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PRINCIPAL INVESTIGATOR: Jeanne A. Petrek, M.D.

CONTRACTING ORGANIZATION: Sloan-Kettering Institute of Cancer Research
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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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## ANNUAL REPORT FOR GRANT NUMBER DAMD17-96-1-6292

# 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).

# **Participant Accrual**

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 participanting 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

# 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

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# 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.

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

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$\Box_{\mathcal{M}}$			
∐ No			
∐ Yes → For	what reas	on:	
In the past 6 months, h line item (a) and (b).	ave you be	een hospi	talized or had surgery? Please mark one box for eac
	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			
Has anything else chan	ged regard	ding either	r your mental or physical health status? Please mark
	em (a) and	d (b).	
one box for each line it			
one box for each line it	No	Yes	What has changed?
one box for each line it  (a) Mental Health?	No	Yes	What has changed?
	No	Yes	What has changed?
	No	Yes	What has changed?
	No	Yes	What has changed?

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5.	Have you had a	any biopsies in the past 6 months?
	□ No	s → If yes, what was biopsied?
		Why was this biopsied?
6.	In the past 6 mo	onths, 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	:

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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 <u>best estimate</u>.

1.	What was the	date of the first day of your <u>last</u>	menstrual pe	eriod (your best guess)?
	Month D	ay Year		
2.	In the past 6	months, have you been sexually a  No →Go to question 6  Yes →Go to question 3	active with a	male partner:
3.	Which metho	od of birth control are you and yo	ur partner us	ing currently? (Check all that
		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

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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 $Yes \rightarrow If yes$ , 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

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# PART III

# **CURRENT MEDICATIONS**

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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 mor lumpectomy or r	ths, has any swelling occurred in your arm or hand on the same side that you had your nastectomy?
2.	Yes → Don't kr	(Go to question 8)  (Continue to question 2)  now → (Go to question 8)  the start of your swelling was related to any of the following?
2.	-	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 (di	d) the swelling occur? (Check all that apply)
		Hand Upper Arm Lower Arm
2c.	Do (did) you co	onsider the swelling to be mostly?
		Mild Moderate Severe
Does (	did) the swelling	g 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:

3.

Patient I.D. :
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4.	Does (did) swelling seem to	get worse with any of the following?
	Don't Yes No 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 diffollowing? (Check all that	agnosis, did you notice swelling in your hand and/or arm with any of the apply)
	Don't Yes No Know	Exercise  Household Chores  Heat/Humidity  Eating salty foods  Drinking alcoholic beverages  Other: Please describe:

6.	Did yo	ou seek treatment for this swelling in the past 6 months?
		No → <u>If no</u> , 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 yo	u have swelling now?
		No $\rightarrow$ (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.		st 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin n your arm or hand on the same side that you had your lumpectomy or mastectomy?
	Y	No→ (Go to question 9)  Yes → (Continue to question 8a)  Son't Know → (Continue to question 9)
	8a. <u>I</u> 1	f yes, did you receive antibiotics?
		Yes No Don't know
9.	-	st 6 months, did you have any infection in the arm or hand on the same side that you had spectomy 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

	<u>If yes</u> , did	you:		·
	9b.	receive antibiot	ics by injection	n?
		No Yes Don't know		
10.	Do you have pain in	the affected arn	n 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 <u>not</u> interfere with usual activities.

Moderate

= symptom interfered somewhat with usual activities.

Severe =

symptom was so bothersome that usual activities could not be performed.

	Symptom did not	Symptom Occurred and Was:				
Symptom	occur	Mild	Moderate	Severe		
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 Occurred and Was:				
Symptom	did not occur	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 sa	y your health	is: (Check on	ie)	
	Excellent V	ery good	Good	Fair	Poor
	llowing questions are abo e activities? If so, how m		ou might do du	ring a typical day.	Does your health now limit you
2.	Moderate activities, such	n as moving a t	table, pushing	a vacuum cleaner, l	powling, 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	
			of the following	ng problems with y	our work or other regular daily
activit	ies <u>as a result of your phy</u>	sical nealth?		Yes	No
4.	Accomplished less than	you would like	e.		
5.	Had difficulty performing for example, it took extra	•	other activities	з, 🗆	
	g the past four weeks, have ies as a result of emotions				our work or other regular daily as)?
				Yes	No
6.	Accomplished less than	you would like	e.		
7.	Didn't do work or other	activities as ca	arefully as usua	al.	

δ.	with your normal so					problems interfered (heck one)				
	Not at all	Slightly	Moderately	Quite a bit	Extremely					
9.	During the past four work outside the hor					ties (including both				
	Not at all	Slightly	Moderately	Quite a bit	Extremely					
each q	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 a	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 o	f energy? (Ch	eck 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 downl	nearted and blu	e? (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	) <b>.</b>	- 17. The state of	
Patient Ac	rostic:		
		okolan kengakan dia pek	ya marandar ketikir.

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>.

number that best describes now true each statement	nas uttii i	or you <u>aar</u>	ing ine pu	<u>si / uuys</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 y	our quality	of life? (C	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 Åt 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, Otherwise, go to question 28.	please ans	swer questi	ons 26-27	•	
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 as	ffect your q	uality of lif	e? (Circle	e one nui	nber.)
0 1 2 3 4 5 Not at all	6	7	8	9	10 Very Much So

Relationsh	ip With I	Ooctor				Not At All	A Little Bit	Some- What	Quite a bit	Very Much
29. I had co	nfidence	in my doo	ctor(s).			1	2	3	4	5
30. My doc	tor was a	vailable to	answer i	ny quest	ions.	1	2	3	4	5
31. How n	nuch does	your <u>Rel</u>	ationship	with you	ır Doctoi	affect your	quality of l	ife? (Circ	ele one nu	ımber.)
0	1	2	3	4	5	6	7	8	9	10
Not at all									Ve	ery Much So
Emotional	Well-Bei	ng				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
32. I felt sa	ıd.					1	2	3	4	5
33. I was p	roud of h	ow I'm co	ping with	n my illn	ess.	1	2	3	4	5
34. I was lo	osing hop	e in the fi	ght again:	st my illr	iess.	1	2	3	4	5
35. I felt ne	ervous.					1	2	3	4	5
36. I worrie	ed about o	lying.				1	2	3	4	5
37. How n	nuch does	your <u>Em</u> 2	otional W	/ell-Bein 4	g affect y	our quality 6	of life? <b>(C</b> )	ircle one 1 8	number.) 9	10
Not at all									Ve	ery Much So
Functional	Well-Be	ing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
38. I was a	ble to wo	rk (includ	e work in	home).		1	2	3	4	5
39. My wo	rk (includ	le work in	home) w	as fulfill	ing.	1	2	3	4	5
40. I was a	ble to enj	oy life "in	the mon	ent."		1	2	3	4	5
41. I had a	ccepted m	y illness.				1	2	3	4	5
42. I was sl	leeping w	ell.				1	2	3	4	5
43. I enjoye	ed my usi	ıal leisure	pursuits.			1	2	3	4	5
44. I was c	ontent wi	th the qua	lity of my	y life righ	nt now.	1	2	3	4	5
45. How n	nuch does	your <u>Fur</u>	ictional V	Vell-Bein	g affect	your quality	of life? (C	ircle one	number.)	
0	1	2	3	4	5	6	7	8	9	10
Not at all										ery Much So

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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 you	ur quality o	of life? (Cir	cle one r	number.)		
0 1 2 3 4 5	6	7	8	9	10	
Not at all				V	ery 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	ŕ				
57. Breasts					
58. Arms					
59. Face					
60. Waist					
61. Hips					
62. Thighs					
63. Overall body					

How	ow much do you agree or dis	sagree with the following s	statement? (Check t	the appropriate box.)	
64.	I. The appearance of my brea	st area is important to me.			
	Strongly Disagree Di	Neither Agree isagree	Agree	Strongly Agree	
65.	i. I view myself as a:				
D A D	Very overweight person  Moderately overweight Normal weight person  Moderately thin person  Very thin person	ht person			
PAK	ART III. SEXUALITY				
Thes perso	nese next questions are about the rsonal, but your answers are in	he way health problems ma mportant in understanding h	y interfere with your low health problems i	sex life. These questions may affect women's sexu	s are ality.
66.	. Have you been sexually ac	tive with a partner during t	he last 6 months?		
	No> (If no, sk: Yes> (If yes, co	ip to Question 79). ontinue to Question 67).			
67.	. How many times have you	ı had sexual intercourse in t	he past month?		
	0 times 1 - 4 times 5 - 10 times 11 or more				

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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.			<u> </u>		
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 <u>best</u> 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
<b>8</b> 0.	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

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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.	befo	re your b	reast canc	e yourself or er, "+5" me ferent but w	ans that ev	erything	is totally d	ifferent bu	our life is t better, a	just the w nd "-5" me	ay it was eans that
-	.5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
,	Worse				S	ame as be	fore				Better
PAF	RT VI	. EM	OTIONA	L FEELIN	GS						
the j	k the past v	box next v <mark>eek, inc</mark>	to the one	sist of grou e statement day. If sev ements in e	in each gr eral staten	oup whic nents with	h <b>best</b> des nin a group	cribes the seem to a	way you apply equ	have been	feeling
93.		I do not	feel sad.								
		I feel sa	d.								
		I am sad	all the tin	ne and I can	't snap ou	t of it.					
-		I am so	sad or unh	appy that I	can't stand	l it.					
94.		I am not	particular	ly discoura	ged about	the future					
		I feel dis	scouraged	about the fu	iture.						
		I feel I h	ave nothir	ng to look fo	orward to.						
		I feel tha	at the futur	re is hopeles	ss and that	things car	nnot impro	ove.			
95.		I do not	feel like a	failure.							
		I feel I h	ave failed	more than t	he average	e person.					
				my life, all			ailures.				
				lete failure a							
96.		I get as 1	much satis	faction out	of things a	s I used to	).				
		I don't e	njoy thing	s the way I	used to.						
	Щ	I don't g	get real sati	isfaction ou	t of anythi	ng anymo	re.				
		I am dis	satisfied of	r bored with	everythin	ıg.					

Patient I.D

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.
	$\Box$	
98.	님	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.	$\Box$	I don't feel disappointed in myself.
77.	一	I am disappointed in myself.
	Ħ	
	一	I am disgusted with myself.
	ш	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.
		1 Would Kill Hij boll II 1 Mad the elimines.
102.	Щ	I don't cry anymore than usual.
		I cry more now than I used to.
	Ц	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	
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.
105.	
	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.
107.	
	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 co	nstipation.
	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.	

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#### SOCIAL SUPPORT FORM

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

1. At the present time, about h ease with and can talk to abo	ow many close out what is on yo	friends and clour mind)? (Pl	ose relatives do ease write the r	you have (peopumber in the	ple you feel a
Number o	f close friends a	nd close relati	ves		
People sometimes look to others fo often is each of the following kind statement.)	or companionsh ds of support av	ip, assistance, vailable to yo	, or other types u if you need i	of support. C	urrently, how box for each
	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.					
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 Acrostic:	Patient	I.D.	- 4-1- Sept.
	Patient	Acrostic:	S. C. S. A. A. M.

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.					

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#### 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.

l.	Do you smoke currently?	
	No Yes	
	If yes, how many cigarettes d	o 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 bev	rerages?
	No Yes	
	If yes, about how many alco drink in an average n	pholic beverages (beer, wine, or mixed drinks) do you currently nonth?
	Beverag	ges per month

3. V	Vhat	is your current weight?		
		pounds		
The follo		ng questions are about your t	ısual p	hysical activity and exercise. This includes walking
		x about the walking you do out ome for more than 10 minutes		e home. In the past month, how often did you walk outside tstopping? (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)
Ļ		2-3 times each week	>	(Go to Question 4a)
Ļ	_	4-6 times each week	>	(Go to Question 4a)
		7 or more times each week	>	(Go to Question 4a)
		_		utside the home for more than 10 minutes without minutes did you usually walk?
			20-39 40-59	than 20 minutes minutes minutes r or more
		4b. What was yo	ur usual	speed?
			Avera Fairly Very	al strolling or walking (less than 2 miles an hour)  age or normal (2-3 miles an hour)  fast (3-4 miles an hour)  fast (more than 4 miles an hour)

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.		OR VERY HARD EX			u work up a sweat and your heart beats fast.) s, swimming laps.
	None		>	(Go to	Question 6)
	1 day p	er 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 mo	ore days per week	>	(Go to	question 5a)
		5a. How long do	you usı	ıally exe	ercise like this at one time?
			Less t	han 20 r	minutes
			20-39	minutes	3
			40-59	minutes	3
			1 hou	r or mor	e
6.					example, biking outdoors, using an exercise lenics, 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)

(Go to Question 6a)

5 or more days per week --->

	6a. How long d	lo you usually ex	ercise like this at one time?
		Less than 20 20-39 minute 40-59 minute 1 hour or more	s s
7. MILD EXER	RCISE. For example	e, slow dancing, l	powling, golf.
	None 1 day per week 2 days per week 3 days per week 4 days per week 5 or more days per	>>> week>	
	7a. How long d	Less than 20 20-39 minute 40-59 minute 1 hour or more	s s

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#### **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.

Your Current Mailin	g Address?			
				<del></del>
Telephone Numbers	Home:	Area Code (		
	Work:	Area Code (	)	
	Other:	Area Code (		
When is the best tim	e to contact	you?	When	re is the best place to contact
Day of week		time(s)		At home At work Other
		time(s)		At home At work

Contact 18 mos. 5/99 Page 1 of 2

answering mach			, may we leave a message to reach you directly?	for you on y
[	No Yes			
			information will help us I not currently married or	
]	First	MI	Last	
know how to co	ntact you if we ar	e unable to reach you		l, who are lik
know how to co  Name:	ntact you if we ar	e unable to reach you		
know how to co	ntact you if we ar	e unable to reach you		·
know how to co  Name:  Address:	ntact you if we ar	e unable to reach you		·
know how to co  Name:  Address:  Phone Number:	ntact you if we ar	re unable to reach you		
know how to co  Name:  Address:  Phone Number:	ntact you if we ar  Area Code  you:	re unable to reach you		
know how to co  Name:  Address:  Phone Number:  Relationship to	ntact you if we ar  Area Code  you:	ce unable to reach you		
know how to co  Name:  Address:  Phone Number:  Relationship to  Name:  Address:	Area Code	ce unable to reach you		

# MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE

### **One-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) 713-4268



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

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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.

Jour	personal breakful
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.)
	НМО
	Group Health Insurance
	V.A./Military Sponsored
	Individual Health Insurance (includes CHAMPUS)
	Medicaid 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)

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5.	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):
belie	This following is a list of employment issues that a person might have. For each statement, cate whether this has happened to you since your diagnosis. If it did occur, indicate whether you eve this situation was related to your diagnosis. (Check the box by the answers that are most true you in each statement.)
Sinc	e your diagnosis have you:
a. 1	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	l or laid off?
		No
		Yes (If yes, was it related to your diagnosis?)  No
		└ Yes
d.	been dem	oted?
		No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes
e.	been deni	ed a promotion?
		No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes
f.	been deni	ed a wage increase?
		No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes

			atient Acrostic:	
_	ad your work responsibilities limited innecessarily?  No  Yes (If yes, was it related No  Yes		Committee of the Commit	
h. be	een promoted?  No Yes (If yes, was it related No Yes	I to your diagnosis?)		
believ	This following is a list of insurate whether this has happened to ye this situation was related to you in each statement.)	you since your diagn	osis. If it did occur	, indicate whether you
Since	your diagnosis have:			
a. yo	ou been denied health insurance?  No Yes (If yes, was it related No	d to your diagnosis?)		
	Yes			
b. yo	ou been denied life insurance?  No  Yes (If yes, was it related No	ed to your diagnosis?)		

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 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:   / // /

Patient I.D.			
Patient Acrostic			
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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.	past six months, which of the following doctors or other health professionals have you (Please Check all that apply)		
	None		Family Therapist
	Acupuncturist		Nutritionist
	Allergist		Obstetrician
	Cardiologist		Medical Oncologist/Chemotherapist
	Chiropractor		Orthopedic Surgeon
	Dentist		Homeopathic/Herbalist/Naturopathic
	Dermatologist		Pain Control Professional
	Ear/Nose/Throat Doctor		Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
	Eye Doctor		Physical Therapist
	Marital Counselor		Plastic Surgeon
	Gastroenterologist		Psychiatrist
	General Practitioner		Clinical Psychologist
	Gynecologist		Radiologist
	Infertility Specialist		Rheumatologist
	Internist		Social Worker
	Massage Therapist		Organized Support Group
	Neurologist		Surgeon
	Sexual Therapist		Urologist
			Other:

Medhist One-Year 1/11/99

2.	In the past 6 months,	have you	been seer	n at an emergency room?
	□No			
		r what rea	ason:	
3.	In the past 6 months, line item (a) and (b).	have you	been hos	pitalized or had surgery? Please mark one box for each
		No	Yes	If yes, for what reason?
	(a) Hospitalized?			
	(b) Had surgery?			
		<u> </u>		
4.	Uas anything also sho	naad raa	andina sitl	how your montal or physical health states 2. Places were
т.	one box for each line			her your mental or physical health status? Please mark
		No	Yes	What has changed?
	(a) Mental Health?	:		
	(b) Physical Health?			
	L	l	<u> </u>	

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5.	Have you had	any biopsies in the past 6 months?
	☐ Ye	es →If yes, what was biopsied?
		Why was this biopsied?
5.	In the past 6 m	onths, have you had a re-occurrence of breast cancer?
		No Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?
	L	Yes → II yes, now 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)?

#### **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 <u>best estimate</u>.

are no	ot sure about th	ie exact date or number of times, p	lease give	your <u>best estimate</u> .		
1.	What was th	e date of the first day of your last	menstrual p	period (your best guess)?		
	Month I	Day Year				
2.	In the past 6	months, have you been sexually a  No →Go to question 6  Yes →Go to question 3	ctive with a	a male partner:		
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 m contraception		ad sexual in	ntercourse without using		
		Times				

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In the past 6 months, have you become pregnant?
No $Y_{es} \rightarrow I_{f} \underline{Y}_{es}$ , are you pregnant now?
No Yes
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				Does Not
				was she was cancer	if she had	Apply	
			Less than 45	45 or older	Don't know age	breast cancer	
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	Don't know if	Does Not Apply	
				l was she v	she had	Appry	
			Less than 45	45 or older	Don't know age	ovarian cancer	
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)						

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#### **CURRENT MEDICATIONS**

Drug Name	Dosage
ease list below all of the <b>non-prescription m</b> tly. (Write "none" if are not taking any non-	nedications or supplements you are taking prescription medications or supplements.  Dosage
tly. (Write "none" if are not taking any non-	prescription medications or supplements
tly. (Write "none" if are not taking any non-	prescription medications or supplements
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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				

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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 pa			s any swelling occurred in your arm or hand on the same side that you had your omy?
		Yes →	(Cont	o question 8) inue to question 2)  (Go to question 8)
2.	Do you	believe	the star	of your swelling was related to any of the following?
	Yes ?	No		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 (di	id) the swelling occur? (Check all that apply)				
		Hand Upper Arm Lower Arm				
2c.	Do (did) you co	onsider the swelling to be mostly?				
		Mild Moderate Severe				
Does	(did) the swelling	g 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:				

3.

|--|

Does (did) swelli	ing seem to g	get worse with any of the following?
Yes   N	Don't No Know	Hot weather  General use of your arm  Exercise  Sauna / Jacuzzi / Hot bath  Airplane travel  Specific foods  Mental / emotional stress  Other: Please describe:
		agnosis, did you notice swelling in your hand and/or arm with any of the apply)
Yes P		Exercise  Household Chores  Heat/Humidity  Eating salty foods  Drinking alcoholic beverages  Other: Please describe:
	Yes 1	Prior to your breast cancer dia following? (Check all that a

5.	Did you seek treatment for this swelling in the past 6 months?
	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:
<b>'</b> .	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 pas	st 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin a your arm or hand on the same side that you had your lumpectomy or mastectomy?		
	Y	No→ (Go to question 9)  es → (Continue to question 8a)  on't Know → (Continue to question 9)		
	8a. <u>If</u>	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:		
	9	9b. receive antibiot	ics by injection	n?
10.	Do you have pair	No Yes Don't know n in the affected arm	n 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 <u>not</u> interfere with usual activities.

Moderate = symptom interfered somewhat with usual activities.

Severe = symptom was so bothersome that usual activities could not be performed.

	Symptom did not	Symptom Occurred and Was:				
Symptom	occur	Mild	Moderate	Severe		
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 Occurred and Was:					
Symptom	did not occur	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							

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### QUALITY OF LIFE FORM

1.	In general, would y	ou say your health	is: (Check o	ne)	
	Excellent	Very good	Good	Fair	Poor
	llowing questions are activities? If so, h		you might do d	uring a typical day.	Does your health now limit you
2.	Moderate activities	s, such as moving a	table, pushing	a vacuum cleaner, l	bowling, or playing golf.
	Limited a l	lot Limited	l a little	Not limited at all	
3.	Climbing several f	lights of stairs.			
	Limited a	lot Limited	l a little	Not limited at all	
	g the <u>past four weeks</u> ies <u>as a result of you</u>		y of the follow	ing problems with y	our work or other regular daily
4.	Accomplished less		ke.	Yes	No
5.	Had difficulty perf for example, it tool	_	es,		
	g the past four week ies as a result of em				our work or other regular daily as)?
6.	Accomplished less	than you would li	ke.	Yes	No
7.	Didn't do work or	other activities as	carefully as usu	nal.	

8. During the <u>past four weeks</u> , to what extent has your <u>physical health or en</u> with your normal social activities with family, friends, neighbors, or gro					lth or emotionars, or groups? (	al problems inte C <b>heck one)</b>	erfered
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
	Ш		L		Ц		
9.	During the past four work outside the he	r weeks, how i	nuch did <u>pain</u> in k and family act	terfere with yo ivities)? (Che	ur normal activ ck one)	vities (including	g both
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
each q	questions are about question, please give ne during the past for	the one answer	nd how things ha	ave been with yest to the way	you <u>during the</u> you have been	past four week feeling. How i	s. For nuch of
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? (Cl	heck one)				
	All of	Most of	A good bit	Some of	A little of	None of	
	the time	the time	of the time	the time	the time	the time	
	Ц	<u>il</u>	Ш		L	Ш	
12.	Have you felt down	hearted and bl	ue? (Check one	)			
	All of	Most of	A good bit	Some of	A little of	None of	
	the time	the time	of the time	the time	the time	the time	

Patient I.D	

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>.

number that best describes now true each statement i	ias deen i	or you <u>aur</u>	ing ine pu	si / auys	•			
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 0 1 2 3 4 5 Not at all	our quality 6	of life? (C	Circle one	number. 9	10 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 aff	fect your q	uality of lif	e? (Circle	e one nu	mber.)			
0 1 2 3 4 5 Not at all	6	7	8	9	10 Very Much So			

Relationship With Doctor						Not At All	A Little Bit	Some- What	Quite a bit	Very Much
29. I had co		•	` '	my quest	ions.	1 1	2 2	3 3	4 4	5 5
31. How 1	much does	s your <u>Re</u>	lationship	with you	ır Doctor	affect you	r quality of l	ife? (Circ	cle one nu	ımber.)
0 Not at all	1	2	3	4	5	6	7	8	9 Va	10
ivot at all									Ve	ry Much So
Emotional	l Well-Bei	ing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
32. I felt s	ad.					1	2	3	4	5
33. I was 1	proud of h	ow I'm c	oping wit	h my illne	ess.	1	2	3	4	5
34. I was 1	osing hop	e in the f	ight again	st my illr	iess.	1	2	3	4	5
35. I felt n	ervous.					1	2	3	4	5
36. I worr	ied about	dying.				1	2	3	4	5
37. How 1	much does	s your <u>En</u>	notional V	/ell-Bein	g affect y	our quality	of life? (Ci	rcle one i	number.)	
0	1	2	3	4	5	6	7	8	9	10
Not at all									Ve	ry Much So
Functiona	l Well-Be	ing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
38. I was a	able to wo	rk (includ	le work in	home).		1	2	3	4	5
39. My wo	ork (includ	le work ir	n home) w	as fulfill	ing.	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 c	ontent wi	th the qua	ality of my	y life righ	t now.	1	2	3	4	5
45. How 1	nuch does	your <u>Fu</u>	nctional V	Vell-Bein	g affect y	our quality	of life? (Ci	ircle one 1	number.)	
0	1	2	3	4	5	6	7	8	9	10
Not at all									Ve	rv Much So

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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	1	2	3	4	5			
members.								
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 Not at all	6	7	8	9 V	10 Tery 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					

DUN	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 Or Disagree
65.	I view myself as a:
	Very overweight person  Moderately overweight person  Normal weight person  Moderately thin person  Very thin person
PAR	T III. SEXUALITY
Thes perso	e next questions are about the way health problems may interfere with your sex life. These questions are nal, but your answers are important in understanding how health problems may affect women's sexuality.
56.	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			

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 <u>best</u> describes how often you experienced these situations in **THE PAST 4 WEEKS**.

<b>7</b> 9.	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

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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.	befo	re your b	reast canc	e yourself or er, "+5" me fferent but w	ans that ev	erything	is totally d	ifferent bu			
-	-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
٦	Worse	e			S	ame as be	fore				Better
PAI	RT V	I. EM	OTIONA	L FEELIN	GS						
the	k the past v	box next	t to the on cluding to	sist of groue statement day. If severents in e	in each gr eral staten	oup which	h <b>best</b> desc iin a group	cribes the seem to a	way you lapply equa	have been	feeling
93.		I do not	feel sad.								
		I feel sa	d.								
		I am sad	l all the tir	ne and I can	i't snap ou	t of it.					
		I am so	sad or unh	appy that I	can't stand	l it.					
94.		I am not	t particular	rly discoura	ged about	the future.					
		I feel di	scouraged	about the fu	iture.						
		I feel I h	nave nothin	ng to look fo	orward to.						
		I feel that	at the futur	re is hopeles	ss and that	things car	nnot impro	ve.			
95.		I do not	feel like a	failure.							
		I feel I h	nave failed	more than	the average	e person.					
				my life, all			ailures.				
		I feel I a	ım a comp	lete failure	as a person	ı <b>.</b>					
96.		I get as:	much satis	sfaction out	of things a	s I used to	).				
				gs the way I							
				isfaction ou		ng anvmo	re.				
				r bored with	•	•					

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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.
	[ <del>-</del> ]
99.	I don't feel disappointed in myself.
	I am disappointed in myself.
	I am disgusted with myself.
	I hate myself.
100	
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.
105.		
	H	I put off making decisions more than I used to.
		I have greater difficulty in making decisions than before.
	LJ	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.
	同	I wake up several hours earlier than I used to and cannot get back to sleep.
		I wake up several nours carner man i used to and cannot get back to steep.

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109.		I don't get more tired than usual.
109.	$\sqcap$	
	H	I get tired more easily than I used to.
	Н	I get tired from doing almost anything.
	Ш	I am too tired to do anything.
110.		My appetite is no worse than usual.
110.	$\sqcap$	
		My appetite is not as good as it used to be.
		My appetite is much worse now.
	Ш	I have no appetite at all anymore.
111.	П	I haven't lost much weight, if any, lately.
111.	Ħ	
		I have lost more than five (5) pounds.
		I have lost more than ten (10) pounds.
		I have lost more than fifteen (15) pounds.
110		Town and the second of the sec
112.		I am no more worried about my health than usual.
	$\vdash$	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.
110		T1
113.	H	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.

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### SOCIAL SUPPORT FORM

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.)

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

Number o	f close friends a	nd close relati	ves		
People sometimes look to others for often is each of the following kind statement.)	-				
	None of the time	A little of the time	Some of the time	Most of the time	All of the time
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.					
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.					
Someone to confide in or talk     to about yourself or your     problems.					

1.

	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.					

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

3. Wh	at is your current weight?		
	pounds		
The follow and sports	ing questions are about your i	usual p	hysical activity and exercise. This includes walking
the	nk about the walking you do ou home <u>for more than 10 minutes</u>	tside the	e home. In the past month, how often did you walk outsided to 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)
			utside the home for more than 10 minutes without minutes did you usually walk?
		20-39 40-59	han 20 minutes minutes minutes r or more
	4b. What was you	ur usual	speed?
		Avera Fairly Very	al strolling or walking (less than 2 miles an hour)  age or normal (2-3 miles an hour)  fast (3-4 miles an hour)  fast (more than 4 miles an hour)  Know

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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.						•	u work up a sweat and your heart beats fast.) s, swimming laps.				
		None			>	(Go to	Question 6)				
		1 day p	v per week vs per week		>	-> (Go to Question 5a)	Question 5a)				
		2 days			>	(Go to	Question 5a)				
		3 days	per week		>	(Go to	Question 5a)				
		4 days	4 days per week		>	(Go to	to Question 5a)				
		5 or m	ore days per w	reek	>	(Go to	question 5a)				
			5a. How	long do y	ou usu	ally exe	ercise like this at one time?				
6.	мог	)ER ATI	E EXERCISE	C (Not exh	20-39 40-59 1 hour	han 20 r minutes minutes or more	S S				
0.							enics, easy swimming, popular or folk dancing.				
			None			>	(Go to Question 7)				
			1 day per we	ek		>	(Go to Question 6a)				
			2 days per w	eek		>	(Go to Question 6a)				
			3 days per w	eek		>	(Go to Question 6a)				
			4 days per w	eek		>	(Go to Question 6a)				
			5 or more da	ys per we	ek	>	(Go to Question 6a)				

	6a. How long do	you usually exe	ercise like this at one time?
		Less than 20 is 20-39 minutes 40-59 minutes 1 hour or more	5
7. MILD EXER	RCISE. For example,	slow dancing, b	owling, golf.
	None 1 day per week 2 days per week 3 days per week 4 days per week 5 or more days per we	> > > eek>	(Go to Question 7a)
	7a. How long do	you usually exe Less than 20 r 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.)

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### 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.)

		YI	ES, and it upset r	ne:
Over the past year:	NO	Not too much	Moderately (Medium)	Very Much
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?				

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### **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.

	_	e our last mailing to es, please provide cui		ing address
Your Current Mailing	Address?			
				<del></del>
Telephone Numbers:	Home:	Area Code (		
	Work:	Area Code (		
	Other:	Area Code (	)	
When is the best time	to contact	you?	Wher	re is the best place to contact
				At home
Day of week		time(s)		At work
			L	Other
				At home
Day of week		time(s)	F	At work

Contact One-Year 1/11/99

		•		j vegados								
In case v answerin	we might ever need to ng machine, (if you h	contact you by telephone ave one), if we are unable	e, may we leave a message for you to reach you directly?	ı on your								
you duri	What is your husband's or partner's legal name? (This information will help us keep in contact v you during the study. Please leave this blank if you are not currently married or with a long-term partner.)											
	First		Last									
Please pa	Please provide the names of two relatives or friends, not living in your household, who are likely know how to contact you if we are unable to reach you.											
Name:												
Address	Name: Address:											
Phone N	Phone Number: Area Code ()											
Relation	ship to you:	***										
Name:												

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

Relationship to you:

Patient I.D.

Patient Acrostic:

Contact One-Year 1/11/99

Address:

# 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 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

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# 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		Family Therapist					
		Acupuncturist		Nutritionist					
		Allergist		Obstetrician					
		Cardiologist		Medical Oncologist/Chemotherapist					
		Chiropractor		Orthopedic Surgeon					
		Dentist		Homeopathic/Herbalist/Naturopathic					
		Dermatologist		Pain Control Professional					
		Ear/Nose/Throat Doctor		Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)					
		Eye Doctor		Physical Therapist					
		Marital Counselor		Plastic Surgeon					
		Gastroenterologist		Psychiatrist					
		General Practitioner		Clinical Psychologist					
		Gynecologist		Radiologist					
		Infertility Specialist		Rheumatologist					
		Internist		Social Worker					
		Massage Therapist		Organized Support Group					
		Neurologist		Surgeon					
		Sexual Therapist		Urologist					
				Other:					

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In the past 6 months, h	ave you b	een seen a	at an emergency room?
□ No			
	what reas	son:	
In the past 6 months, haline item (a) and (b).	ave you b	een hospi	talized or had surgery? Please mark one box for each
	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			
(b) Had surgery:	:		
Has anything else chan	ged regar	ding eithe	er your mental or physical health status? Please mark
one box for each line it	em (a) an	d (b).	your memar or physical nearth status. Trease mark
	No	Yes	What has changed?
(a) Mental Health?			
(1) Pl : 111 110			
(b) Physical Health?			
	l		

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?
	<ul> <li>No</li> <li>Yes → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?</li> </ul>
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   Page 1   Page 2   Pa

Patient I.	D.		
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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 <u>best estimate</u>.

1.		date of the first day of your <u>last</u> may  Year	enstrual po	eriod (your best guess)?
2.	In the past 6 i	months, have you been sexually act  No $\rightarrow$ Go to question 6  Yes $\rightarrow$ Go to question 3	ive with a	male partner:
3.	Which metho	d of birth control are you and your	partner us	ing currently? (Check all that
		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

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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 $ \begin{array}{c}                                     $
	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

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	_			
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			in Haliyaya	
Datio	nt Acrostic:			A HONGSHIM
rauci	ir wei name			
REFERENCE	gial iffición develor		halad dajo 2411.)	Lagrande Alender La Frideire

### PART III

### **CURRENT MEDICATIONS**

Drug Name	Dosage
Please list below all of the <b>non-prescription med</b> (Write "none" if are not taking any non-prescription	ications or supplements you are taking cu
Please list below all of the <b>non-prescription med</b> (Write "none" if are not taking any non-prescription  Drug Name	ications or supplements you are taking cu on medications or supplements at this time.  Dosage
(Write "none" if are not taking any non-prescription	on medications or supplements at this time.
(Write "none" if are not taking any non-prescription	on medications or supplements at this time.
Please list below all of the <b>non-prescription med</b> (Write "none" if are not taking any non-prescription  Drug Name	on medications or supplements at this time.
(Write "none" if are not taking any non-prescription	on medications or supplements at this time.
(Write "none" if are not taking any non-prescription	on medications or supplements at this time.

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Patient I.D.	
Patient Acrostic	
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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 m lumpectomy o		s any swelling occurred in your arm or hand on the same side that you had your comy?
	Yes -	→ (Con	o question 8) tinue to question 2)  (Go to question 8)
2.	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 (die	d) the swelling occur? (Check all that apply)	
		Hand Upper Arm Lower Arm	
2c.	Do (did) you co	onsider the swelling to be mostly?	
		Mild Moderate Severe	
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:	

3.

		Patient I.D.  Patient Acrostic:
4.	Does (did) swelling seem to  Don't Yes No Know  Don't On't On't On't On't On't On't On't O	get worse with any of the following?  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 d following? (Check all that  Don't Yes No Know	

6.	Did yo	ou seek treatment for this swelling in the past 6 months?
		No → <u>If no</u> , 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	ı 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:		
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8.		st 6 months, do you remember any breaks in your skin, infected hang nails, or slight skin in your arm or hand on the same side that you had your lumpectomy or mastectomy?
	Y	No→ (Go to question 9)  Yes → (Continue to question 8a)  Don't Know → (Continue to question 9)  If yes, did you receive antibiotics?  Yes  No
		Don't know
9.	-	st 6 months, did you have any infection in the arm or hand on the same side that you had appectomy 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 antibio	tics by injection	n?
10.	Do you have pair	No Yes Don't know		(Check one box for each site)
		Yes	No	
	hand			
	arm			
	hand and arm			

#### 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 <u>not</u> interfere with usual activities.

Moderate

= symptom interfered somewhat with usual activities.

Severe

symptom was so bothersome that usual activities could not be performed.

	Symptom did not	Symptom Occurred and Was:					
Symptom	occur	Mild	Moderate	Severe			
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	Sym	Symptom Occurred and Was:							
Symptom	did not occur	Mild	Moderate	Severe						
13. Constipation										
14. Abdominal pain/cramps										
15. Vaginal dryness										
16. Muscle pain/ache/or cramp										
17. Weight gain										
18. Weight loss				<del>- , ,</del> .						
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										

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er Zij	r	LLI	CII		^(		)21			-	78.4 45.43	144 144	141	Stell	94 20	256 256		7429 2429	VLD.	54 <b>9</b> 1: 224 (1)	

### QUALITY OF LIFE FORM

1.	In general, would ye	ou say your health	is: (Check o	one)		
	Excellent	Very good	Good	Fair	Poor	
	llowing questions are activities? If so, he	•	you might do	during a typical day.	. Does your health now limit yo	<u>u</u>
2.	Moderate activities,	such as moving a	table, pushin	g a vacuum cleaner,	bowling, or playing golf.	
	Limited a lo	ot Limited	l a little	Not limited at all	1	
3.	Climbing several fli	ights of stairs.				
	Limited a l	ot Limited	l a little	Not limited at all	1	
_	the past four weeks es as a result of your		y of the follow	ving problems with	your work or other regular daily	
4.	Accomplished less		ke.	Yes	No	
5.	Had difficulty perfor for example, it took		r other activiti	es,		
	the past four weeks es as a result of emo				your work or other regular daily ous)?	
6.	Accomplished less	than you would li	ke.	Yes	No	
7.	Didn't do work or o	other activities as	carefully as us	ual.		

8.	During the past four with your normal so						red
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
9.	During the past four work outside the ho					ities (including bo	oth
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
each qu	questions are about huestion, please give to during the past fou	he one answer	nd how things hat that comes close	est to the way	you <u>during the p</u> you have been f	oast four weeks. Feeling. How muc	For ch of
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	of energy? (Cl	heck 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 down	hearted and bl	ue? (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	

A SECTION DAY	
Patient	
Patient	
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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 <u>during the past 7 days</u>.

number that best describes now true such statements		J <u></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 yo	our quality	of life? (C	ircle one	number.)	)			
0 1 2 3 4 5 Not at all	6	7	8	9	10 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			
Otherwise, go to question 28.	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		4	5			
27. I was satisfied with my sex life.	1	2	3	4	5			
28. How much does your Social/Family Well-Being aff	fect your q	uality of lif	e? (Circle	e one nur	nber.)			
0 1 2 3 4 5 Not at all	6	7	8	9	10 Very Much So			

Relationsh	ip With D	Ooctor				Not At All	A Little Bit	Some- What	Quite a bit	Very Much	
29. I had co	nfidence i	in my doc	ctor(s).			1	2	3	4	5	
30. My doc	tor was av	ailable to	answer	my quest	ions.	1	2	3	4	5	
31. How r	nuch does	your <u>Rel</u>	ationship	with you	ır Doctor	affect you	r quality of l	ife? (Circ	ele one nu	ımber.)	
0	1	2	3	4	5	6	7	8	9	10	
Not at all									Ve	ry Much So	1
Emotional	Well-Beii	ng				Not at All	A Little Bit	Some- what	Quite a bit	Very Much	
32. I felt sa	ıd.					1	2	3	4	5	
33. I was p	roud of ho	w I'm co	ping wit	h my illne	ess.	1	2	3	4	5	
34. I was le	osing hope	in the fi	ght again	st my illr	ness.	1	2	3	4	5	
35. I felt no	ervous.					1	2	3	4	5	
36. I worri	ed about d	ying.				1	2	3	4	5	
37. How n	nuch does	your <u>Em</u>	otional V	Vell-Bein	g affect y	our quality	of life? (Ci	ircle one 1	number.)		
0	1	2	3	4	5	6	7	8	9	10	
Not at all									Ve	ry Much So	l
Functional	Well-Bei	ng				Not at All	A Little Bit	Some- what	Quite a bit	Very Much	
38. I was a	ble to wor	k (includ	e work ir	n home).		1	.2	3	4	5	
39. My wo	rk (includ	e work in	home) v	vas fulfill	ing.	1	2	3	4	5	
40. I was a	ble to enjo	y life "in	the mon	nent."		1	2	3	4	5	
41. I had a	ccepted m	y illness.				1	2	3	4	5	
42. I was sleeping well.						1	2	3	4	5	
43. I enjoy	ed my usu	al leisure	pursuits			1	2	3	4	5	
44. I was c	ontent wit	h the qua	lity of m	y life righ	nt now.	1	2	3	4	5	
45. How n	nuch does	your <u>Fur</u>	octional V	Well-Bein	g affect	our quality	y of life? (C	ircle one	number.)		
0	1	2	3	4	5	6	7	8	9	10	
Not at all									V/a	ry Much So	

Patient I.	D.	
Patient A	crostic:	

Addition	al Concer	ns			Not At All	A Little Bit	Some- what	Quite a bit	Very Much	
46. I was	short of b	reath.			1	2	3	4	5	
47. I was	self-conso	cious abo	ut the way	I dressed.	1	2	3	4	5	
48. My a	rms were s	swollen o	r tender.		1	2	3	4	5	
49. I felt	sexually a	ttractive.			1	2	3	4	5	
50. I was	bothered 1	by hair lo	SS.		1	2	3	4	5	
	rried abou ibers.	t the risk	of cancer	in other family	1	2	3	4	5	
52. I wo	rried abou	t the effe	ct of stres	s on my illness.	1	2	3	4	5	
53. I was	s bothered	by a cha	nge in we	ight.	1	2	3	4	5	
54. I was	s able to fe	eel like a	woman.		1	2	3	4	5	
55. Hov	v much do	these Ac	lditional C	Concerns affect yo	our quality o	of life? (Cin	cle one i	number.)	ı	
0	1	2	3	4 5	6	7	8	9	10	
Not at all								V	ery Much S	Sc

#### 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					

		Strongly	D.	Neither Agree		Strongly	
	}	Disagree	Disagree	or Disagree	Agree	Agree	
65.	I view my	vself as a:					
	Mod Norn	overweight plerately overwinal weight pelerately thin person	veight person				
Thes perso	e next ques	our answers a	ut the way he	n understanding how	health problen	ur sex life. These questions may affect women's sex	
66.	No No	> (If no	, skip to Ques	a partner <u>during the la</u> stion 79). Question 67).	ast 6 months?		
67.	How man	y times have	you had sexu	al intercourse in the p	past month?		
	1 - 5 -	times - 4 times - 10 times or more					

P	atient	I.D.					
100	atient						
r	allent	MCF	osuc		mananan () Mananan	100	

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 <u>best</u> 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?

33.	Overall, now was your typical night's sleep during the past 4 weeks?
	Very sound or restful
	Sound or restful
	Average quality
	Restless
	Very restless
34.	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**.

Quite Very A little bit Somewhat a bit much Not at all 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.	before	e your t	reast canc	e yourself or er, "+5" me ferent but w	ans that ev	erything i	s totally d	ifferent bu			
-	5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
V	Worse				Sa	ame as be	fore				Better
PAR	et VI.	EM	IOTIONA	L FEELIN	GS						
chec the p	k the b	ox nex	t to the on c <b>luding to</b>	sist of grou e statement day. If sev ements in e	in each gr eral staten	oup which	h <b>best</b> des in a group	cribes the seem to	way you i	have been	feeling
93.		I feel sa	d all the tir	ne and I car nappy that I	•						
94.		l feel di I feel I l	scouraged	rly discoura about the fi ng to look for re is hopele	uture.  forward to.			ove.			
95.		I feel I l	ok back on	a failure. I more than my life, all olete failure	I can see i	s a lot of t	failures.				
96.		I don't I don't	enjoy thing	sfaction out gs the way I tisfaction ou or bored wit	used to.	ing anymo					

	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 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	
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	Touche de Committee de la lance de la lanc
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	
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.

		表	ient I.D.	
		Pat	ient Acrostic:	
109.		I don't get more tired than usual.		
	Щ	I get tired more easily than I used to.		
	Щ	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.		
	Ц	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 p		; or constipation.
	$\square$	I am very worried about physical problems and it's hard t		
		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.		

Pa	tient I.	.D.		
Da		crostic:		
Га	lient a	icrostic.	a Carborbera do. Aconamicatoria	

#### 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	e sometimes look to others for companionship, assistance, or other types of support. Currently, how

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 A	crostic:	

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.					

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#### 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 be	everages?
	No Yes	
	If yes, about how many alc drink in an average	coholic beverages (beer, wine, or mixed drinks) do you currently month?
	Bevera	ages per month

3.	What	is your current weight?		
		pounds		
The fo		ng questions are about your u	sual pl	nysical activity and exercise. This includes walking
4.		c about the walking you do out ome for more than 10 minutes		home. In the past month, how often did you walk outside 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)
	Ш	7 or more times each week	>	(Go to Question 4a)
		•		tside the home for more than 10 minutes without minutes did you usually walk?
			20-39 40-59	han 20 minutes minutes minutes r or more
		4b. What was you	ır usual	speed?
			Avera Fairly Very	Il strolling or walking (less than 2 miles an hour)  ge or normal (2-3 miles an hour)  fast (3-4 miles an hour)  fast (more than 4 miles an hour)  Know

Patient	1.D.	
Patien	Acrostic:	
I AUCIII		

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.					-	work up a sweat and your heart beats fast.) , swimming laps.
		None 1 day per week 2 days per week 3 days per week 4 days per week	k	-> -> ->	(Go to (Go to	Question 6) Question 5a) Question 5a) Question 5a) Question 5a)
		5 or more days 5a.	•		,	question 5a) rcise like this at one time?
6.	МОГ	DERATE EXER		)-39 r )-59 r hour	an 20 m minutes minutes or more	
		None  I day p  2 days  3 days  4 days		mill),		enics, easy swimming, popular or folk dancing.  (Go to Question 7)  (Go to Question 6a)  (Go to Question 6a)  (Go to Question 6a)  (Go to Question 6a)  (Go to Question 6a)

	6a. How long do	you usually exe	ercise like this at one time?
7. MILD EXER	RCISE. For example, s	Less than 20 r 20-39 minutes 40-59 minutes 1 hour or mor slow dancing, b	6 e
	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 w	eek>	(Go to Question 7a)
	7a. How long do	you usually exe	ercise like this at one time?
		Less than 20 i	minutes
		20-39 minutes	S
		40-59 minute	s
		1 hour or mor	re

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#### **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.

Your Current Mailing	g Address?			
Telephone Numbers:	Home:	Area Code (		
	Work:	Area Code (	)	
	Other:	Area Code (		
When is the best time	to contact	you?	When	re is the best place to contact
Day of week		time(s)		At home At work Other
Day of week		time(s)		At home At work

Contact 18 mos. 5/99

answering n	•	contact you by telephone we one), if we are unable	e, may we leave a message for you to reach you directly?	on yo
	☐ No ☐ Yes			
-	_		information will help us keep in co not currently married or with a lo	
	First	MI	Last	_
know how t	o contact you if we	e are unable to reach you		e like
know how t  Name:  Address:			•	
Name: Address: Phone Num	ber: Area Co	ode ()		
Name: Address: Phone Num	ber: Area Co	ode ()		
Name: Address: Phone Num	ber: Area Co	ode ()		
Name: Address: Phone Num Relationship Name: Address:	ber: Area Co	ode ()		

Contact 18 mos. 5/99 Page 2 of 2

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

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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.

your	personal situation in the past year. Thease 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 kep 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)
	Under

	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, 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):
indica	This following is a list of employment issues that a person might have. For each ment, indicate whether this has happened to you since your diagnosis. If it did occur, ate whether you believe this situation was related to your diagnosis. (Circle the answers are most true for you on each line.)
Since	your diagnosis have you:
	elieved you could not change jobs for fear  f losing your health insurance?  No  Yes (If yes, was it related to your diagnosis?)  No
	Yes

Patient I.D. \_\_\_\_\_

b.	lost your	health insurance due to sick leave?
		No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes
c.	been fired	l or laid off?
		No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes
d.	been dem	oted?
		No
		Yes (If yes, was it related to your diagnosis?)
		No No
		Yes
e.	been deni	ed a promotion?
		No No
		Yes (If yes, was it related to your diagnosis?)
		No
		Yes
f.	been deni	ed a wage increase?
		No
		Yes (If yes, was it related to your diagnosis?)
		No No
		Yes

		:	Patient I.D					
			Patient Acrostic:					
g.	had your unnecessa	work responsibilities limited sarily?  No  Yes (If yes, was it related to your diagn  No  Yes	osis?)					
h.	been pron	moted?  No  Yes (If yes, was it related to your diagn  No  Yes	osis?)					
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.)								
Sin	ce your d	liagnosis have:						
a.	you been	denied health insurance?						
b.	you been	No Yes (If yes, was it related to your diagram of the No Yes adenied life insurance? No Yes (If yes, was it related to your diagram of the No						
		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 No
f.	you had trouble changing from group health
1.	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		•	m
Patient Acrosti	c:		-

#### 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		Family Therapist			
		Acupuncturist		Nutritionist			
		Allergist		Obstetrician			
		Cardiologist		Medical Oncologist/Chemotherapist			
		Chiropractor		Orthopedic Surgeon			
		Dentist		Homeopathic/Herbalist/Naturopathic			
		Dermatologist		Pain Control Professional			
		Ear/Nose/Throat Doctor		Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)			
		Eye Doctor		Physical Therapist			
		Marital Counselor		Plastic Surgeon			
		Gastroenterologist		Psychiatrist			
		General Practitioner		Clinical Psychologist			
		Gynecologist		Radiologist			
		Infertility Specialist		Rheumatologist			
		Internist		Social Worker			
		Massage Therapist		Organized Support Group			
		Neurologist		Surgeon			
		Sexual Therapist		Urologist			
				04			

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In the past 6 months, ha	ve you be	een seen a	t an emergency room?
□No			
$\square$ Yes $\rightarrow$ For v	vhat reaso	on:	
		· · · · · · · · · · · · · · · · · · ·	
In the past 6 months, ha item (a) and (b).	ve you be	en hospit	alized or had surgery? Please mark one box for each li
	No	Yes	If yes, for what reason?
(a) Hospitalized?			
(b) Had surgery?			
	<b></b>		
Has anything else chang box for each line item (a	ed regard ) and (b).	ing either	your mental or physical health status? Please mark or
`	No	Yes	What has shown 10
(a) Mental Health?	NO	165	What has changed?
(b) Physical Health?			
f			

2 of 5

		2* *** *******************************	Patient I.D
			Patient Acrostic:
5.	Have you had a	any biopsies in the past 6 months?	
	☐ Ye	es →If yes, what was biopsied?	
		Why was this biopsied?	
6.	In the past 6 me	onths, 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 e	xample, biopsy, lab tests)?

Medhist Two-Year 1/1/00

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Patient Acrostic:	
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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 <u>best estimate</u>.

1.	What was th	e date of the first day of your <u>last</u> m	enstrual p	period (your best guess)?
	Month I	Day Year		
2.	In the past 6	months, have you been sexually act  No →Go to question 6  Yes →Go to question 3	ive with ε	n male partner:
3.	Which metho	od of birth control are you and your	partner us	sing currently? (Check all that
4.	In the past m	No method Condoms (rubbers) Birth control pills Foams/jellies/suppositories Sponge Withdrawal (pulling out) Diaphragm onth, how many times have you had		Safe periods (rhythm or counting days)  Norplant Cervical cap  Tubal ligation (tubes tied)  Vasectomy Other ( Please describe:)  Don't know  Intercourse without using
	contraception	n? Times		or a comp

Medhist Two-Year 1/1/00 4 of 5

5.	In the past 6 months, have you become pregnant?
	$ \begin{array}{c}                                     $
	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	Does Not	
			How old was she when her first breast cancer occurred?		if she had	Apply	
			Less than 45	45 or older	Don't know age	breast cancer	
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)						

FamHist Two-Year 1/1/00

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		Don't	Does	
				l was she v rian cance	when her occurred?	know if she had ovarian	Not Apply
			Less than 45	45 or older	Don't know age	cancer	
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.	
٠,	Committee Commit	
	Patient Acrostic:	
	<u>, vigoros está liberator en fielac</u>	

#### **CURRENT MEDICATIONS**

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Dosage

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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				

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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.

for ea	ach quest	tion.		
1.			onths, ha	s any swelling occurred in your arm or hand on the same side that you had your omy?
		Yes -	• (Cont	inue to question 2)  (Go to question 8)
2.	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 (die	d) the swelling occur? (Check all that apply)
		Hand Upper Arm Lower Arm
2c.	Do (did) you co	nsider the swelling to be mostly?
		Mild Moderate Severe
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:

3.

		Patient I.D
		Patient Acrostic:
1.	Does (did) swelling seem to  Don't Yes No Know  Don't One Control Control One	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 d following? (Check all that	agnosis, did you notice swelling in your hand and/or arm with any of the apply)
	Yes No 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 $\rightarrow$ 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. <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

	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)
	9a. If yes, did you receive antibiotics by mouth?
	No Yes Don't know

Patient I.D.

	9b. <u>If y</u>	es, did you recei	ve antibiotics	oy injection?
		No Yes Don't kn	ow	
10.	Do you have pain in	the affected arm	n and/or hand?	(Check one box for each site)
		Yes	No	
	hand			
	arm			

Patient Acrostic:		Patient	I.D.	
Patient Acrostic:				
	١,	Patient	Acrostic:	<del></del>

#### 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 <u>not</u> interfere with usual activities.

Moderate = symptom interfered somewhat with usual activities.

Severe = symptom was so bothersome that usual activities could not be performed.

	Symptom did not	Symptom Occurred and Was:			
Symptom	occur	Mild	Moderate	Severe	
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	Symp	Symptom Occurred and W		
Symptom	did not occur	Mild	Moderate	Severe	
13. Constipation	-	<del></del>			
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					

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# QUALITY OF LIFE FORM

#### PART I. ACTIVITIES

1.	In general, would yo	u say your health	is: (Check o	one)		
	Excellent	Very good	Good	Fair	Poor	
	llowing questions are e activities? If so, ho		you might do o	luring a typical day.	Does your	health now limit you
2.	Moderate activities,	such as moving a	a table, pushin	g a vacuum cleaner,	bowling, or	playing golf.
	Limited a lo	t Limited	i a little	Not limited at all	I	
3.	Climbing several fli	ghts of stairs.				
	Limited a lo	t Limited	d a little	Not limited at all	I	
	g the past four weeks, ies as a result of your			ving problems with		r other regular daily
4.	Accomplished less t	han you would li	ke.	Yes	No	
5.	Had difficulty perfo for example, it took	_	r other activiti	es,		
During activit	g the <u>past four weeks</u> ies <u>as a result of emo</u>	, have you had an tional problems (	y of the follow such as feeling	ving problems with g	your work o ous)?	r other regular daily

				Yes	No		
6.	Accomplished less	than you woul	d like.				
7.	Didn't do work or o	other activities	as carefully as u	sual.			
8.	During the past four with your normal so	r weeks, to whocial activities	nat extent has you with family, frie	ır <u>physical hea</u> nds, neighbors	Ith or emotiona, or groups? ((	<u>l problems</u> inte C <b>heck one)</b>	rfered
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
9.	During the past four work outside the ho	r weeks, how i me, housewor	much did <u>pain</u> in k and family acti	terfere with you	ur normal activ ck one)	ities (including	both
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
each q	questions are about huestion, please give to during the past fou	he one answer	nd how things ha	est to the way	you during the p	past four weeks feeling. How m	. For nuch of
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 o	of energy? (Cl	neck 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 downl	hearted and bl	ue? (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 <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 y	our quality	`	Circle one	number.)	10

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

Relationsl	nip With	Doctor				Not At All	A Little Bit	Some- What	Quite a bit	Very Much
29. I had co	onfidence	e in my do	octor(s).			1	2	3	4	5
30. My doo	ctor was	available t	to answer	my quest	ions.	1	2	3	4	5
31. How 1	much do	es your <u>Re</u>	elationship	with you	ur Doctoi	affect your	r quality of l	ife? (Circ	ele one nu	mber.)
0	1	2	3	4	5	6	7	8	9	10
Not at all									Ve	ery Much So
Emotional	Well-Be	eing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
32. I felt s	ad.					1	2	3	4	5
33. I was p	oroud of	how I'm c	oping wit	h my illn	ess.	1	2	3	4	5
34. I was 1						1	2	3	4	5
35. I felt n		-		•		1	2	3	4	5
36. I worri	ed about	dying.				1	2	3	4	5
37. How 1	much doe	es your <u>En</u>	notional V	Well-Bein	g affect y	our quality	of life? (Ci	rcle one i	number.)	
0	1	2	3	4	5	6	7	8	9	10
Not at all									Ve	ry Much So
Functional	l Well-B	eing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
38. I was a	ble to w	ork (includ	de work ii	n home).		1	2	3	4	5
39. My wo	ork (inclu	de work i	n home) v	vas fulfill	ing.	1	2	3	4	5
40. I was a	ble to en	joy life "i	n the mon	nent."		1	2	3	4	5
41. I had a	ccepted 1	my illness	•			1	2	3	4	5
42. I was sleeping well.					1	2	3	4	5	
43. I enjoy	ed my us	sual leisur	e pursuits			1	2	3	4	5
44. I was c					nt now.	1	2	3	4	5
45. How 1	nuch doe	es your <u>Fu</u>	nctional \	Well-Bein	g affect y	our quality	of life? (Ci	ircle one 1	number.)	
0	1	2	3	4	5	6	7	8	9	10
Not at all										ry Much So

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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 you	r quality o	f life? (Cir	cle one r	umber.)	
0 1 2 3 4 5 Not at all	6	7	8	9 V	10 ery 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 agr	ee or disagree wit	h the following state	ement? (Check	the appropriate box.)
64.	The appearance of	my breast area is i	mportant to me.		
	Strongly Disagree		Neither Agree or Disagree	Agree	Strongly Agree
65.	I view myself as a	:			
<b>D.</b> D.	Normal weig  Moderately t  Very thin per	overweight person tht person hin person			
PAR	T III. SEXUA	LITY			
These perso	e next questions are onal, but your answ	e about the way he ers are important in	alth problems may in n understanding how	terfere with your health problems	sex life. These questions are may affect women's sexuality.
66.	Have you been sex	xually active with	a partner during the la	ast 6 months?	
	No> (I	If no, skip to Ques	etion 79). Question 67).	·	
67.	How many times l	have you had sexua	al intercourse <u>in the p</u>	ast month?	
	0 times 1 - 4 times 5 - 10 time 11 or more				

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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 <u>best</u> 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 ID.
	Patient Acrostic
33.	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
34.	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

Patient I.D.

#### SPIRITUAL BELIEFS PART V.

10 or more hours

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.	befo	re your b	reast canc	e yourself or eer, "+5" me fferent but v	ans that ev	erything i	is totally d	ifferent bu			
-	5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
7	Worse	:			S	ame as be	efore				Better
PAR	RT VI	. EM	IOTIONA	L FEELIN	IGS						
chec past	k the week	box nex	t to the on ling today	sist of grou e statement . If several ents in each	in each gr statement	oup which	h <b>best</b> dese	cribes the em to appl	way you l	have been	feeling the
93.			feel sad.								
	H	I feel sa		1.7	•.						
				ne and I car appy that I	•					-	
94.		I am no	t particular	rly discoura	ged about	the future.					
	H		_	about the fi							
				ng to look fo							
		I feel th	at the futur	re is hopele	ss and that	things car	nnot impro	ove.			
95.		I do not	feel like a	failure.				·			
		I feel I h	nave failed	more than	the average	e person.					
		As I loo	k back on	my life, all	I can see is	s a lot of f	ailures.				
		I feel I a	am a comp	lete failure	as a persor	1.					
96.		I get as	much satis	sfaction out	of things a	is I used to	<b>)</b> .				
	H	I don't e	enjoy thing	gs the way I	used to.						
		I don't g	get real sat	isfaction ou	t of anythi	ng anymo	re.				
		I am dis	satisfied o	r bored witl	h everythin	ıg.					

		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 mista	kes.
	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 of	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 the	nough I want to.
		<del>-</del>

103.		I am no more irritated now than I ever am.
	Щ	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.
	Щ	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.
	$\sqcup$	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 ache I am very worried about physical problems and it's I am so worried about my physical problems that I	s hard to think of much else.
113.	I have not noticed any recent change in my interest 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.	t in sex.

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## **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.					
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.					

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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.		
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Patient Acro		

#### 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 d	to 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 bev	verages?				
	No Yes					
	If yes, about how many alcoholic beverages (beer, wine, or mixed drinks) do you currentl drink in an average month?					
	Beverag	ges per month				

3.	What is your current weight?					
			pounds			
The fand s	followi sports.	ng questions ar	re about your 1	usual p	hysical activity and exercise. This includes walking	
<b>1</b> .	Thin the h	k about the wall ome <u>for more tl</u>	king you do out nan 10 minutes	side the	e home. In the past month, how often did you walk outside stopping? (Mark only one.)	
		Rarely or nev	er	>	(Go to Question 5)	
		<ul><li>1-3 times each month</li><li>1 time each week</li><li>2-3 times each week</li></ul>		>	(Go to Question 4a)	
				>	(Go to Question 4a)	
				>	(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 wastopping, how			alked outside the home for more than 10 minutes without wany minutes did you usually walk?		
				20-39 40-59	han 20 minutes minutes minutes r or more	
		4b.	speed?			
				Avera Fairly Very	al strolling or walking (less than 2 miles an hour) age or normal (2-3 miles an hour) fast (3-4 miles an hour) fast (more than 4 miles an hour) Know	

						Patient Acrostic:
0	utside the	e home,				moderate, and mild). Not including walking usually do the following strenuous,
5.			OR VERY HARD EX robics, aerobic dancing,		•	u work up a sweat and your heart beats fast.) s, swimming laps.
		None		>	(Go to	Question 6)
			per week	>	`	Question 5a)
			per week	>	(Go to	Question 5a)
		3 days	s per week	>	(Go to	Question 5a)
		4 days	s per week	>	(Go to	Question 5a)
		5 or m	ore days per week	>	(Go to	question 5a)
			5a. How long do	you usı	ally exe	ercise like this at one time?
				20-39 40-59	han 20 i minute minute r or mor	S S
6.			•		•	example, biking outdoors, using an exercise tenics, 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 w	eek	>	(Go to Question 6a)

Patient I.D.

	6a. How long do	you usually exe	ercise like this at one time?			
7. MILD EXER		Less than 20 r 20-39 minutes 40-59 minutes 1 hour or mor	s s e			
7. WILD EXER	CISE. For example,	slow dancing, b	owling, 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 w	eek>	(Go to Question 7a)			
	7a. How long do you usually exercise like this at or					
		Less than 20 minutes  20-39 minutes  40-59 minutes				
		1 hour or more	e ·			

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Patient Ac	rostic:	
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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.)

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#### 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.**)

		Yl	ES, and it upset	me:
Over the past year:	NO	Not too much	Moderately (Medium)	Very Much
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?				
<ol> <li>Did a close friend or family member die or have a serious illness (other than your spouse or partner.)</li> </ol>				
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 Acros	stic:

#### **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.

Your Current Mailing			- NAME AND A STREET	
Telephone Numbers:	Home:	Area Code (	)	<del>-</del>
	Work:	Area Code (	)	
	Other:	Area Code (	)	
When is the best time	to contact	you?	Where	e is the best place to contac
Day of week	<u>.</u>	time(s)		At home At work Other
Day of week		time(s)		At home At work

Contact Two-Year 1/1/00 1 of 2

				Patient I.D. Patient Acro	stic:					
4.	In case we might ev answering machine,	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 husbar you during the study partner.)	nd's or partner's l	egal name? (T is blank if you	This information are not currently	will help us keep y married or with	o in contact with a long-term				
	First	t	MI		Last					
6.	Please provide the nknow how to contact	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:									

Contact Two-Year 1/1/00

# 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

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## 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.	past six months, which of the following Check all that apply)	ng docto	ors or other health professionals have you seen?
	None		Family Therapist
	Acupuncturist		Nutritionist
	Allergist		Obstetrician
	Cardiologist		Medical Oncologist/Chemotherapist
	Chiropractor		Orthopedic Surgeon
	Dentist		Homeopathic/Herbalist/Naturopathic
	Dermatologist		Pain Control Professional
	Ear/Nose/Throat Doctor		Alternative Therapist (Homeopath, herbalist, naturopathologist, etc.)
	Eye Doctor		Physical Therapist
	Marital Counselor		Plastic Surgeon
	Gastroenterologist		Psychiatrist
	General Practitioner		Clinical Psychologist
	Gynecologist		Radiologist
	Infertility Specialist		Rheumatologist
	Internist		Social Worker
	Massage Therapist		Organized Support Group
	Neurologist		Surgeon
	Sexual Therapist		Urologist
			Other:

Medhist 30 mos. 7/00 Page 1 of 6

2.	In the past 6 months, ha	ave you b	een seen a	at an emergency room?
	□ No □ Yes → For	what reas	on:	
3.	In the past 6 months, ha line item (a) and (b).	ave you b	een hospi	talized or had surgery? Please mark one box for each
		No	Yes	If yes, for what reason?
	(a) Hospitalized?			
	(b) Had surgery?		•	
<b>1.</b> .	Has anything else chan box for each line item (	a) and (b)	).	r your mental or physical health status? Please mark one
	(a) Mental Health?	No	Yes	What has changed?
	(b) Physical Health?			

		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 month	ns, have you had a recurrence of breast cancer?
	□ No	es → If yes, how was this diagnosis made. (For example, biopsy, lab tests)?
7.	Have you been dia	gnosed with any other cancer in the past 6 months?
/.	□ No	
		es → If yes, what type?
	Н	ow was this diagnosis made? (For example, biopsy, lab tests)?
	_	
8.	Today's date is:	Month Day Year

Patient I.D.			
Patient Acro	ostic:		
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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 <u>best estimate</u>.

1.	What was the	e date of the first day of your <u>last</u>	menstrual pe	eriod (your best guess)?
	Month D	ay Year		
2.	In the past 6	months, have you been sexually a	active with a	male partner:
		No $\rightarrow$ Go to question 6		
		Yes $\rightarrow$ Go to question 3		
3. <b>apply</b>		od of birth control are you and yo	ur partner us	ing currently? (Check all that
		No method		Safe periods (rhythm or counting days)
		Condoms (rubbers)		Norplant
		Birth control pills		Cervical cap
		Foams/jellies/suppositories		Tubal ligation (tubes tied)
		Sponge		Vasectomy
		Withdrawal (pulling out)		Other ( Please describe: )
		Diaphragm		Don't know

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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?
	$ \begin{array}{c}                                     $
	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

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#### PART III

#### CURRENT MEDICATIONS

PARI III	CURRENT MEDI	CATIONS			
Please list below all of the pare not taking any prescript	ist below all of the <b>prescription medications</b> you are taking currently. (Write "none" if you taking any prescription medications at this time.)				
Drug Name		Dosage			
. Please list below all of the (Write "none" if are not tak	non-prescription medicating any non-prescription	ations or supplements you are taking curren medications or supplements at this time.)			
Drug Name		Dosage			

Medhist 30 mos. 7/00 Page 6 of 6

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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.

for ea	ch ques	tion.		
1.			onths, ha	as any swelling occurred in your arm or hand on the same side that you had your omy?
		Yes -	(Con	o question 8) tinue to question 2)  (Go to question 8)
2.	Yes	No 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 (di	d) the swelling occur? (Check all that apply)
		Hand Upper Arm Lower Arm
2c.	Do (did) you co	onsider the swelling to be mostly?
		Mild Moderate Severe
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:

3.

		Patient I.D.
		Patient Acrostic:
		(1) 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
4.	Does (did) swelling seem to  Don't Yes No Know  Don't One of the control of the c	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 d following? (Check all that	iagnosis, did you notice swelling in your hand and/or arm with any of the apply)
	Yes No Know	

6.	Did y	ou seek treatment for this swelling in the past 6 months?
		No $\rightarrow$ 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 yo	u 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 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
9.	Don't know  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?

 $No \rightarrow$  (Go to question 10)

No

Yes

Don't know

If yes, did you:

Yes  $\rightarrow$  (Continue to question 9a)

Don't Know  $\rightarrow$  (Continue to question 10)

9a. receive antibiotics by mouth?

Patient I.D.

	If yes, die	i you:		
	9b.	receive antibiot	ics by injection	n?
		No Yes Don't know		
10.	Do you have pain in	the affected arn	n and/or hand?	(Check one box for each site)
		Yes	No	_
	hand			
	arm			

hand and arm

Patient I.	D.	
Patient A	Acrostic:	<u></u>

#### 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

Severe

symptom interfered somewhat with usual activities.

symptom was so bothersome that usual activities could not be performed.

	Symptom did not	Symptom Occurred and Was:			
Symptom .	occur	Mild	Moderate	Severe	
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 did not	Symptom Occurred and Was:							
Symptom	occur	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									

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#### QUALITY OF LIFE FORM

1.	In general, would yo	u say your health	is: (Check or	ne)	
	Excellent	Very good	Good	Fair	Poor
	llowing questions are e activities? If so, ho	•	you might do du	uring a typical day.	Does your health now limit you
2.	Moderate activities,	such as moving a	table, pushing	a vacuum cleaner,	bowling, or playing golf.
	Limited a lo	t Limited	l a little	Not limited at all	
3.	Climbing several fli	ghts of stairs.			
	Limited a lo	ot Limited	i a little	Not limited at all	
			y of the following	ng problems with y	our work or other regular daily
activit	ies as a result of your	physical health?		Yes	No
4.	Accomplished less t	han you would lil	ke.		
5.	Had difficulty perfor for example, it took	•	r other activities	s, 🗆	
	g the past four weeks, ies as a result of emot				our work or other regular daily as)?
				Yes	No
6.	Accomplished less t	han you would li	ke.		
7.	Didn't do work or o	ther activities as	carefully as usu	al.	

8.	During the past four with your normal so	weeks, to what cial activities	at extent has you with family, frie	r <u>physical heal</u> nds, neighbors	th or emotional, or groups? (C	l problems interf Check one)	ered
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
9.	During the past four work outside the hor	weeks, how ne, housework	nuch did <u>pain</u> int c and family acti	erfere with you vities)? (Chec	ur normal activ	ities (including l	ooth
	Not at all	Slightly	Moderately	Quite a bit	Extremely		
each qu	questions are about huestion, please give to during the past fou	he one answer	nd how things hat that comes close	we been with yest to the way y	ou <u>during the r</u> you have been f	east four weeks. Feeling. How mu	For ich of
10.	Have you felt calm a	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 o	f energy? (Ch	eck 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 downl	hearted and blu	ie? (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		
<b>Patient Acrostic</b>		

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>.

number that best describes now true each statement	uas deen i	or you <u>aar</u>	ing ine pu	<u>si / aays</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 you on the second of t	our quality 6	of life? (C	Circle one	<b>numbe</b> r. 9	10 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, otherwise, go to question 28.	please ans	swer questi	ons 26-27	•	
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 aff	ect your q	uality of lif	e? (Circle	e one nu	mber.)
0 1 2 3 4 5 Not at all	6	7	8	9	10 Very Much So

Relations	hip With	Doctor				Not At All	A Little Bit	Some- What	Quite a bit	Very Much
29. I had c	onfidence	in my do	octor(s).			1	2	3	4	5
30. My do				my quest	ions.	1	2	3	4	5
31. How	much doe	s your <u>R</u> e	elationshir	o with you	ır Doctor	affect you	r quality of li	fe? (Circ	le one nu	mber.)
0 Not at all	1 .	2	3	4	5	6	7	8	9 Ve	10 ery Much So
Emotiona	l Well-Be	ing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
32. I felt s	sad.					1	2	3	4	5
33. I was	proud of h	ow I'm c	oping wit	h my illn	ess.	1	2	3	4	5
34. I was						1	2	3	4	5
35. I felt r				J		1	2	3	4	5
36. I worr	ied about	dying.				1	2	3	4	5
37. How	much doe	s your <u>Er</u>	notional V	Vell-Bein	g affect y	our quality	of life? (Ci	rcle one 1	number.)	
0 Not at all	1	2	3	4	5	6	7	8	9 Ve	10 ery Much So
Functiona	ıl Well-Be	eing				Not at All	A Little Bit	Some- what	Quite a bit	Very Much
38. I was	able to wo	ork (inclu	de work ir	n home).		1	2	3	4	5
39. My w	ork (inclu	de work i	n home) v	vas fulfill	ing.	1	2	3	4	5
40. I was	able to enj	joy life "i	n the mon	nent."		1	2	3	4	5
41. I had a	accepted n	ny illness	<b>.</b>			1	2	3	4	5
42. I was	sleeping v	vell.				1	2	3	4	5
43. I enjoy	yed my us	ual leisur	e pursuits			1	2	3	4	5
44. I was	content w	ith the qu	ality of m	y life righ	nt now.	1	2	3	4	5
45. How	much doe	s your <u>Fu</u>	ınctional V	Well-Bein	g affect	your quality	of life? (C	ircle one	number.)	
0 Not at all	1	2	3	4	5	6	7	8	9 . Ve	10 ery Much So

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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 you	r quality o	f life? (Cir	cle one n	umber.)	
0 1 2 3 4 5 Not at all	6	7	8	9 V	10 Yery 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		- 77 8			

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 Or Disagree
65.	I view myself as a:
	Very overweight person  Moderately overweight person  Normal weight person  Moderately thin person  Very thin person
	T III. SEXUALITY  e next questions are about the way health problems may interfere with your sex life. These questions are
perso	nal, 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

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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 <u>best</u> 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
	Ves 5 or more times a week

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

#### PART V. SPIRITUAL BELIEFS

10 or more hours

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.	befor	e your bi	reast canc	e yourself or er, "+5" mea ferent but w	ans that ev	erything i	s totally di	ifferent bu	our life is t better, ar	just the ward of the me	ay it was cans that
-	-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5
٦	Worse				Sa	ame as be	fore				Better
PAF	RT VI.	EMO	OTIONA	L FEELIN	GS						
chec the	k the t past w	oox next eek, inc	to the one	sist of group e statement day. If seve e statement	in each gr eral statem	oup which nents with	n <b>best</b> dese in a group	cribes the seem to a	way you lapply equa	have been	feeling
93.		I do not i	feel sad.								
		I feel sad	l.								
		I am sad	all the tin	ne and I can	't snap out	of it.					
		I am so s	ad or unh	appy that I	can't stand	it.					
94.		I am not	particular	ly discourag	ged about t	he future.				·	
		I feel dis	couraged	about the fu	iture.						
		I feel I h	ave nothir	ng to look fo	orward to.						
		I feel tha	t the futur	re is hopeles	s and that	things car	not impro	ove.			
95.		I do not :	feel like a	failure.							
		I feel I h	ave failed	more than t	he average	e person.					
	1 1			my life, all			ailures.				
		I feel I aı	m a comp	lete failure a	as a person	ı <b>.</b>					
96.		I get as n	nuch satis	faction out	of things a	s I used to	).				
		I don't e	njoy thing	s the way I	used to.						
		I don't g	et real sat	isfaction ou	t of anythi	ng anymo	re.				
				r bored with							

		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.
	Щ	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.
	$\sqsubseteq$	I have thoughts of killing myself, but I would not carry them out.
	Щ	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.
	Ш	I used to be able to cry, but now I can't cry even though I want to.

Patient I.D.

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.
		Thave 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.
		s a comparation of the comparati
108.	Щ	I can sleep as well as usual.
	Щ	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.

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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.

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#### 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
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.					

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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.

l.	Do you smoke currently?	
	No Yes	
	If yes, how many cigarettes do	o 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 beve	erages?
	No Yes	
	If yes, about how many alcol drink in an average m	holic beverages (beer, wine, or mixed drinks) do you currently nonth?
	Beverag	es per month

3.	What	t is your current	t weight?		
			pounds		
The fand s	ollowii ports.	ng questions ai	re about your i	usual p	hysical activity and exercise. This includes walking
4.	Thinl	k about the wallome for more the	king you do out nan 10 minutes	tside the	s home. In the past month, how often did you walk outside stopping? (Mark only one.)
		Rarely or nev	er	>	(Go to Question 5)
		1-3 times eac	h month	>	(Go to Question 4a)
		1 time each w	veek	>	(Go to Question 4a)
		2-3 times each	h week	>	(Go to Question 4a)
		4-6 times eac	h week	>	(Go to Question 4a)
		7 or more tim	es each week	>	(Go to Question 4a)
		4a.			ntside the home for more than 10 minutes without minutes did you usually walk?
				20-39 40-59	han 20 minutes minutes minutes r or more
		4b.	What was yo	ur usual	speed?
				Avera Fairly Very	al strolling or walking (less than 2 miles an hour) age or normal (2-3 miles an hour) afast (3-4 miles an hour) afast (more than 4 miles an hour) Know

					ent f.Dent Acrostic:
outs	ide the	-			moderate, and mild). Not including walking usually do the following strenuous,
		UOUS OR VERY HARD EX		•	u work up a sweat and your heart beats fast.) s, swimming laps.
		None 1 day per week 2 days per week 3 days per week 4 days per week 5 or more days per week	>>>>	(Go to	Question 6) Question 5a) Question 5a) Question 5a) Question 5a) Question 5a) question 5a)
6.		DERATE EXERCISE (Not ex	Less t 20-39 40-59 1 hou	han 20 minute minute r or more	S .
		None  1 day per week		>	(Go to Question 7)  (Go to Question 6a)

(Go to Question 6a)

(Go to Question 6a)

(Go to Question 6a)

(Go to Question 6a)

Personal Habits 30 mos. 7/00

2 days per week

3 days per week

4 days per week

5 or more days per week

	6a. How long do	you usually exe	ercise like this at one time?
		Less than 20 r 20-39 minutes 40-59 minutes 1 hour or mor	5
7. MILD EXER	RCISE. For example,	slow dancing, b	owling, golf.
	None 1 day per week 2 days per week 3 days per week 4 days per week 5 or more days per w	>>> veek>	(Go to Question 7a)
	7a. How long do	you usually exe Less than 20 r 20-39 minutes 40-59 minutes 1 hour or mor	3

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### **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.

Has your address changed since our last mailing to you?  ☐ No ☐ Yes → If yes, please provide current mailing address									
Your Current Mailing	g Address?								
Telephone Numbers:				_					
	Work:	Area Code (		<b>-</b> ,					
	Other:	Area Code (		_					
When is the best time	to contact	you?	Where is the best plac	e to contact					
Day of week		time(s)	At home At work Other						
Day of week		time(s)	At home At work Other						

Contact 30 mos. 7/00 Page 1 of 2

4.	In case we might ever answering machine,	er need to contact (if you have one)	you by teleph if we are una	ione, may we le able to reach yo	ave a message for u directly?	you on your
		No Yes				
5.	What is your husban you during the study partner.)	d's or partner's le . Please leave thi	gal name? (7 s blank if you	This information are not current	n will help us keep ly married or with	o in contact with a a long-term
	First		MI		Last	
6.	Please provide the naknow how to contact				our household, w	ho are likely to
	Name:					
	Address:					
	Phone Number:	Area Code (			_	
	Relationship to you:					
	Name:					
	Phone Number:	Area Code (		-	_	
	Relationship to you:					

Appendix F	SEPTEMBE	R 2000	
Patient I.D.:		Acrostic:	
IF YOU'VE NOT HAD	ANY BLEEDING DURING THIS M	IONTH, CHECK THIS BOX:	
information on ANY vagir	nal BLEEDING or SPOTTING you	eck the appropriate box below referring to may have. A BLEEDING day is defined a on or pad. A SPOTTING day is defined as mpon or pad.	ıs a

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					Spotting Bleeding: Light Medium Heavy	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 Bleedling: 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
	only. No de questions d cycles - ple	octor who is tre or concerns - w ase discuss the	stionnaires you o ating you will se hether emotiona em with your doo	e these forms. I, physical, or a ctor.	If you have any bout your mens	r strual
	Call Judy a	t 336-716-2116	or Kathy at 336-7	716-9486 if you	have questions	<b>5.</b>

# 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

QOLSN: March 2000

#### **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.

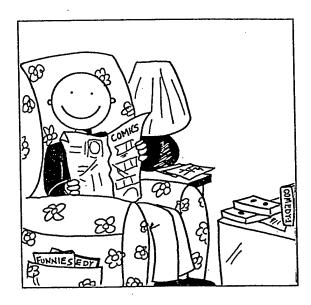
Pat Kellly, one of our Project Coordinators in Texas was familiar with the book and recommended it for our Newsletter. I called Eileen to get the story behind the book. In 1992 Eileen says, "Life was good. I was 44, eating healthy, exercising and taking time for myself to live life on life's terms when 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 <a href="https://www.metroplexweb.com/oas">www.metroplexweb.com/oas</a> 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 relationship15% have never been married10% 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 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 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. 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.

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# **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 preserves1 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

## MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE AFTER BREAST CANCER TREATMENT

## Jeanne A. Petrek, MD Ruby Senie, PhD

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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.

The U.S. Army Medical Research and Materiel Command under DAMD17-96-1-6292 supported this work.

# **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 premenopausal 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. <sup>(3)</sup> 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. <sup>(4)</sup> 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. <sup>(5,6)</sup>

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. <sup>(7)</sup> In 1962 a series of 52 patients from Memorial Hospital had an overall five year survival rate of 52%. <sup>(8)</sup> Another similar-sized study reported in 1969 <sup>(9)</sup> 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. <sup>(10)</sup> Fifty percent of patients in a 1973 series survived five years. <sup>(11)</sup>

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 <sup>(16)</sup> 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 <sup>(14)</sup> and the Memorial Hospital series, <sup>(13)</sup> 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 <sup>(20)</sup> 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 longterm 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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