling or walking (less than 2 miles an hour)
- ☐ Average or normal (2-3 miles an hour)
- ☐ Fairly fast (3-4 miles an hour)
- ☐ Very fast (more than 4 miles an hour)
- ☐ Don't Know

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

Following are three categories of exercise, (strenuous, moderate, and mild). Not including walking outside the home, how often each week (7 days) do you usually do the following strenuous, moderate, and mild types of exercise?

5. **STRENUOUS OR VERY HARD EXERCISE.** (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

- ☐ None ---> (Go to Question 6)
- ☐ 1 day per week ---> (Go to Question 5a)
- ☐ 2 days per week ---> (Go to Question 5a)
- ☐ 3 days per week ---> (Go to Question 5a)
- ☐ 4 days per week ---> (Go to Question 5a)
- ☐ 5 or more days per week ---> (Go to question 5a)

5a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

6. **MODERATE EXERCISE** (Not exhausting). For example, biking outdoors, using an exercise machine (like a stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

- ☐ None ---> (Go to Question 7)
- ☐ 1 day per week ---> (Go to Question 6a)
- ☐ 2 days per week ---> (Go to Question 6a)
- ☐ 3 days per week ---> (Go to Question 6a)
- ☐ 4 days per week ---> (Go to Question 6a)
- ☐ 5 or more days per week ---> (Go to Question 6a)

6a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

7. **MILD EXERCISE**. For example, slow dancing, bowling, golf.

- ☐ None
- ☐ 1 day per week ---> (Go to Question 7a)
- ☐ 2 days per week ---> (Go to Question 7a)
- ☐ 3 days per week ---> (Go to Question 7a)
- ☐ 4 days per week ---> (Go to Question 7a)
- ☐ 5 or more days per week ---> (Go to Question 7a)

7a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

We are interested in how your life, in general, has been since your diagnosis.

1. What major challenges have you faced since your diagnosis?

2. What positive experiences have you had? (For example, things you learned about yourself, how you interact with your family, etc.)

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

LIFE EVENTS

Below are things that sometimes happen to people. Please try to think back over the **past year** to remember if any of these things happened. (**Mark only one box on each line.**)

Over the past year:	**NO**	**YES, and it upset me:** Not too much	**Moderately (Medium)**	**Very Much**
1. Did you have any major problems with money.				
2. Did you or a family member or close friend lose their jobs or retire?				
3. Did you have a major conflict with children?				
4. Did you have a divorce or break-up with a spouse or partner?				
5. Did a family member or close friend have a divorce or breakup?				
6. Did a close friend or family member die or have a serious illness (other than your spouse or partner.)				
7. Did you have any major accidents, disasters, muggings, unwanted sexual experiences, robberies, or similar events?				
8. Did your spouse or partner die or have a serious illness?				
9. Were you physically abused by a family member or close friend?				
10. Were you verbally abused by a family member or close friend?				
11. Did a pet die?				

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

CONTACT INFORMATION FORM

We would like you to update your contact information so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. **Has your address changed since our last mailing to you?**

   ☐ No ☐ **Yes → If yes, please provide current mailing address**

   Your Current Mailing Address?

   ____

   ____

   ____

2. Telephone Numbers:

   Home: Area Code (__ __ __) __ __ __ - __ __ __ __

   Work: Area Code (__ __ __) __ __ __ - __ __ __ __

   Other: Area Code (__ __ __) __ __ __ - __ __ __ __

3. When is the best time to contact you?

   ______________ ______________
   Day of week time(s)

   ______________ ______________
   Day of week time(s)

   Where is the best place to contact you?

   ☐ At home
   ☐ At work
   ☐ Other

   ☐ At home
   ☐ At work
   ☐ Other

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

4. In case we might ever need to contact you by telephone, may we leave a message for you on your answering machine, (if you have one), if we are unable to reach you directly?

   ☐ No
   ☐ Yes

5. What is your husband's or partner's legal name? (This information will help us keep in contact with you during the study. Please leave this blank if you are not currently married or with a long-term partner.)

   ______________________ ______ __________________________

   First MI Last

6. Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we are unable to reach you.

   Name: ____

   Address: ____

   ____

   Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

   Relationship to you: ____

   Name: ____

   Address: ____

   ____

   Phone Number: Area Code (__ __ __) __ __ __ - __ __ __ __

   Relationship to you: ____

Appendix E

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE

30-Month Follow-up Survey

Clinical Coordinating Center

Wake Forest University School of Medicine
Department of Public Health Sciences
Winston-Salem, North Carolina 27157-1063
(336) 713-4268

Funded by
The U.S. Army Medical Research and Material Command:
Breast Cancer Research Program A

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

PART I

MEDICAL and REPRODUCTIVE HISTORY FOLLOW-UP QUESTIONNAIRE

The following questions ask about health professionals you may have seen in the past 6 months. This information will help us describe in general terms the kinds of services being used.

1. In the past six months, which of the following doctors or other health professionals have you seen? **(Please Check all that apply)**

- ☐ None
- ☐ Acupuncturist
- ☐ Allergist
- ☐ Cardiologist
- ☐ Chiropractor
- ☐ Dentist
- ☐ Dermatologist
- ☐ Ear/Nose/Throat Doctor
- ☐ Eye Doctor
- ☐ Marital Counselor
- ☐ Gastroenterologist
- ☐ General Practitioner
- ☐ Gynecologist
- ☐ Infertility Specialist
- ☐ Internist
- ☐ Massage Therapist
- ☐ Neurologist
- ☐ Sexual Therapist
- ☐ Family Therapist
- ☐ Nutritionist
- ☐ Obstetrician
- ☐ Medical Oncologist/Chemotherapist
- ☐ Orthopedic Surgeon
- ☐ Homeopathic/Herbalist/Naturopathic
- ☐ Pain Control Professional
- ☐ Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
- ☐ Physical Therapist
- ☐ Plastic Surgeon
- ☐ Psychiatrist
- ☐ Clinical Psychologist
- ☐ Radiologist
- ☐ Rheumatologist
- ☐ Social Worker
- ☐ Organized Support Group
- ☐ Surgeon
- ☐ Urologist
- ☐ Other:____________________

2. In the past 6 months, have you been seen at an emergency room?

☐ No

☐ Yes → For what reason: ______________________________

____

3. In the past 6 months, have you been hospitalized or had surgery? Please mark one box for each line item (a) and (b).

	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			

4. Has anything else changed regarding either your mental or physical health status? Please mark one box for each line item (a) and (b).

	No	Yes	What has changed?
(a) Mental Health?			
(b) Physical Health?			

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

5. Have you had any biopsies in the past 6 months?

☐ No

☐ Yes →If yes, what was biopsied?______________________

Why was this biopsied?______________________

____

6. In the past 6 months, have you had a recurrence of breast cancer?

☐ No

☐ Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?

____

7. Have you been diagnosed with any other cancer in the past 6 months?

☐ No

☐ Yes → If yes, what type?______________________

How was this diagnosis made? (For example, biopsy, lab tests)?

____

8. Today's date is: ☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

PART II **REPRODUCTIVE HISTORY**

The following questions ask about your menstrual cycles and reproductive history. We are very interested in this information so that we can understand more about women's health during their childbearing years. Some of the questions ask you to give dates or the number of times when certain things happened. If you are not sure about the exact date or number of times, please give your best estimate.

1. What was the date of the first day of your last menstrual period (your best guess)?

☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

2. In the past 6 months, have you been sexually active with a male partner:

☐ No → Go to question 6
☐ Yes → Go to question 3

3. Which method of birth control are you and your partner using currently? **(Check all that apply.)**

☐ No method
☐ Condoms (rubbers)
☐ Birth control pills
☐ Foams/jellies/suppositories
☐ Sponge
☐ Withdrawal (pulling out)
☐ Diaphragm
☐ Safe periods (rhythm or counting days)
☐ Norplant
☐ Cervical cap
☐ Tubal ligation (tubes tied)
☐ Vasectomy
☐ Other (Please describe: ___________)
☐ Don't know

4. <u>In the past month</u>, how many times have you had sexual intercourse without using contraception?

☐☐ Times

5. <u>In the past 6 months</u>, have you become pregnant?

☐ No
☐ Yes → <u>If yes</u>, are you pregnant now?

☐ No
☐ Yes

6. <u>In the past month</u>, have you had any hot flashes or night sweats (hot flashes that occur during sleep)?

☐ No
☐ Yes ----> <u>If yes</u>, how many have you had in the **past week**?

☐☐☐ hot flashes/night sweats

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

PART III **CURRENT MEDICATIONS**

1. Please list below all of the **prescription medications** you are taking currently. (Write "none" if you are not taking any prescription medications at this time.)

Drug Name	Dosage

2. Please list below all of the **non-prescription medications or supplements** you are taking currently. (Write "none" if are not taking any non-prescription medications or supplements at this time.)

Drug Name	Dosage

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

SWELLING FORM

The following questions concern swelling in your arm and/or hand. Please mark the appropriate box(es) for each question.

1. In the past 6 months, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 2)
☐ Don't know → (Go to question 8)

2. Do you believe the start of your swelling was related to any of the following?

Yes	No	Don't Know	
☐	☐	☐	Radiation treatment
☐	☐	☐	Breast reconstruction
☐	☐	☐	Infection or injury to arm / hand
☐	☐	☐	Weather changes
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Airplane travel
☐			Other: Please describe: ________________________________

____

2a. How soon after you had surgery and/or began treatment did this swelling occur?

- ☐ Less than 1 week
- ☐ 1 week to 4 weeks
- ☐ 1 month to 3 months
- ☐ 4 months to 6 months
- ☐ 7 months to 9 months
- ☐ 10 months to 12 months
- ☐ 13 months to 15 months

2b. Where does (did) the swelling occur? **(Check all that apply)**

- ☐ Hand
- ☐ Upper Arm
- ☐ Lower Arm

2c. Do (did) you consider the swelling to be mostly?

- ☐ Mild
- ☐ Moderate
- ☐ Severe

3. Does (did) the swelling interfere with any of the following?

Yes	No	
☐	☐	Clothing that you wear
☐	☐	Your ability to do routine activities, such as household chores or grooming.
☐	☐	Exercise
☐	☐	Your appearance
☐		Other, please describe: ______________________

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

4. Does (did) swelling seem to get worse with any of the following?

Yes	No	Don't Know	
☐	☐	☐	Hot weather
☐	☐	☐	General use of your arm
☐	☐	☐	Exercise
☐	☐	☐	Sauna / Jacuzzi / Hot bath
☐	☐	☐	Airplane travel
☐	☐	☐	Specific foods
☐	☐	☐	Mental / emotional stress
☐			Other: Please describe: ________________________________

____

5. Prior to your breast cancer diagnosis, did you notice swelling in your hand and/or arm with any of the following? **(Check all that apply)**

Yes	No	Don't Know	
☐	☐	☐	Exercise
☐	☐	☐	Household Chores
☐	☐	☐	Heat/Humidity
☐	☐	☐	Eating salty foods
☐	☐	☐	Drinking alcoholic beverages
☐			Other: Please describe: ________________________________

____

6. Did you seek treatment for this swelling in the past 6 months?

☐ No → <u>If no</u>, why not?

____

____

☐ Yes → <u>If yes</u>, what type of treatment did you receive? **(Check all that apply)**

- ☐ Compression therapy by machine
- ☐ Glove / Sleeve Compression / Garment
- ☐ Physical therapy
- ☐ Manual lymphatic drainage
- ☐ Bandaging technique
- ☐ Other, please describe: ___________________________

____

7. Do you have swelling now?

☐ No → (Go to question 8)
☐ Yes → (Continue to question 7a)

7a. <u>If yes</u>, how long have you had swelling?

- ☐ Less than 1 week
- ☐ 2 - 4 weeks
- ☐ 1 - 3 months
- ☐ 4 - 6 months
- ☐ 7 - 9 months
- ☐ 10 - 12 months

8. In the past 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin injuries in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 9)
☐ Yes → (Continue to question 8a)
☐ Don't Know → (Continue to question 9)

8a. If yes, did you receive antibiotics?

☐ Yes
☐ No
☐ Don't know

9. In the past 6 months, did you have any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 10)
☐ Yes → (Continue to question 9a)
☐ Don't Know → (Continue to question 10)

If yes, did you:

9a. receive antibiotics by mouth?

☐ No
☐ Yes
☐ Don't know

If yes, did you:

9b. receive antibiotics by injection?

☐ No
☐ Yes
☐ Don't know

10. Do you have pain in the affected arm and/or hand? **(Check one box for each site)**

	Yes	No
hand		
arm		
hand and arm		

Patient I.D.	__ __ - __ __ __ __
Patient Acrostic:	__ __ __ __ __ __

SYMPTOMS QUESTIONNAIRE

Below are statements about symptoms some people may experience. For each statement, check the appropriate box for the response that best describes how bothersome the symptom was for you **during the past month**. If you did not have the problem, check the box under the column titled "symptom did not occur". Please do not skip any questions. **Mark only one box on each line.**

If you experienced the symptom, use the following key to indicate how bothersome it was:

Mild = **symptom did not interfere with usual activities.**
Moderate = **symptom interfered somewhat with usual activities.**
Severe = **symptom was so bothersome that usual activities could not be performed.**

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
1. Fatigue or low energy level				
2. Mouth ulcers				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Lightheadedness when standing up				
9. Faintness or dizziness at rest				
10. Headaches				
11. Swelling of ankles or feet				
12. Diarrhea				

Symptom	Symptom did not occur	Symptom Occurred and Was: Mild	Moderate	Severe
13. Constipation				
14. Abdominal pain/cramps				
15. Vaginal dryness				
16. Muscle pain/ache/or cramp				
17. Weight gain				
18. Weight loss				
19. General aches and pains				
20. Hot flashes				
21. Joint pains				
22. Night sweats				
23. Aches in back of neck and skull				
24. Forgetfulness				
25. Difficulty concentrating				
26. Increased appetite				
27. Short temper				
28. Decreased efficiency				
29. Loss of interest in work/activities				
30. Lowered work performance				
31. Blind spots, fuzzy vision				
32. Breast sensitivity/tenderness				
33. Avoidance of social affairs				
34. Cold sweats				
35. Decreased appetite				
36. Feelings of suffocation				
37. Difficulty healing				
38. Bloating				

Patient I.D. __ __ - __ __ __ __
Patient Acrostic: __ __ __ __ __ __

QUALITY OF LIFE FORM

1. In general, would you say your health is: **(Check one)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

3. Climbing several flights of stairs.

Limited a lot	Limited a little	Not limited at all
☐	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like.	☐	☐
5. Had difficulty performing the work or other activities, for example, it took extra effort.	☐	☐

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like.	☐	☐
7. Didn't do work or other activities as carefully as usual.	☐	☐

8. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

9. During the past four weeks, how much did pain interfere with your normal activities (including both work outside the home, housework and family activities)? **(Check one)**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

10. Have you felt calm and peaceful? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

11. Did you have a lot of energy? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

12. Have you felt downhearted and blue? **(Check one)**

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐	☐

Patient I.D.	___ ___ - ___ ___ ___ ___
Patient Acrostic:	___ ___ ___ ___ ___ ___

Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you *during the past 7 days*.

Physical Well-Being	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
13. I had a lack of energy.	1	2	3	4	5
14. I had nausea.	1	2	3	4	5
15. I had trouble meeting the needs of my family.	1	2	3	4	5
16. I had pain.	1	2	3	4	5
17. I was bothered by side effects of treatment.	1	2	3	4	5
18. In general, I felt sick.	1	2	3	4	5
19. I was forced to spend time in bed.	1	2	3	4	5

20. How much does your Physical Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Social/Family Well-Being	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
21. I felt distant from my friends	1	2	3	4	5
22. I got emotional support from my family.	1	2	3	4	5
23. I got support from my friends and neighbors.	1	2	3	4	5
24. My family had accepted my illness.	1	2	3	4	5
25. Family communication about my illness was poor.	1	2	3	4	5

If you have a spouse/partner, or are sexually active, please answer questions 26-27. Otherwise, go to question 28.

26. I felt close to my partner (or main support).	1	2	3	4	5
27. I was satisfied with my sex life.	1	2	3	4	5

28. How much does your Social/Family Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Relationship With Doctor	Not At All	A Little Bit	Some-What	Quite a bit	Very Much
29. I had confidence in my doctor(s).	1	2	3	4	5
30. My doctor was available to answer my questions.	1	2	3	4	5

31. How much does your Relationship with your Doctor affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Emotional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
32. I felt sad.	1	2	3	4	5
33. I was proud of how I'm coping with my illness.	1	2	3	4	5
34. I was losing hope in the fight against my illness.	1	2	3	4	5
35. I felt nervous.	1	2	3	4	5
36. I worried about dying.	1	2	3	4	5

37. How much does your Emotional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Functional Well-Being	Not at All	A Little Bit	Some-what	Quite a bit	Very Much
38. I was able to work (include work in home).	1	2	3	4	5
39. My work (include work in home) was fulfilling.	1	2	3	4	5
40. I was able to enjoy life "in the moment."	1	2	3	4	5
41. I had accepted my illness.	1	2	3	4	5
42. I was sleeping well.	1	2	3	4	5
43. I enjoyed my usual leisure pursuits.	1	2	3	4	5
44. I was content with the quality of my life right now.	1	2	3	4	5

45. How much does your Functional Well-Being affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

Patient I.D.	___ ___ - ___ ___ ___ ___
Patient Acrostic:	___ ___ ___ ___ ___ ___

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
46. I was short of breath.	1	2	3	4	5
47. I was self-conscious about the way I dressed.	1	2	3	4	5
48. My arms were swollen or tender.	1	2	3	4	5
49. I felt sexually attractive.	1	2	3	4	5
50. I was bothered by hair loss.	1	2	3	4	5
51. I worried about the risk of cancer in other family members.	1	2	3	4	5
52. I worried about the effect of stress on my illness.	1	2	3	4	5
53. I was bothered by a change in weight.	1	2	3	4	5
54. I was able to feel like a woman.	1	2	3	4	5

55. How much do these Additional Concerns affect your quality of life? **(Circle one number.)**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very Much So

YOUR APPEARANCE

This section asks you about your general perceptions regarding your body. Right now, how satisfied are you with these parts of your body? Please check the appropriate box for the response that best describes your satisfaction with each body part.

	Very dissatisfied	Somewhat dissatisfied	Neutral	Somewhat satisfied	Very satisfied
56. Hair					
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How much do you agree or disagree with the following statement? (Check the appropriate box.)

64. The appearance of my breast area is important to me.

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

65. I view myself as a:

☐ Very overweight person
☐ Moderately overweight person
☐ Normal weight person
☐ Moderately thin person
☐ Very thin person

PART III. SEXUALITY

These next questions are about the way health problems may interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems may affect women's sexuality.

66. Have you been sexually active with a partner during the last 6 months?

☐ No ----> (If no, skip to Question 79).
☐ Yes ----> (If yes, continue to Question 67).

67. How many times have you had sexual intercourse in the past month?

☐ 0 times
☐ 1 - 4 times
☐ 5 - 10 times
☐ 11 or more

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Never	**Almost Never**	**Sometimes**	**Almost Always**	**Always**
68. How often were you aware of wetness in your vagina as you became sexually excited?					
69. How often did it take a long time for your vagina to become wet or slippery as you became sexually excited?					
70. During sexual relations, how frequently did you notice dryness of your vagina?					
71. How often did you feel pain or discomfort during vaginal penetration?					
72. How often did you feel satisfied after sexual activity?					
73. How often were you satisfied with the frequency of sexual activity?					
74. How frequently did you feel tense or nervous after a sexual experience?					

For the following questions, please check the box for the response that best describes your sexual feelings and experiences **DURING THE PAST MONTH.**

	Strongly disagree	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly agree**
75. I avoided having my breast area fondled or kissed.					
76. My partner avoided fondling or kissing my breast area.					
77. I notice I didn't hug or kiss my partner much.					
78. I notice my partner didn't hug and kiss me much.					

PART IV. SLEEP HABITS

The next group of questions ask about your sleep habits. Please check the appropriate box for the one response that best describes how often you experienced these situations in **THE PAST 4 WEEKS**.

79. Did you have trouble falling asleep?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

80. Did you wake up several times a night?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

81. Did you wake up earlier than you planned to?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

82. Did you have trouble getting back to sleep after you woke up too early?

- ☐ No, not in the past 4 weeks
- ☐ Yes, less than once a week
- ☐ Yes, 1 or 2 times a week
- ☐ Yes, 3 or 4 times a week
- ☐ Yes, 5 or more times a week

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

83. Overall, how was your typical night's sleep during the past 4 weeks?

- ☐ Very sound or restful
- ☐ Sound or restful
- ☐ Average quality
- ☐ Restless
- ☐ Very restless

84. About how many hours of sleep did you get on a typical night during the past 4 weeks?

- ☐ 5 or less hours
- ☐ 6 hours
- ☐ 7 hours
- ☐ 8 hours
- ☐ 9 hours
- ☐ 10 or more hours

PART V. SPIRITUAL BELIEFS

The following questions are about spiritual beliefs. Please check the appropriate box indicating how true the statement has been for you during **THE PAST WEEK.**

	Not at all	A little bit	Somewhat	Quite a bit	Very much
85. I felt peaceful.					
86. I had a reason for living.					
87. I felt a sense of purpose in my life.					
88. I was able to reach down deep into myself for comfort.					
89. I felt a sense of harmony within myself.					
90. I found comfort in my faith.					
91. I found strength in my faith.					

92. Where would you place yourself on the following scale, if "0" means that your life is just the way it was before your breast cancer, "+5" means that everything is totally different but better, and "-5" means that everything is totally different but worse. ***(Please circle ONE number).***

-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
Worse					Same as before					Better

PART VI. EMOTIONAL FEELINGS

The following questions consist of groups of statements. After reading each group of statements carefully, check the box next to the one statement in each group which **best** describes the way you have been feeling **the past week, including today**. If several statements within a group seem to apply equally, check each one. **Be sure to read all the statements in each group before making your choice.**

93. ☐ I do not feel sad.
    ☐ I feel sad.
    ☐ I am sad all the time and I can't snap out of it.
    ☐ I am so sad or unhappy that I can't stand it.

94. ☐ I am not particularly discouraged about the future.
    ☐ I feel discouraged about the future.
    ☐ I feel I have nothing to look forward to.
    ☐ I feel that the future is hopeless and that things cannot improve.

95. ☐ I do not feel like a failure.
    ☐ I feel I have failed more than the average person.
    ☐ As I look back on my life, all I can see is a lot of failures.
    ☐ I feel I am a complete failure as a person.

96. ☐ I get as much satisfaction out of things as I used to.
    ☐ I don't enjoy things the way I used to.
    ☐ I don't get real satisfaction out of anything anymore.
    ☐ I am dissatisfied or bored with everything.

Patient I.D.	___ ___ - ___ ___ ___ ___
Patient Acrostic:	___ ___ ___ ___ ___ ___

97. ☐ I don't feel particularly guilty.
☐ I feel guilty a good part of the time.
☐ I feel quite guilty most of the time.
☐ I feel guilty all of the time.

98. ☐ I don't feel I am being punished.
☐ I feel I may be punished.
☐ I expect to be punished.
☐ I feel I am being punished.

99. ☐ I don't feel disappointed in myself.
☐ I am disappointed in myself.
☐ I am disgusted with myself.
☐ I hate myself.

100. ☐ I don't feel I am any worse than anybody else.
☐ I am critical of myself for my weaknesses or mistakes.
☐ I blame myself all the time for my faults.
☐ I blame myself for everything bad that happens.

101. ☐ I don't have any thoughts of killing myself.
☐ I have thoughts of killing myself, but I would not carry them out.
☐ I would like to kill myself.
☐ I would kill myself if I had the chance.

102. ☐ I don't cry anymore than usual.
☐ I cry more now than I used to.
☐ I cry all the time now.
☐ I used to be able to cry, but now I can't cry even though I want to.

103. ☐ I am no more irritated now than I ever am.
☐ I get annoyed or irritated more easily than I used to.
☐ I feel irritated all the time now.
☐ I don't get irritated at all by the things that used to irritate me.

104. ☐ I have not lost interest in other people.
☐ I am less interested in other people than I used to be.
☐ I have lost most of my interest in other people.
☐ I have lost all of my interest in other people.

105. ☐ I make decisions about as well as I ever could.
☐ I put off making decisions more than I used to.
☐ I have greater difficulty in making decisions than before.
☐ I can't make decisions at all anymore.

106. ☐ I don't feel I look any worse than I used to.
☐ I am worried that I am looking old or unattractive.
☐ I feel that there are permanent changes in my appearance that make me look unattractive.
☐ I believe that I look ugly.

107. ☐ I can work about as well as before.
☐ It takes an extra effort to get started at doing something.
☐ I have to push myself very hard to do anything.
☐ I can't do any work at all.

108. ☐ I can sleep as well as usual.
☐ I don't sleep as well as I used to.
☐ I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
☐ I wake up several hours earlier than I used to and cannot get back to sleep.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___

109. ☐ I don't get more tired than usual.
☐ I get tired more easily than I used to.
☐ I get tired from doing almost anything.
☐ I am too tired to do anything.

110. ☐ My appetite is no worse than usual.
☐ My appetite is not as good as it used to be.
☐ My appetite is much worse now.
☐ I have no appetite at all anymore.

111. ☐ I haven't lost much weight, if any, lately.
☐ I have lost more than five (5) pounds.
☐ I have lost more than ten (10) pounds.
☐ I have lost more than fifteen (15) pounds.

112. ☐ I am no more worried about my health than usual.
☐ I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
☐ I am very worried about physical problems and it's hard to think of much else.
☐ I am so worried about my physical problems that I cannot think about anything else.

113. ☐ I have not noticed any recent change in my interest in sex.
☐ I am less interested in sex than I used to be.
☐ I am much less interested in sex now.
☐ I have lost interest in sex completely.

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

SOCIAL SUPPORT FORM

The following are questions about the support that is available to you.

1. At the present time, about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)? **(Please write the number in the boxes below.)**

☐☐ Number of close friends and close relatives

People sometimes look to others for companionship, assistance, or other types of support. Currently, how often is each of the following kinds of support available to you if you need it? (Check one box for each statement.)

	None of the time	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
2. Someone to help you if you were confined to bed.					
3. Someone you can count on to listen to you when you need to talk.					
4. Someone to give you good advice about a crisis.					
5. Someone to take you to the doctor if you needed it.					
6. Someone who shows you love and affection.					
7. Someone to have a good time with.					
8. Someone to give you information to help you understand a situation.					
9. Someone to confide in or talk to about yourself or your problems.					

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
10. Someone who hugs you.					
11. Someone to get together with for relaxation.					
12. Someone to prepare your meals if you were unable to do it yourself.					
13. Someone whose advice you really want.					
14. Someone to do things with to help you get your mind off things.					
15 Someone to help with daily chores if you were sick.					
16. Someone to share your most private worries and fears with.					
17. Someone to turn to for suggestions about how to deal with a personal problem.					
18. Someone to do something enjoyable with.					
19. Someone who understands your problems.					
20. Someone to love you and make you feel wanted.					

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

For the following questions, please check the box that is the most true for you at the present time. (Check only one box for each statement.)

Of the people who are important to you, how many:

	None	**One**	**Some**	**Most**	**All**
21. Don't understand you.					
22. Get on your nerves.					
23. Ask too much of you.					
24. Argue with you.					
25. Don't include you.					
26. Show that they don't like you.					
27. Boss you.					
28. Try to get you to do things you don't want to do.					

Patient I.D. ___ ___ - ___ ___ ___ ___
Patient Acrostic: ___ ___ ___ ___ ___ ___

PERSONAL HABITS FORM

These questions are about habits that may affect your health (smoking, alcohol use, weight, and exercise). Please answer each question as accurately as possible.

1. Do you smoke currently?

☐ No
☐ Yes

If yes, how many cigarettes do you smoke per day? (1 pack = 20 cigarettes)

☐ I smoke occasionally.
☐ 0 - 5 cigarettes a day
☐ 6 - 20 cigarettes a day
☐ 21 - 30 cigarettes a day
☐ 31 - 40 cigarettes a day
☐ more than 40 cigarettes a day

2. Do you currently drink alcoholic beverages?

☐ No
☐ Yes

If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currently drink in an average month?

☐☐☐ Beverages per month

3. What is your current weight?

☐☐☐ pounds

The following questions are about your usual physical activity and exercise. This includes walking and sports.

4. Think about the walking you do outside the home. In the past month, how often did you walk outside the home for more than 10 minutes without stopping? **(Mark only one.)**

- ☐ Rarely or never ---> (Go to Question 5)
- ☐ 1-3 times each month ---> (Go to Question 4a)
- ☐ 1 time each week ---> (Go to Question 4a)
- ☐ 2-3 times each week ---> (Go to Question 4a)
- ☐ 4-6 times each week ---> (Go to Question 4a)
- ☐ 7 or more times each week ---> (Go to Question 4a)

4a. When you walked outside the home for more than 10 minutes without stopping, how many minutes did you usually walk?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

4b. What was your usual speed?

- ☐ Casual strolling or walking (less than 2 miles an hour)
- ☐ Average or normal (2-3 miles an hour)
- ☐ Fairly fast (3-4 miles an hour)
- ☐ Very fast (more than 4 miles an hour)
- ☐ Don't Know

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

Following are three categories of exercise, (strenuous, moderate, and mild). Not including walking outside the home, <u>how often each week (7 days</u>) do you usually do the following strenuous, moderate, and mild types of exercise?

5. **STRENUOUS OR VERY HARD EXERCISE.** (You work up a sweat and your heart beats fast.) For example, aerobics, aerobic dancing, jogging, tennis, swimming laps.

☐	None	--->	(Go to Question 6)
☐	1 day per week	--->	(Go to Question 5a)
☐	2 days per week	--->	(Go to Question 5a)
☐	3 days per week	--->	(Go to Question 5a)
☐	4 days per week	--->	(Go to Question 5a)
☐	5 or more days per week	--->	(Go to question 5a)

5a. How long do you usually exercise like this at one time?

☐ Less than 20 minutes

☐ 20-39 minutes

☐ 40-59 minutes

☐ 1 hour or more

6. **MODERATE EXERCISE** (Not exhausting). For example, biking outdoors, using an exercise machine (like a stationary bike or treadmill), calisthenics, easy swimming, popular or folk dancing.

☐	None	--->	(Go to Question 7)
☐	1 day per week	--->	(Go to Question 6a)
☐	2 days per week	--->	(Go to Question 6a)
☐	3 days per week	--->	(Go to Question 6a)
☐	4 days per week	--->	(Go to Question 6a)
☐	5 or more days per week	--->	(Go to Question 6a)

6a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

7. **MILD EXERCISE**. For example, slow dancing, bowling, golf.

☐	None		
☐	1 day per week	--->	(Go to Question 7a)
☐	2 days per week	--->	(Go to Question 7a)
☐	3 days per week	--->	(Go to Question 7a)
☐	4 days per week	--->	(Go to Question 7a)
☐	5 or more days per week	--->	(Go to Question 7a)

7a. How long do you usually exercise like this at one time?

- ☐ Less than 20 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ 1 hour or more

Patient I.D. ___ ___ - ___ ___ ___ ___

Patient Acrostic: ___ ___ ___ ___ ___ ___

CONTACT INFORMATION FORM

We would like you to update your contact information so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. **Has your address changed since our last mailing to you?**

   ☐ No ☐ **Yes → If yes, please provide current mailing address**

   Your Current Mailing Address?

   ____

   ____

   ____

2. Telephone Numbers:

Home:	Area Code	(___) ___ - ____
Work:	Area Code	(___) ___ - ____
Other:	Area Code	(___) ___ - ____

3. When is the best time to contact you? / Where is the best place to contact you?

Day of week	time(s)	Place
________	________	☐ At home ☐ At work ☐ Other
________	________	☐ At home ☐ At work ☐ Other

4. In case we might ever need to contact you by telephone, may we leave a message for you on your answering machine, (if you have one), if we are unable to reach you directly?

   ☐ No
   ☐ Yes

5. What is your husband's or partner's legal name? (This information will help us keep in contact with you during the study. Please leave this blank if you are not currently married or with a long-term partner.)

   ______________________ ______ ________________________

   First MI Last

6. Please provide the names of two relatives or friends, not living in your household, who are likely to know how to contact you if we are unable to reach you.

   Name: ____

   Address: ____

   ____

   Phone Number: Area Code (_ _ _) _ _ _ - _ _ _ _

   Relationship to you:____

   Name: ____

   Address: ____

   ____

   Phone Number: Area Code (_ _ _) _ _ _ - _ _ _ _

   Relationship to you:____

Appendix F

SEPTEMBER 2000

Patient I.D.: ☐ - ☐ - ☐☐☐☐ Acrostic: ☐☐☐☐☐☐

IF YOU'VE NOT HAD ANY BLEEDING DURING THIS MONTH, CHECK THIS BOX: ☐

OTHERWISE, for each day you bled or spotted, please check the appropriate box below referring to information on ANY vaginal BLEEDING or SPOTTING you may have. A BLEEDING day is defined as a day on which your blood loss requires the use of a tampon or pad. A SPOTTING day is defined as a day on which your blood loss does not require the use of a tampon or pad.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					1 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	2 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy
3 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	4 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	5 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	6 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	7 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	8 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	9 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy
10 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	11 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	12 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	13 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	14 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	15 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	16 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy
17 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	18 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	19 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	20 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	21 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	22 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	23 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy
24 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	25 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	26 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	27 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	28 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	29 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy	30 ☐ Spotting Bleeding: ☐ Light ☐ Medium ☐ Heavy

This calendar and the questionnaires you complete are for research purposes only. No doctor who is treating you will see these forms. If you have any questions or concerns - whether emotional, physical, or about your menstrual cycles - please discuss them with your doctor.

Call Judy at 336-716-2116 or Kathy at 336-716-9486 if you have questions.

NEWS From the Menstrual Cycle Maintenance and Quality of Life in Young Women with Breast Cancer Study

Spring 2000

A Message From the Coordinating Center

Hello from everyone at the Coordinating Center. First, I want to thank everyone who provided feedback on our first newsletter. For me, hearing from participants is one of the highlights of my day. Thanks for your calls, e-mails and notes.

Spring is a time of new beginnings and new growth. In this newsletter several cancer survivors share their stories in hopes of providing inspiration to you so that your own experience with cancer can lead to personal growth. We also highlight the staff at the Memorial Sloan-Kettering Cancer Center, and share some information about what our participants are like. Enclosed with the newsletter is the 1999 Breast Cancer Handbook from SELF magazine. In the magazine you will find an article about Jeanne Petrek, the lead investigator at Memorial Sloan Kettering, Myths about breast cancer, Portrait's of Survivors, and a list of important resources that may be of interest. We hope you will enjoy the newsletter and perhaps pass it on to a friend. One of our participants was kind enough to share a great cookie recipe. I've made it twice and it was a hit.

The new millennium is an exciting and yet challenging time for scientific research. Every week new articles are released describing research to detect, and treat breast cancer. Better surgical techniques are being developed, new drug therapies are being tested, and interventions are being implemented to help with the physical and emotional problems encountered by patients and their families. What the countless lectures and research articles don't tell you, is perhaps the most important piece of information. None of these advancements would have been possible without women like you participating in research in the hopes of making a difference for women in the future. As one of our participants has said, " here's Hoping for a Cancer-Free New Millennium".

Judy Bahnson

New Books

Eileen Marian, author of the book Chemotherapy Gives New Meaning to A Bad Hair Day, says, "Disease isn't funny, humor, however, is healing." The book is a cartoon book that helps individuals find humor in difficult situations.

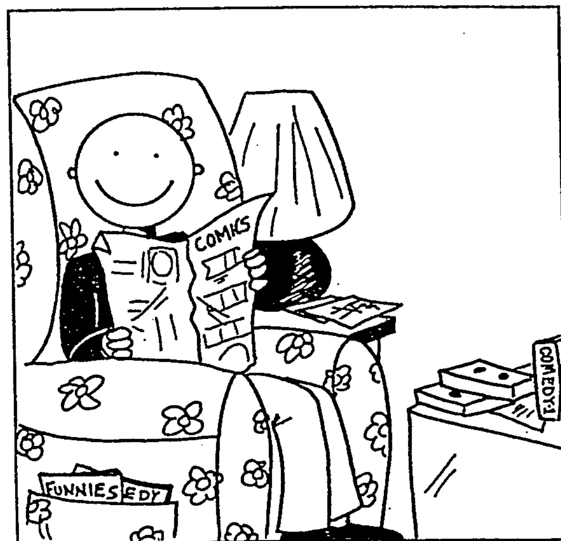
Pat Kellly, one of our Project Coordinators in Texas was familiar with the book and recommended it for our Newsletter. I called Eileen to get the story behind the book. In 1992 Eileen says, "Life was good. I was 44, eating healthy, exercising and taking time for myself to live life on life's terms when I was diagnosed with breast cancer." She relates that coping with surgery and facing radiation treatment was a piece of cake compared to confronting the fears of her teenage son. Eileen said that, humor was included in her bag of tools to help her live through this life crisis. "Over the next few years," she says, "humor took on a life of its own" as she was diagnosed with another breast cancer and then colon cancer. Eileen says, "From the start of this journey, I quickly learned the importance of being an empowered patient; to speak up and ask questions and not to stop until I got the answer." She found groups to be educational and supportive at various stages of her disease. In addition, she says, "I used the safety of a journal to revel my fears and confusion that I wouldn't share with another person."

Eileen's cousin was diagnosed with breast cancer several years later, and she began to send her little notes with humorous statements and drawings related to some of the tests that cancer patients go through. Those simple drawing and statements grew to become a book.

Eileen's book has some wonderful light hearted cartoons. In addition, she provides thought provoking sayings and space for writing your own thoughts.

Eileen says, "Cancer is a horrible disease, but it has helped me a great deal to learn about myself. It continues to teach me lessons and has given me permission to take risks necessary to live life to the fullest regardless of how many days, weeks, or years I have."

Want to see the book? Check out www.metroplexweb.com/oas or you can order the book for $15.15 from On a Shoestring, P.O. Box 831537, Richardson Texas 75083



Laughter is the best medicine.
It's free and doesn't have to be filed with insurance.

Who's Participating in the Study?

We now have 523 women enrolled in the Menstrual Cycle Maintenance and Quality of Life After Breast Cancer Study. For those of you receiving the newsletter for the first time, we have four Clinical Centers enrolling participants: Memorial Sloan Kettering in New York: M.D. Anderson and Presbyterian Hospital in Texas; and Wake Forest University Baptist Medical Center in North Carolina.

Age of participants

The average age of our participants at entry into this study is 39 years old.

1% are age 21 - 25
3% are age 26 - 30
33% are age 31 - 39
49% are age 40 - 45
14% are 45 years old or older.

Educational Status

2% have less than a high school education
9 % graduated from high school or received a GED
63% had some college or are college graduates
26% have a Master's or Doctoral degree

Racial Status

86% are White
6 % are African American
4 % are Hispanic
3 % are Asian
1% are American Indian

Employment Status

17% work full time as homemakers
56% are employed full time at a paid job
13% are employed part time at a paid job
6 % are on disability

Marital Status

75% are married or have a live-in relationship
15% have never been married
10% are separated, divorced or widowed.

Seventy-four percent of our participants have children.

INFORMATIVE WEB SITES

The following web-site was recommended by one of our study participants.

Health Insurance Rights:
www.georgetown.edu/research/ihcrp/hipaa
This site lists, by state, consumer guides to getting and keeping health insurance and/or switching health insurance if you have a pre-existing condition. Participant Linda Pollitz writes, "This site was/is the brainchild of a breast cancer survivor (my sister)."

If you know of other web sites that participants might find interesting or useful, let us know and we will put them in our next newsletter.

Who's Who at the Memorial Sloan-Kettering Cancer Center Clinic Site

Jeanne Petrek - Principal Investigator

Dr. Jeanne Petrek, Principal Investigator for the study at the Memorial Sloan-Kettering Cancer Center in New York, grew up in Ohio and received her MD from Case Western Reserve in Cleveland. She is an attending breast surgeon at Memorial Sloan-Kettering and the Director of the Surgical Program at the Evelyn H. Lauder Breast Center. She is also an Associate Professor of Surgery at the Cornell University School of Medicine, and she serves on the Breast Cancer Council of the National Society of the American Cancer Society. She has authored several books and many scientific articles on breast cancer.

Ten years ago, Dr. Petrek developed a special interest in breast cancer in young women and the issues they face, such as the ability to have children after breast cancer treatment, problems of lymphedema and in issues associated with their quality of life. At that time, very little research was being done on women, and no research was being done with young women with breast cancer. In hopes of making a difference to science and young women, Dr. Petrek began to focus on breast surgery and the problems associated with breast cancer. She was the primary motivator in planning the study in which you are now participating in.

In her leisure time, Dr. Petrek enjoys outdoor activities, such as, hiking, snorkeling and rafting. She lives in Manhattan with her husband and two children.

Joanna Winawer, Study Coordinator

Joanna grew up in New York City. After receiving her B.S. in Classical Humanities from the University of Wisconsin at Madison, she spent a year traveling and studying in Israel. Medicine has been a life long interest for Joanna, who decided to gain some experience in the field before applying to medical school. When Joanna isn't working, she enjoys traveling, hiking, swimming, going to the opera, and devouring sushi!

Lisa Loudon - Research Coordinator

For the first 23 years of her life, Lisa lived in the quiet country side of Virginia. Her future husband convinced her to leave the country...and move to the city....New York City. Lisa says she went from one extreme to another, and what an experience! She says, although she loves the city, her heart belongs to Virginia.

Lisa has worked at Memorial Sloan-Kettering for five years. She started as a medical secretary where she enjoyed working with patients and learning about the disease. Dr. Petrek then offered her the opportunity to work with her as her research coordinator which Lisa enjoys. "I am very excited to be a part of this very important study", she says.

Lisa says she has the typical Type B personality; fairly laid back and calm. When I first met her, I would have agreed with that. However, last year she was working full-time, going to school, and doing an internship while she was pregnant! Sounds Type A to me. In May of 1999 she finished her Masters in Childhood Development. In June, she gave birth to her first child, James Anthony, and life really got busy.

Participant Profile

Last week while I was working on this Newsletter, I recieved a call from one of our participants, Ricka Powers, who apologized that some of her study forms were late. When she said she had been incredibly busy I asked her what was going on. " I'm running for the House of Representatives in Minnesota," she said. After chatting for a few minutes, I told Ricka I was working on the Newsletter and asked her if she wanted to share her experience with our other study participants. She was happy to do so.

Ricka was 39 when she found she had Stage II breast cancer. For three years her HMO had been reassuring her that her growing lump was not breast cancer. Ricka says, "I finally arranged my own biopsy against my doctor's wishes, and received the diagnosis. She was assigned a general surgeon but insisted on a second opinion with a surgical oncologist experienced with breast cancer. She says, "I spent three days pleading for a second opinion, and finally gave up and went on my own to Hennepin County Medical Center so I could have a surgical oncologist perform my lumpectomy and auxiliary lymph node dissection".

"My HMO battle continued, and with the support of the Medical Center and the National Breast Cancer Coalition, I was asked to speak at the White House with President Clinton, Vice President Gore, Secretary Donna Shalala, Alexix Herman, and AMA Board member, Dr. Regina Benjamin, in support of the Patients Bill of Rights."

Two days after her first chemotherapy treatment she was asked to meet with the Vice President again and a month later with the National Breast Cancer Coalition.

"Instead of focusing on my healing, my energy was used in battling my HMO, which took place during my chemotherapy treatment," she said. In the end, her HMO did pay for her medical bills.

So how did she get through it all? Ricka says, "Thanks to the strength that God has given me, I'm standing on solid ground and ready to start my life over with new meaning and challenges. I am passionate about health care, and I am driven to take my personal experience and the voice of the community, and transform them into constructive activism. I'm running for the House of Representatives because one of God's greatest miracles is to enable ordinary people to do extraordinary things. "

Ricka says, " I decided to share my story with you because it gives me the opportunity to reassure you that we will get through the horror of our diagnosis, chemotherapy, radiation, and endless treatments. Our hair will slowly grow back again, and as we awkwardly remove our hat or wig for the first time and go out into the crowd looking like GI Jane, perhaps we will think of all the breast cancer survivors: a ballet of warriors on the front line against cancer. We come to terms with fear and cast it out in prayer. We conquer healing through faith. We experience the metamorphosis of a new sense of forgiveness, examine our demands on ourselves and others, and speak love more openly and freely."

" My sisters in survival," she says, "you can't be brave if you've only had good things happen to you." Ricka closes with a stanza from a poem she wrote while battling cancer:

We can do great things
Only small things with great love.
And when you think it's impossible, well,
Reality is what you rise above.

I'm sure all of us wish Ricka luck in her fight for health care reform and patients rights, and her race in the House of Representatives. Win or lose, there is no doubt she is a woman who is making a difference and is certainly a winner.

Ricka can be reached at rickapowers@ isd.net

QUICK RECIPES

The following recipe was sent in by one of our participants. It was quick and tasted great. You can experiment using different types of jam in this recipe. For example, I used ½ jar of peach jam and ½ a jar of raspberry and that was good too.

Raspberry Preserves Snack Bars

1 package vanilla cake mix
2 ½ cups Oatmeal (uncooked)
3/4 cup melted butter

12 oz. Jar of raspberry preserves
1 tablespoon of water

Pre-heat oven to 375 degrees.
Grease a 13 X 9 inch pan.
Combine cake mix and oatmeal.
Add butter and stir until mixture is crumbly. Pat ½ the mixture in the bottom of the pan. Mix water and preserves and spread on top.
Sprinkle the remaining crumbs over the preserves and pat down firmly to make it even. Bake 20 - 25 minutes and enjoy!

We Would Like To Hear From You!

We welcome any questions or thoughts you have for the newsletter. Please drop us a line. Fold the paper in half and staple or tape it closed. We have put our address on the back for your convenience. You may also e-mail us at: jbahnson@wfubmc.edu

Appendix H

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE AFTER BREAST CANCER TREATMENT

Jeanne A. Petrek, MD
Ruby Senie, PhD

Memorial Sloan-Kettering Cancer Center
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About 15% of the 175,000 estimated cases of invasive breast cancer this year will occur in women of childbearing age, and the majority will be long-term survivors. Most will undergo adjuvant chemotherapy and almost half will suffer therapy-induced menopause. Even without desire for childbearing, the quality of life of these young patients may be compromised by premature menopause with typical symptoms of hot flashes, sleep disturbances, decreased libido, and vaginal dryness.

Very little is known about the drugs and dosage causing premature menopause, although such a risk profile could be critical to the clinician and to the young patient in decision-making about chemotherapy. This is especially true since the improved survival following chemotherapy appears independent of menopause induction.

Since no prospective study exists, this current research was undertaken. The goal is to accrue 800 young breast cancer patients within eight months of diagnosis, obtaining extensive baseline and treatment data and following them for medical and reproductive events. These women have consented to report bleeding through a daily calendar and health-related quality of life as related to the menopausal state. Specific questionnaires are administered every six months: Rand Health Status Profile Short Form-12, FACT-B (Functional Assessment of Cancer Therapy-Breast), Self-Concept Scale, Watts Sexual Functioning Questionnaires, Sleep Disturbance Scale, Spirituality Subscale, Beck Depression Inventory, and Medical Outcomes Study/Social Support Questionnaire.

Eligible women must be less than age 45 with regular menstrual periods pre-diagnosis since menstrual cycle maintenance is used as the surrogate of ovarian function. Accrual began January 1998 and there are more than 500 study subjects at present. Publication of results is planned for January 2002.

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Appendix I

Pregnancy after Breast Cancer

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ABSTRACT

BACKGROUND: The issue of having children after breast cancer treatment is extremely important, since as many as 10% of the 175,000 new cases of invasive breast cancer estimated for 1999 occur in women of childbearing age.

METHODS: Data on pregnancy in breast cancer survivors are scanty and consist only of retrospective data. This paper reviews the published literature on pregnancy after breast cancer, including the four recent large scale, population based studies.

RESULTS: The survival of women with breast carcinoma is not decreased in any of the published reports. However, several biases due to study design may be present in the retrospective studies which justify the concern over the conclusions.

CONCLUSIONS: A prospective study on pregnancy after breast carcinoma treatment is needed. To address these issues we are presently accruing patients for a large, multicenter study of young breast carcinoma patients funded by the Army Breast Cancer Research fund. *(1-877-636-7562)*

INTRODUCTION

The issue about safety after treatment of breast cancer is of great concern for the breast cancer survivor as well as her physician. Many women are delaying childbearing for different reasons (educational, professional, and personal) and it is becoming increasingly more common for them to undergo breast cancer diagnosis and treatment before completing their childbearing. The delay in childbearing to age 30's or 40's occurs concordantly with an increasing incidence of breast cancer in those ages. Ten percent of the 175,000 new cases of breast cancer estimated for 1999 occur in women of childbearing age. [(1)] Physicians have stressed the complete rehabilitation of breast cancer patients, and successfully reassuming life roles. It is thus natural following the completion of therapy for the patient to inquire about an integral and treasured part of life – pregnancy and childbearing.

The hormonal influence of mammary carcinogenesis is well known. The effects of first full term pregnancy, age at menarche/menopause, usage of postmenopausal hormone replacement are definite factors in the pathogenesis of breast cancer. Aside from carcinogenesis, the importance of breast cancer promotion by the endogenous hormonal milieu has been recognized for over 100 years. Beatson, in 1896, noted regression after oophorectomy in pre-menopausal patients with advanced local disease. [(2)] The possible promotional effects of endogenous ovarian or placental hormone production on causing acceleration of the growth rate of micrometastases, or stimulation of dormant micrometastases evaluated are of concern in patients with breast cancer.

Few studies have evaluated women who become pregnant after breast cancer treatment. There are several retrospective studies, each with a limited number of patients, and only recently

population-based studies have been published. A presently ongoing large prospective multicenter study sponsored by the Army Breast Cancer Research program will help to address some of these issues.

RETROSPECTIVE SERIES

The earlier literature stated that at least 7% of women who did not undergo oophorectomy underwent one or more pregnancies. Seventy percent of these pregnancies were to be expected in the first five years after cancer treatment. [3] Adjuvant cytotoxic chemotherapy depletes the number of fertile patients by causing premature menopause, but as many as 11% had a deliberate or unplanned pregnancy in a short- term chemotherapy study. [4] From the scanty literature available it has been generally observed that breast cancer patients who subsequently become pregnant have good survival rates, often the same or sometimes better than patients with no subsequent pregnancy. [5,6]

There have been sporadic retrospective studies from single institutions with each comprising less than 100 patients. In 1954, White reported that eight (67%) of the patients who became pregnant lived at least 5 years, and 58% survived ten years. [7] In 1962 a series of 52 patients from Memorial Hospital had an overall five year survival rate of 52%. [8] Another similar-sized study reported in 1969 [9] included 53 patients with five and ten year survival rates of 77% and 69% respectively. In 1970 Cooper reported a 75% five-year survival rate in 32 patients. [10] Fifty percent of patients in a 1973 series survived five years. [11]

Case matching studies were also performed in order to lessen the influence of pregnancy occurring only in those with a good prognosis. Peters, et al., in 1965 matched ninety-six patients with subsequent pregnancy over several decades with patients with similar age and clinical stage.[12] The patients with subsequent pregnancy had a longer disease-free and overall survival

than those without subsequent pregnancy. In an analysis from 1970, Cooper [10] matched each of 40 patients who subsequently became pregnant with two controls as determined by the clinical stage, age, status of lymph node involvement, and equal survival at least to the time of pregnancy. The patients with subsequent pregnancy had a survival time superior to that of the controls.

Memorial Sloan-Kettering Cancer Center reported an 80% 5-year survival rate for 41 Stage I and II (AJCC classification) patients after subsequent pregnancy who were collected over 30 years. No detrimental effect was noted of subsequent pregnancy even among patients with positive axillary lymph nodes or among those who had a pregnancy less than 2 years following mastectomy. [13] In a 1986 nationwide French study, the ten year survival rate of 68 patients who had subsequent pregnant was 71%. The survival of the negative-node patients was 90% at ten years with no difference between cases and controls. [14] In 1989 Ariel and Kempner found that subsequent pregnancies did not affect overall prognosis in a large private practice experience. [15] The largest series is by Clark et.al, [16] of 136 patients diagnosed over five decades at the Princess Margaret Hospital in Toronto and is an update of the series reported by Peters in 1965.[12] They reported an excellent overall five year survival rate of 78%.

Data on subsequent pregnancy have also been reported in the analysis of adjuvant chemotherapy trials, showing similar recurrence rates and survival for patients who had undergone subsequent pregnancy compared to those who did not. [4] Recently a study from Athens was reported with twenty-one patients under the age of 35 who had a pregnancy after treatment for breast cancer. The recurrence rate and survival of the 21 women was similar to patients of similar age and stage without pregnancy. [17]

INTERVAL

Three retrospective studies have examined the question of the timing of the subsequent pregnancy on breast cancer prognosis. The effect of interval length between breast cancer diagnosis and pregnancy affects prognosis because women who defer a pregnancy for many years are also those who have remained disease-free for greater periods.

Clark and Chua [16] found that 72% of their patients became pregnant within two years of treatment. Those who became pregnant within six months had a comparatively poor prognosis -- a five-year survival rate of 54% compared with a 78% five-year survival rate among those who waited six months to two years to become pregnant after breast cancer diagnosis. Those who waited five years or more to become pregnant had 100% five-year survival from that point. The data are consistent with the fact that the longer survival after diagnosis is, per se, an indicator of the patients' better prognosis (whether pregnancy occurs or not). The French series [14] and the Memorial Hospital series, [13] which are smaller, do not find a statistically significant difference between outcome of patients based on the interval.

RETROSPECTIVE STUDY - POSSIBLE RECOLLECTION BIAS

How much reliance can be placed on these optimistic reports to allow us to adequately advise patients on subsequent pregnancy after breast cancer treatment? Since pregnancy is not coded as a disease or coded in any other way by the Record Room or Tumor Registry, cases over the previous decades are not found systematically, as is the situation with the Memorial Hospital series. [13] Even if a chart or tumor registry review of all premenopausal women had been undertaken, the occurrence of subsequent pregnancy may not be noted.

The Methods section of all of the retrospective series ignores the question of the denominator, the total number of patients with subsequent pregnancies. The largest series states simply, "We have reviewed patients whose case histories are currently available". [16] Since cases over the decades have been obtained in these reports from the many clinicians' memories, and since it is human nature to remember those who have been seen more recently, the design of these studies is predisposed to find and report on the patients who are alive, a recollection bias.

For all of these reasons, each report probably contains a small fraction of such patients from that institution. For example, consider a typical series, that from Memorial Sloan-Kettering Cancer Center: over 30 years, 41 Stage I and II patients were found who became pregnant after breast cancer treatment and they had an outstanding 80% 5-year survival. [13] However, based on the numbers and ages of women seen in those 30 years, as I was able to obtain from the Memorial Hospital Tumor Registry, and assuming only 7% of breast cancer patients less than 40 years became pregnant, this study should have reported on at least 450 women. Therefore, the patients reported from Memorial Hospital represent a highly selected subset, possibly 10% or so of the total who became pregnant after breast cancer treatment. It may be that this subset does not represent the whole.

POPULATION- BASED REPORTS

In an effort to avoid recollection bias, four large population based studies have been published since 1994. The first three studies are similar because they all depend upon the National Health Service record keeping and a unique identifying number that is assigned to each person at birth and is used for every hospitalization and every reportable event such as a cancer diagnosis.

Finland - The Finnish population based study used the personal identification number of women diagnosed with breast cancer and searched the national birth certificate registry for those numbers in the years following the women's diagnosis. [18] They found 91 breast cancer patients with subsequent deliveries. They found 471 breast cancer controls without subsequent births matched for stage, age and living at least as many years as the case to which they were matched. Those with a subsequent birth had statistically better survival rates than controls of the same age and stage with no subsequent births. The controls had a 4.8 fold (CI 2.2 – 10.3) increased risk of death compared with those who delivered after the diagnosis of breast cancer.

The flaw of national cancer registry information is that only dates of breast cancer diagnosis and death for both cases (with subsequent pregnancy) and controls (without subsequent pregnancy) were available, with no information on recurrence data. It is likely that breast cancer patients who chose to become pregnant and give birth were disease free, as opposed to an unknown proportion of controls who had a recurrence at the time of matching (but had not yet died). Thus, this bias would have contributed to controls having a poor survival rate and thereby making the cases appear to have a particularly good survival rate. The authors termed this bias "a healthy mother effect" in the title to denote the flaw that tumor registry data could not overcome.

Sweden - The next published study is from the Stockholm Breast Cancer Study Group. This Swedish study in 1995 [19] also addressed the influence of subsequent pregnancy on breast cancer prognosis. The study population consisted of 2,119 women with primary operable breast cancer who were less than 50 years of age and treated in the Stockholm region between 1971 and 1988. The study population was matched to the inpatient care registry -- by computerized record linkage through use of the unique personal identification number -- to obtain information about the patient's pregnancy history. A total of 50 pregnancies in 2,119 patients occurred after the

diagnosis of breast cancer. The relative hazard for these patients adjusted for nodal status and age was 0.48 (95% CI 0.18 – 1.29) at a median follow-up of 7 years (range 1- 19 years).

This was also the first study to report on estrogen receptor status, which was recorded in 70% of patients. The women with subsequent pregnancies had better survival rates if their cancer had positive estrogen receptors, which at first seems counter-intuitive. However, this finding is probably related to the mere fact that positive receptors predict better survival rates in general and less likelihood of micrometastatic disease.

Denmark - The Danish [20] study used computer linkage of the national records of Denmark on births, abortions, and breast cancer diagnosis. The authors identified 173 women, of 5725 with primary breast cancer, 45 years or younger, who became pregnant after treatment for breast cancer. Women who had a full-term pregnancy after treatment had a non-significantly reduced risk of dying (relative risk of 0.55 CI 0.28 – 1.06) compared with other women with no full term pregnancy.

In this study [18] the authors made an attempt to adjust for recurrence. Because virtually all women who undergo subsequent pregnancy are recurrence-free, the need of appropriate recurrence-free controls is key for matching. In the Danish study computer - matched linkage was accomplished on 93% of women, and information on recurrence was available on 82%. A national survey, however, may not have complete information on recurrence which is often obtained from office records. For example, the date when the patient suspected recurrence would influence her desire and likelihood of becoming pregnant at that point. Furthermore, in an attempt to include as many pregnancies as possible they entered cases up until 1994, and thus some had one year of follow-up.

USA - In 1999, this issue was analyzed with Surveillance Epidemiology and End Results (SEER) data in Washington State with a population-based cohort of 618 women less than 40 years old diagnosed with Stage I and II breast cancer between 1983 and 1992. [21] The investigators began collecting reproductive event data in 1994 when 119 of the 618 patients were dead. Questions concerning births, induced and spontaneous abortions, and timing of breast cancer recurrence were asked of the patients themselves or of the husbands or relatives of the deceased in the 70% of proxies who could be located. Reproductive events were obtained on a total of 520 women. The "cases" are 53 women who had a pregnancy after breast cancer diagnosis with 36 having a live birth. These were matched with control breast cancer patients without subsequent pregnancies who had the same stage and a recurrence-free survival time equal to the interval between diagnosis and pregnancy of the women who became pregnant.

There was a non-significant increased relative risk of dying with a completed pregnancy (as opposed to induced or spontaneous abortion) after breast cancer treatment (RR = 1.1; 95% CI, 0.4-3.7) overall and for those with positive lymph nodes (RR = 1.4; 95% CI, 0.4-5.2). If under-reporting of pregnancies was greater among the dead women, the adverse prognosis with subsequent pregnancy would be underestimated.

PROSPECTIVE STUDY

Population- based studies try to avoid the recollection bias prevalent in the retrospective studies, but add other biases, particularly in the choice of controls for the matching. The four studies above show no statistically significant detriment to subsequent pregnancy after breast cancer treatment. However, peculiar biases to each type of retrospective study design exist.

Until the issue is subjected to a prospective study, the effect of subsequent pregnancy is not really known. Only a prospective study provides comprehensive information on each patient at baseline including clinical characteristics, treatment variables and follow-up for medical status and recurrence, as well as any reproductive events. However, a prospective trial design is lengthy, as well as expensive, with results obtained perhaps ten years after its inception. The design of an ideal prospective study would include accruing breast cancer patients at diagnosis in order to have the extensive and comprehensive baseline data. We at Memorial Sloan-Kettering Cancer Center have launched such a prospective study starting in January 1998 with accrual of young women within eight months of diagnosis, collecting data on menstrual cycles, quality of life, and any reproductive events. More than 500 participants have been accrued. One of our short-term goals is the study of premature menopause, addressing symptoms, and sexual dysfunction. The statistical center is Wake Forest University, which is handling similar data for Women's Health Intervention, a study of women undergoing "natural" menopause. Our long-term goal is to obtain information on subsequent pregnancies. No in-patient visits are necessary; all data is obtained by mail and phone. The study intervention consists of medical record data, menstrual cycle diaries, and questionnaires. Patient referrals can be directed to Dr. Petrek (1-877-636-7562). Unfortunately statistics on survival following subsequent pregnancy will be forthcoming only after the next several years.

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