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Award Number: DAMD17-01-1-0447

TITLE: Quality of Life and Functional Status Across the Life Course

Project 2: Investigating Mechanisms to Explain Age Associated Differences in Quality of Life Among Breast Cancer Patients

PRINCIPAL INVESTIGATOR: Michelle J. Naughton, Ph.D.
Nancy E. Avis, Ph.D.
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CONTRACTING ORGANIZATION: Wake Forest University School of Medicine
Winston-Salem, North Carolina 27157

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13. ABSTRACT ***(Maximum 200 Words)***

The primary purpose of this study is to examine mechanisms that may explain age differences in the health-related quality of life of women who have been diagnosed with a first-time breast cancer. The study will examine psychosocial factors such as social support, coping strategies, resiliency, and the impact of cancer on life responsibilities as explanations of age-associated factors affecting HRQL. This project is an observational, longitudinal study of women aged 18 and over who are newly diagnosed with breast cancer. In order to examine both the short- and longer-term impact of breast cancer on HRQL, the study will survey women post diagnosis and follow them at 3, 6, 12, and 18 months. A secondary purpose of the proposed study is to have this large cohort of breast cancer patients serve as a comparison group for the other studies in the Behavioral Center of Excellence. Patients for the proposed study will be recruited from two clinical centers: Memorial Sloan-Kettering Cancer Center (MSK) and University of Texas - Southwestern University (UT-SW).

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Table of Contents

PART I - INTRODUCTION

The primary purpose of this research is to examine mechanisms that may explain age differences in the health-related quality of life of women who have been diagnosed with a first-time breast cancer. The study examines psychosocial factors such as social support, coping strategies, resiliency, and the impact of cancer on life responsibilities as explanations of age-associated factors affecting HRQL. This project is an observational, longitudinal study of women aged 18 and over who are newly diagnosed with breast cancer. In order to examine both the short- and longer-term impact of breast cancer on HRQL, the study will survey women post diagnosis and follow them at 3, 6, 12, and 18 months. A secondary purpose of the study is to have this large cohort of breast cancer patients serve as a comparison group for the other studies in the Behavioral Center of Excellence. Patients for the proposed study will be recruited from two clinical centers: Memorial Sloan-Kettering Cancer Center (MSK) and University of Texas - Southwestern University (UT-SW).

PART II – BODY: STATEMENT OF WORK

The primary activities during this first year of the study have been to obtain Human Subjects Protection approval from the Department of Defense, finalize study forms, develop the Manual of Operations, and develop the data management system. The tasks described in the original statement of work have not changed. However, time involved in obtaining Human Subjects approval from the Department of Defense was not included as part of the original timeline. This approval has taken an enormous amount of time and has essentially moved the timeline back over a year. Because of these delays we recently received additional funding for a 5th project year. Thus, the following represents a change in months of activity from the original Statement of Work

Task 1: Develop research protocol (months 1-15)

a. Finalize research questionnaires

The questionnaires have been finalized and are include in the Appendix.

b. Review protocol with sites

The protocol has received approval from the Wake Forest University IRB. The protocol was previously approved by the site IRBs, but revisions to the consent form and protocol were required by the DOD Office of Human Subjects Protection. We have made these revisions and are waiting to hear from the Office of Human Subjects Protection that they now meet all requirements. Once these are approved, the two sites will resubmit the revised protocol and consent forms to their IRBs. Subject recruitment will begin as soon as we receive approval to recruit from the D.O.D.

Task 2: Develop data management system (months 3-12)

a. Develop data management requirements
b. Develop reporting requirements
c. Develop contact record
d. Train data manager

These tasks have all been completed and are described in the Biostatistics Core.

None of the following tasks have begun.

Task 3: Identify, recruit, and conduct baseline interviews of eligible patients (months 16-33)

a. Study sites identify and recruit eligible patients
b. Patients recruited and interviewed
c. Quality control (ongoing)
d. Medical record review
e. Data entry system developed
f. Data entry of questionnaires (ongoing)

Task 4: Ongoing follow-up of patients (months 19-52)

a. Tracking of women in study
b. Mailing of follow-up questionnaires
c. Contacting non-responders
d. Mailing of incentives
e. Follow-up medical record reviews

Task 5: Data Analysis and Report Writing (months 33-60)

a. Merging of data management, questionnaire, and medical record files
b. Date cleaning
c. Data analysis
d. Presentation of results at professional meetings
e. Initial manuscripts prepared

Part III - KEY RESARCH ACCOMPLISHMENTS

- Finalization of study forms
- Obtaining human subjects protection approval (in progress)
- Developing data management system
- Development of a Manual of Operations

PART IV - REPORTABLE OUTCOMES

Naughton MJ, Avis NE, Anderson RT, Ribisl P, Petrek J, Naftalis E. Quality of Life and Functional Status Across the Life Course: A Behavioral Center of Excellence in Breast Cancer. Era of Hope, Department of Defense Breast Cancer Research Meeting. September 27, 2002, Orlando, Florida. (Poster)

Part V - CONCLUSIONS

This section is not applicable at this point.

PART VI - REFERENCES

Not applicable

APPENDIX

Attached are the Manual of Operations and the Study Forms

MANUAL OF OPERATIONS

INVESTIGATING MECHANISMS TO EXPLAIN AGE ASSOCIATED DIFFERENCES IN QUALITY OF LIFE AMONG BREAST CANCER PATIENTS

OCTOBER, 2002

TABLE OF CONTENTS

CHAPTER 1

STUDY ORGANIZATIONAL STRUCTURE

1.1 INTRODUCTION

This manual will serve as your guide to the conduct of the study entitled: Investigating Mechanisms to Explain Age Associated Differences in Quality of Life Among Breast Cancer Patients. The following chapters will provide crucial information regarding study procedures and follow-up.

1.2 CHANGES IN THE MANUAL OF PROCEDURES

The Manual of Procedures (MOP) will be updated throughout the study to reflect suggestions from clinical center staff and investigators, changes in the protocol or procedures, changes in the study organization or administration, and omissions in earlier versions. The clinical coordinating center will keep copies of all sequential MOPs. The clinical centers are expected to keep copies of the current version of the MOP.

When changes are made to the MOP, the clinical coordinating center will circulate copies of all pages affected by the changes. The clinical centers will be required to insert these updated pages in their MOPs, and may discard earlier versions of these pages. Each page of the MOP will include a version date. Only the most recent version should be included in the clinical center MOP.

1.3 STUDY ORGANIZATION

The organizational structure of this study includes the following components: the Clinical Centers (CC) and the Clinical Coordinating Center (CCC).

1.3.1 Clinical Centers. Two clinical centers are participating in the current protocol:

Memorial Sloan-Kettering Cancer Center, New York City, New York
University of Texas - Southwestern Medical Center, Dallas, Texas

Each clinical center is composed of an inter-disciplinary team of clinical investigators and staff who provide the areas of expertise necessary for the successful completion of the study. The responsibilities of the clinical center staff and investigators include:

1. Identifying and recruiting eligible participants for the study.

2. Completing medical record chart reviews regarding breast cancer diagnosis, treatment, and comorbidities.

3. Collecting high quality data in accordance with the study protocol.

4. Collaborating in the analysis, writing and dissemination of study results.

1.3.2 Clinical Coordinating Center. The clinical coordinating center for the current study will be located at the Wake Forest University School of Medicine, Department of Public Health Sciences, (Nancy Avis, Ph.D., Principal Investigator).

The clinical coordinating center has the primary responsibility for collecting follow-up data, monitoring the quality of all data collected, managing the study data, and analyzing data generated by the clinical centers. Additional responsibilities of the CCC include:

1. Preparing (with the aid of the clinical center investigators and staff) the protocol, forms, and Manual of Operations.

2. Working with the investigators in the development and pre-testing of forms and procedures, and assuming responsibility for the reproduction and distribution of forms.

3. Training study coordinators, data coordinators and other clinical center personnel.

4. Managing quality control aspects associated with the collection and management of the study data.

5. Monitoring clinical center performance through the use of summary date reports generated by the CCC (i.e., participant recruitment reports; quality control checks of collected data).

6. Developing the statistical analysis plan for the study data.

7. Monitoring follow-up activities, and monitoring quality control of follow-up data collected by the CCC staff.

8. Preparing, in collaboration with the clinical investigators, various manuscripts of the study results.

1.4 ORGANIZATION OF THE CLINICAL COORDINATING CENTER

The Clinical Coordinating Center (CCC) is organized to coordinate the tasks of the multicenter study. The Principal Investigator is directly responsible for all facets of the study, and works closely with coordinating center staff to complete study tasks. The Project Manager oversees the day-to-day management of the research project, and serves as the point of contact for staff within the coordinating center and staff at each of the clinical centers. Data programming, management and analyses are completed under the direction of Dr. Doug Case.

Study Leadership:	Nancy Avis, Ph.D., Principal Investigator Michelle Naughton, Ph.D., Co-Investigator

Study Coordination:	Carol Corum, M.A., Project Manager Doris Clark, Assistant Project Manager Debbie Allen, Administrative Secretary
Data Management/ Analysis:	Doug Case, Ph.D., Biostatistic's Core Director Julia Robertson, Programmer Amy Jiang, Programmer Lin Gu, Biostatistician Jianzhao Xu, Programmer

Regular meetings of all investigators and staff are held at the Clinical Coordinating Center. The agenda for each meeting includes progress reports of study tasks, as well as discussions of current problems and solutions.

1.5 FUNDING SOURCE

This study is one of three projects funded by the U.S. Army Medical Research and Material Command as part of a DOD Center of Excellence in Breast Cancer awarded to Wake Forest University of September of 2001 (Dr. Michelle Naughton, Ph.D., PI).

1.6 STUDY-WIDE MEETINGS AND DISTRIBUTION OF MINUTES

Quarterly conference calls will be held between staff from the clinical centers and the Project Manager and Assistant Project Manager at the coordinating center. It is the responsibility of the coordinating center staff to compile and distribute the minutes of these calls to all participating individuals. Minutes are circulated no later than two weeks after the date of the call. The coordinating center will maintain a master archive of minutes from all conference calls and meetings.

Quarterly conference calls are held between the Principal Investigators of the recruiting clinical centers (i.e., Memorial Sloan-Kettering; University of Texas-Southwestern) and the Principal Investigator of the clinical coordinating center. In addition, one face-to-face meeting is planned per year of all clinical center and coordinating investigators and key staff.

1.7 STUDY PERSONNEL

Names, addresses, and telephone numbers of study personnel at all both clinical centers and the coordinating center are listed on the following pages. These lists will be updated periodically by the clinical coordinating center.

AGE DIFFERENCES STUDY

CLINICAL CENTER
MEMORIAL SLOAN-KETTERING CANCER CENTER

Jeanne Petrek, M.D.
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AGE DIFFERENCES STUDY

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AGE DIFFERENCES STUDY

CLINICAL COORDINATING CANCER CENTER
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October 2002

CHAPTER 2

RECRUITMENT, SCREENING AND REGISTRATION

2.1 RECRUITMENT GOALS

Timely and successful recruitment of participants is important in order to obtain sufficient numbers of patients to perform meaningful, follow-up analyses. An 18 month recruitment period for new participants is planned for both clinical centers, beginning January 1, 2003 - June 30, 2004. All participants recruited to this study will be reassessed at 3, 6, 12 and 18 months post-recruitment. Thus, 18 months of follow-up data will be obtained on all participants.

A total of 800 additional women will be recruited to this protocol in the following age strata: 1) ages 18-45; 2) ages 45-54 years; 3) ages 55-64 years; and 4) ages 65+ years. Two hundred participants will be recruited in each of the four strata. Participants will be recruited from two clinical centers: Memorial Sloan-Kettering Cancer Center, and the University of Texas-Southwestern. The total participant recruitment goals for each center are given below:

Memorial Sloan-Kettering Cancer Center	600
University of Texas-Southwestern	200

The clinical coordinating center will monitor recruitment, and issue monthly recruitment reports to each participating institution. Strategies will be developed to assist the clinical centers in meeting their recruitment goals, if necessary.

2.2. RECRUITMENT STRATEGIES

Establish mechanisms for participant recruitment will be employed at the participating clinical centers. Patients will be identified used the following strategies:

a) identification through cancer registries or billing records
b) physician referrals
c) self-referral

2.2.1 Patient Identification Through Cancer Registries or Billing Records

The majority of patients will be identified through tumor and/or surgical registries at the participating institutions. Once potentially eligible women have been identified from registry or billing data, the patients= oncologists/surgeons will be contacted by clinic staff to obtain approval to approach the patient. If the physician approves, the patient will be approached at the clinic site, (if she is scheduled for a follow-up or treatment visit), or the patient will be sent a letter describing the purpose of the study, which will be followed by a telephone call. The clinic coordinator will screen the person using the Participant Eligibility Form to ensure she meets the eligibility criteria, and then will ask the patient to participate in the study if she is eligible. If the patient is interested in participating, the staff person will schedule her for the baseline clinic visit at which time she will sign the informed consent form, a medical record release form, and will

complete all baseline study questionnaires. If the patient is unable to come to the clinical center for a baseline visit, she can also be recruited through telephone and mail. (See Chapter 3 for specific recruitment procedures for in-person recruitment at a baseline clinic visit, or via telephone and mail.) Patients' physicians will be notified when a patient has enrolled in the study.

2.2.2 Referral Through Physicians

Participants will also be identified by the clinical center=s participating investigators, oncologists, surgeons, and radiologists. In most instances, these physicians will have already explained the study to the participant, and the clinic staff will contact the patient to invite her to participate in the study. The patient will be screened to ensure that she meets all eligibility criteria. If the patient is eligible and willing to participate, she will be scheduled for a baseline clinic visit, at which time she will sign the informed consent form, a medical record release form, and will complete all baseline study questionnaires. If the patient is unable to come to the clinical center for a baseline visit, she can also be recruited through telephone and mail. (See Chapter 3 for specific recruitment procedures for in-person recruitment at a baseline clinic visit, or via telephone and mail.) Patients= physicians will be notified when a patient has enrolled in the study.

2.2.3 Self-Referral

Women receiving treatment for breast cancer may also hear of the study from various sources and want to participate. These women may self-refer with physician approval. They will be screened for study eligibility, and will be asked to join the study if the eligibility criteria are met. The participants will be scheduled for the baseline clinic visit, if possible, at which time they will sign the informed consent form, a medical record release, and will complete all baseline study questionnaires. If the patient is unable to come to the clinical center for a baseline visit, she can also be recruited through telephone and mail. (See Chapter 3 for specific recruitment procedures for in-person recruitment at a baseline clinic visit, or via telephone and mail.) The patient's physicians will be notified if she enrolls in the study.

2.3 SCREENING AND ELIGIBILITY

The first contact between clinical staff and participants will be recorded using the Participant Eligibility Form. The eligibility form consists of questions designed to determine whether the participant is eligible to participate in the current protocol. Eligibility for the current study is based on the following inclusion and exclusion criteria.

Inclusion Criteria

1. Must be female

2. At least age 18 years at the time of diagnosis
3. Community dwelling as opposed to living in a residential care or correctional facility
4. Be diagnosed with a first-time invasive breast cancer Stage I, II, III within the previous six months
5. Provide informed consent.

Exclusion Criteria

Any of the following will exclude the participant:

1. Psychiatric or cognitive difficulty precluding the informed consent process or which would impact on compliance
2. Previous or another concurrent malignancy (excepting basal and squamous skin cancer and stage 0 cervical cancer)
3. Stage IV breast malignancy

Women will be screened in clinic or by telephone to determine if they are eligible to participate in the study. The Participant Eligibility Form has been designed to assist the clinic staff in determining eligibility. (Please see Appendix for a copy of this form.) Interested women meeting the screening eligibility criteria are scheduled for a baseline clinic visit as soon as is convenient. (In some situations, the pre-screening and baseline visit may occur during the same contact.) Participants who are unable to come to the clinic for a baseline visit, may also be recruited via telephone and mail, as described in Chapter 3.

2.4 DESIGNATED PHYSICIAN CONTACT

Upon entering the study, each participant will be asked to name the physician who has primary responsibility for her treatment. Once this physician has been named, a letter will be sent informing the physician that his/her patient is participating in the study.

2.5 ONLINE PATIENT ELIGIBILITY AND REGISTRATION

All patients enrolled in this study will be registered on-line using a web-based patient screening and eligibility system developed by the Biostatistic's Core for this project. All study coordinators who will be utilizing this system will be trained by Core personnel in the proper use of this system.

The on-line registration system uses information collected on the Participant Screening Form to verify her eligibility for the study, assign her an ID number, and register her for the protocol. Patient screening must have been completed prior to patient registration. The appendix to this chapter provides a step-by-step guide to logging on to this system, generating

participant ID labels, verifying patient eligibility, and patient registration. All clinic coordinators will be given a user name and password via separate communication with Biostatistic's Core personnel.

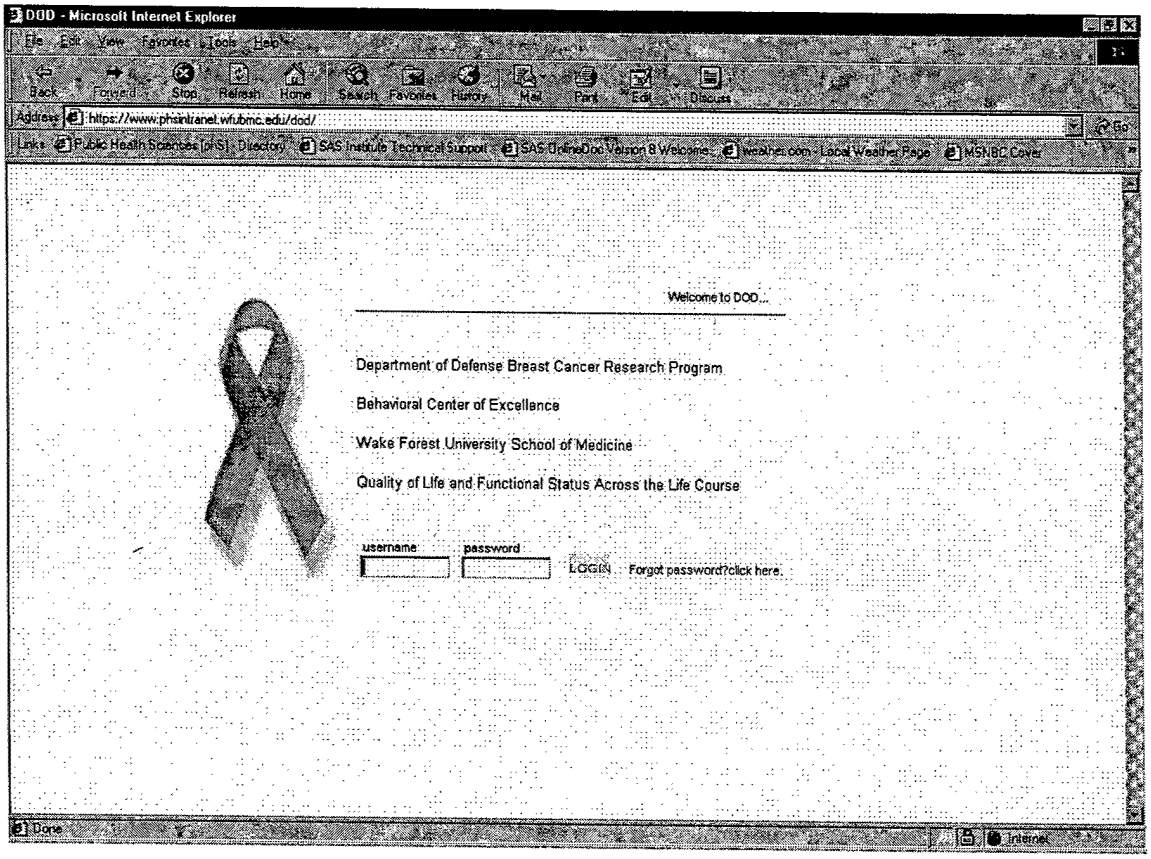
APPENDIX

ILLUSTRATION OF PATIENT REGISTRATION

Patient Registration will be completed in the following way:

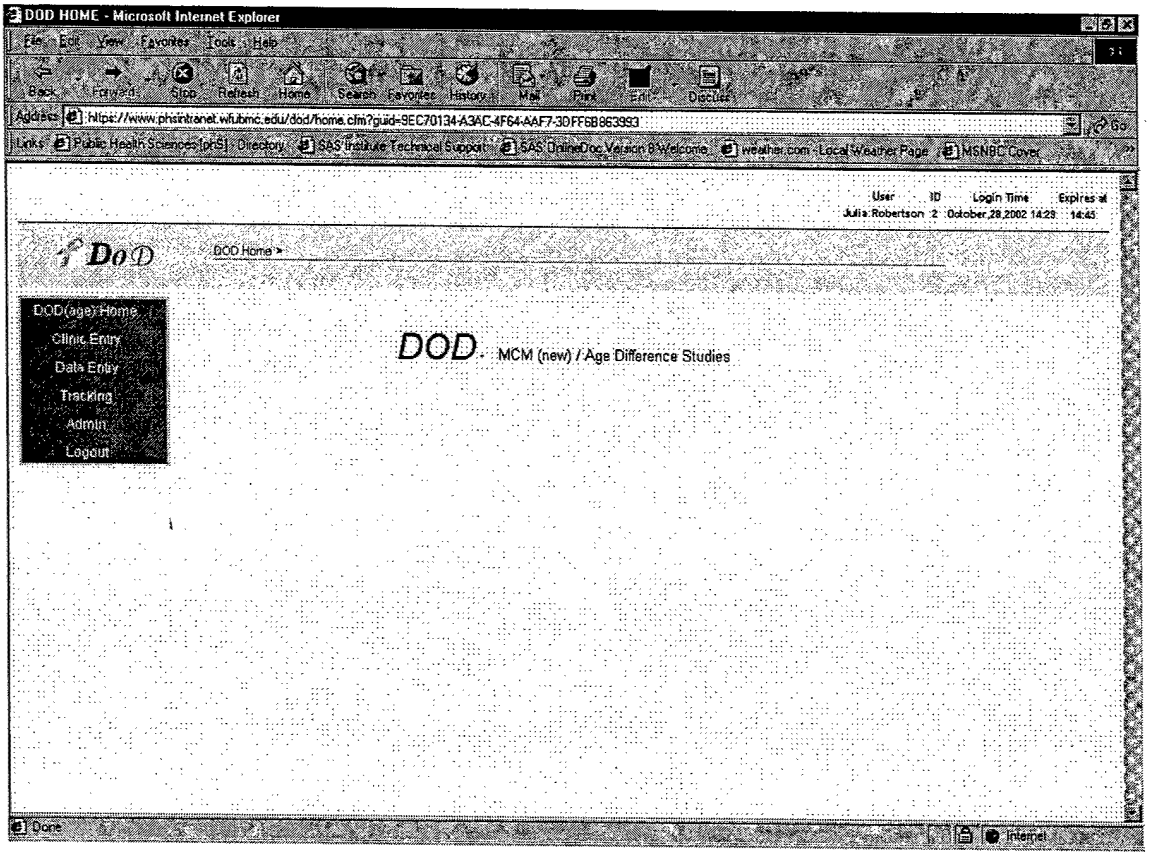
Logging In

After entering the above web site address, the log in screen will be displayed. To log into the site, enter the username and password and click 'LOGIN'.



Screen Layout

After logging in, the first page is the DOD home page:



A menu will be displayed on the left side of the screen with the following options:

DOD (age) Home - from any page, takes you back to the first screen displayed after logging in

Clinic Entry:

- **ID Labels** - print ID labels, 9 labels per ID
- **Eligibility** - eligibility form
- **Registration** - registration form

Reports - future reports

Admin - area to change the password

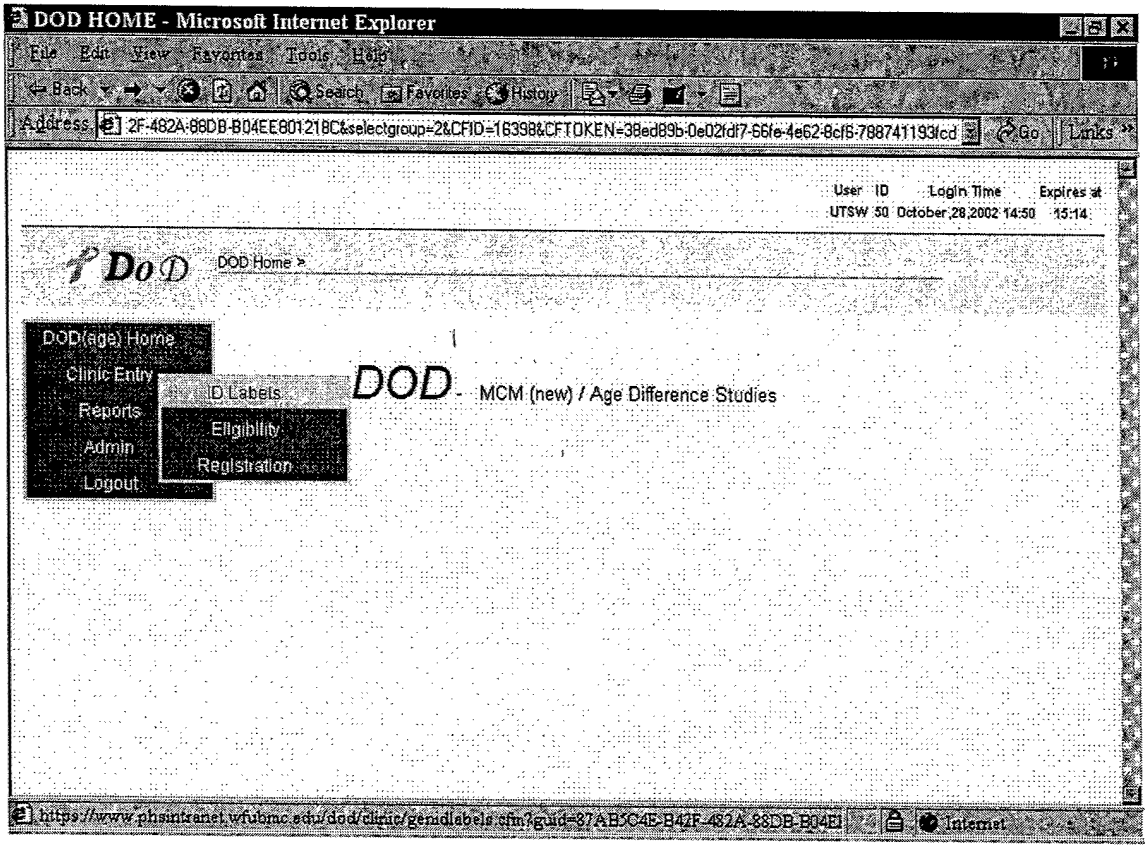
Logout - returns to the login screen

Participant ID Generation

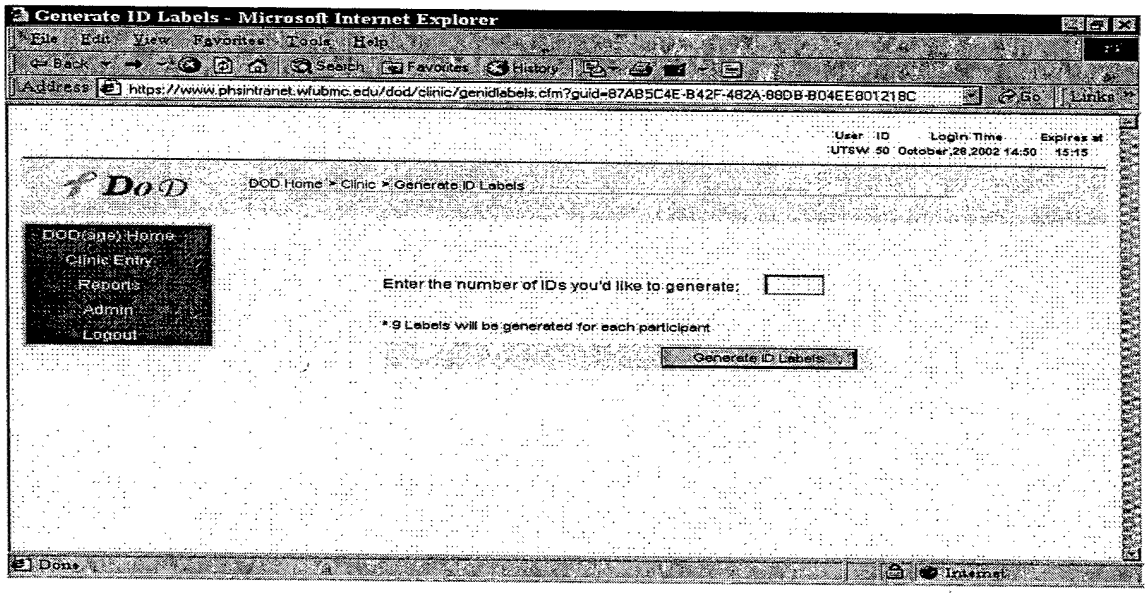
The first step in the data entry process is generation of participant IDs. The clinics will use the ID labels on forms and the generated ID to enter the eligibility and registration forms.

To generate participant IDs:

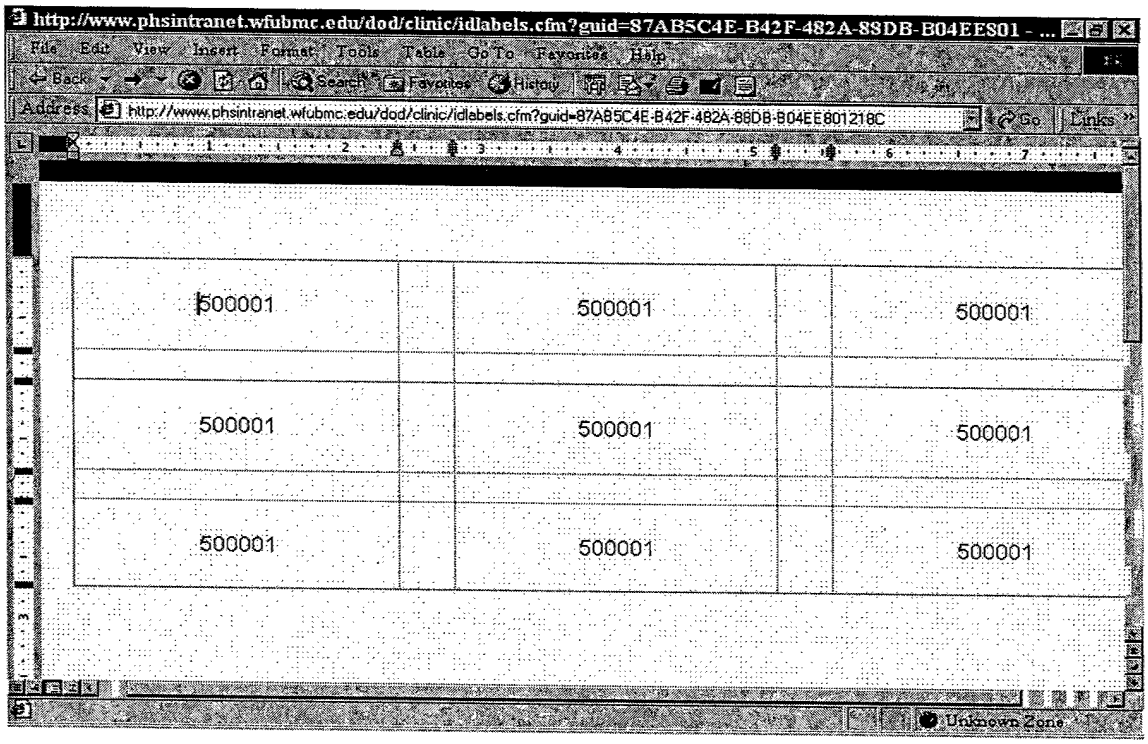
- From the menu on the left, choose *'Clinic'*, then *'ID Labels'*



- A screen will display 'Enter number of IDs you'd like to generate'
- Enter the number of IDs needed and click on *'Generate ID Labels'*

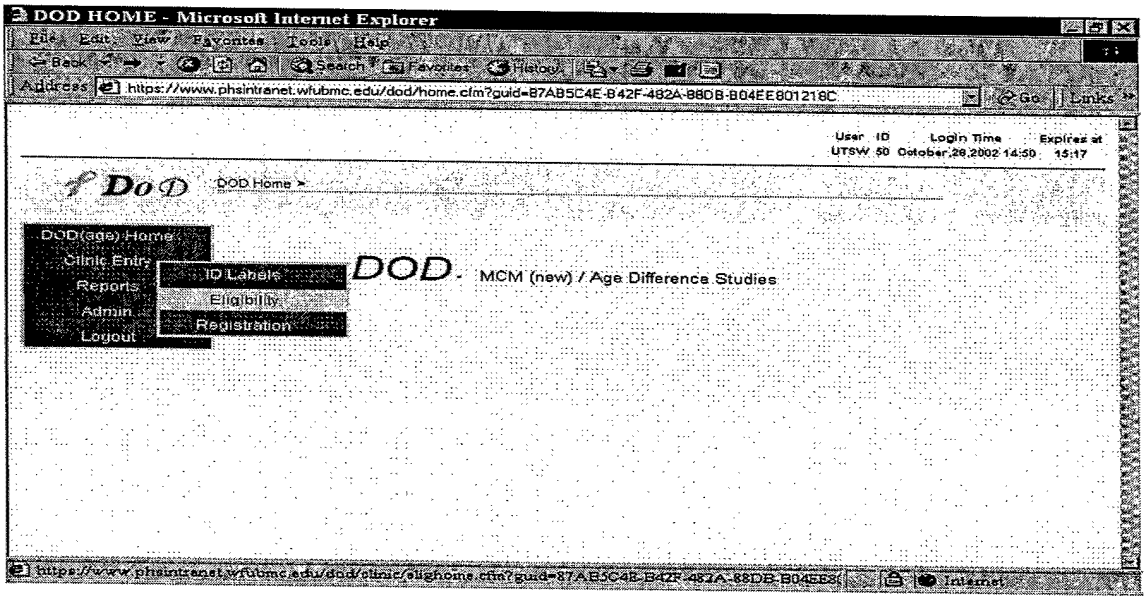


- A screen will display 9 labels for each participant ID
- Click 'print' (or choose 'File', 'Print') to print the labels (click the back button to return to the previous screen

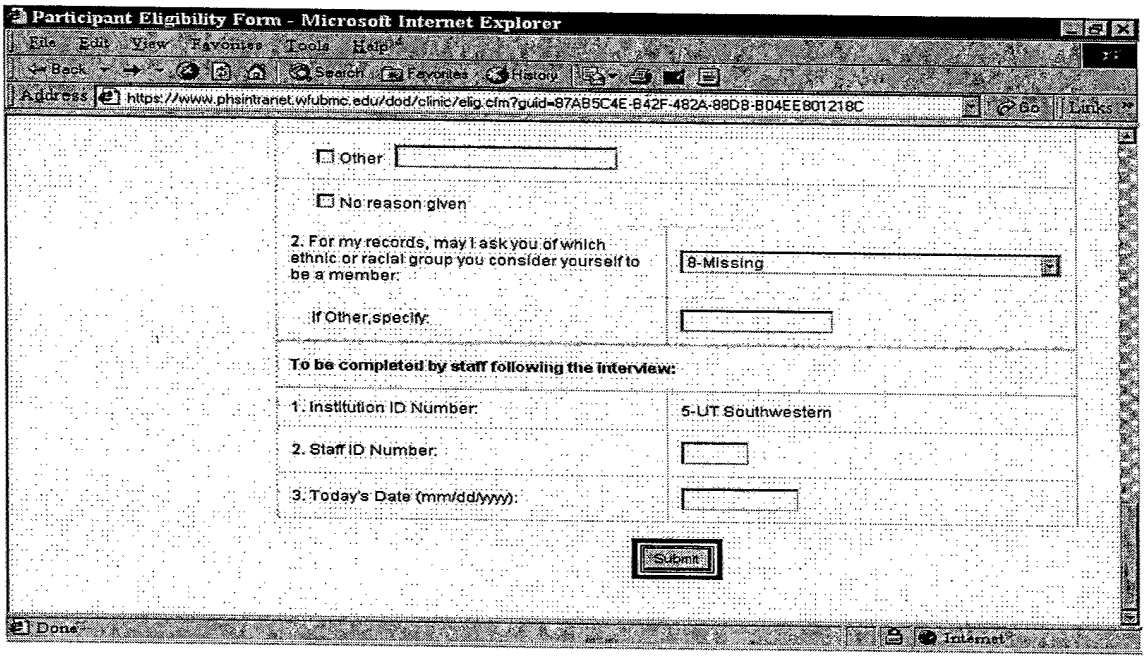


Eligibility and Registration Data Entry

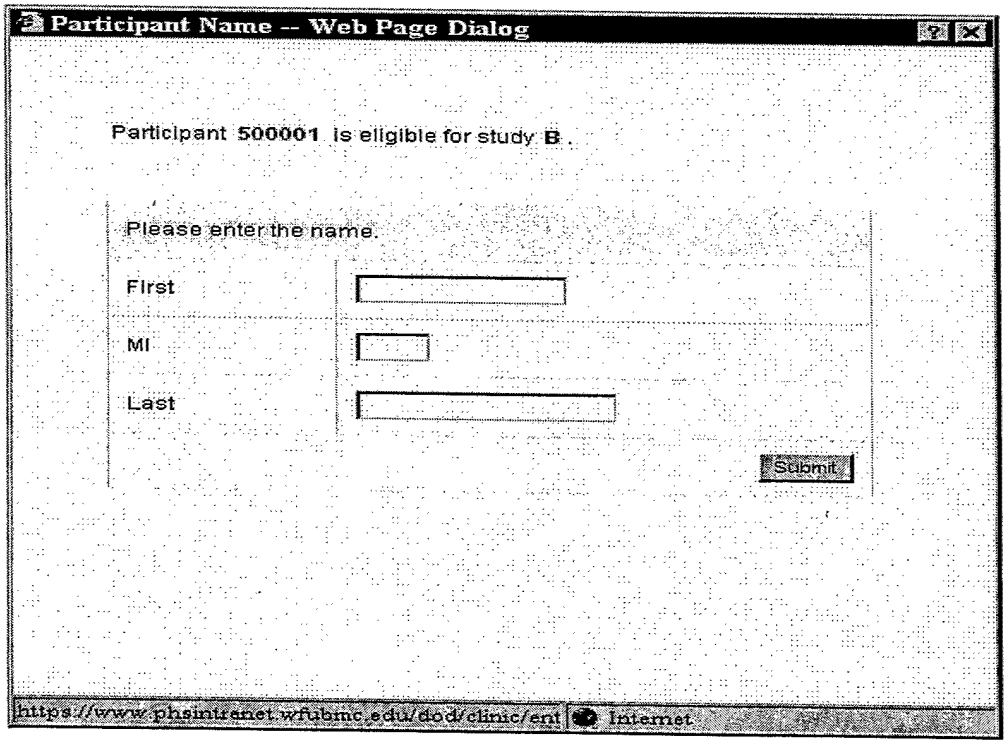
- **To enter eligibility form data:**
  - From the menu on the left, choose *'Clinic'*, then *'Eligibility'*:



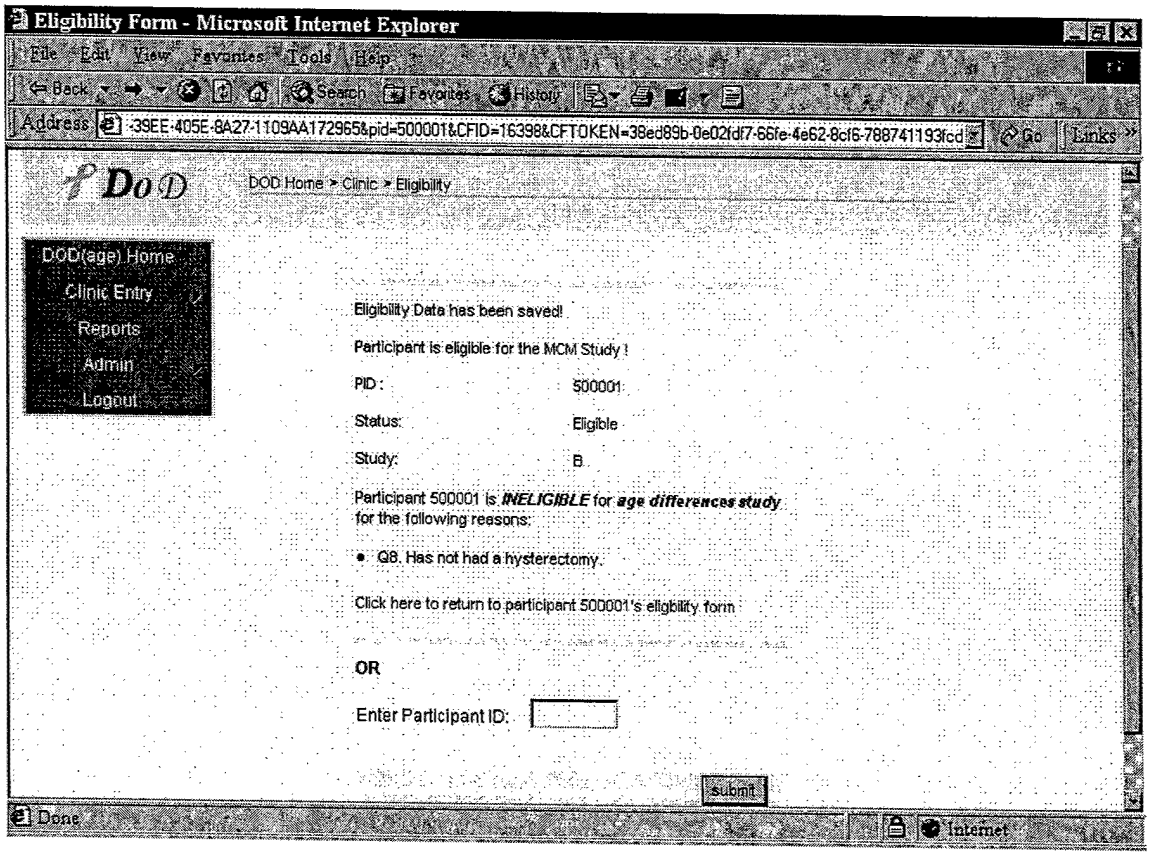
- After entering the form data, click *'Submit'* at the bottom of the page to save the data.



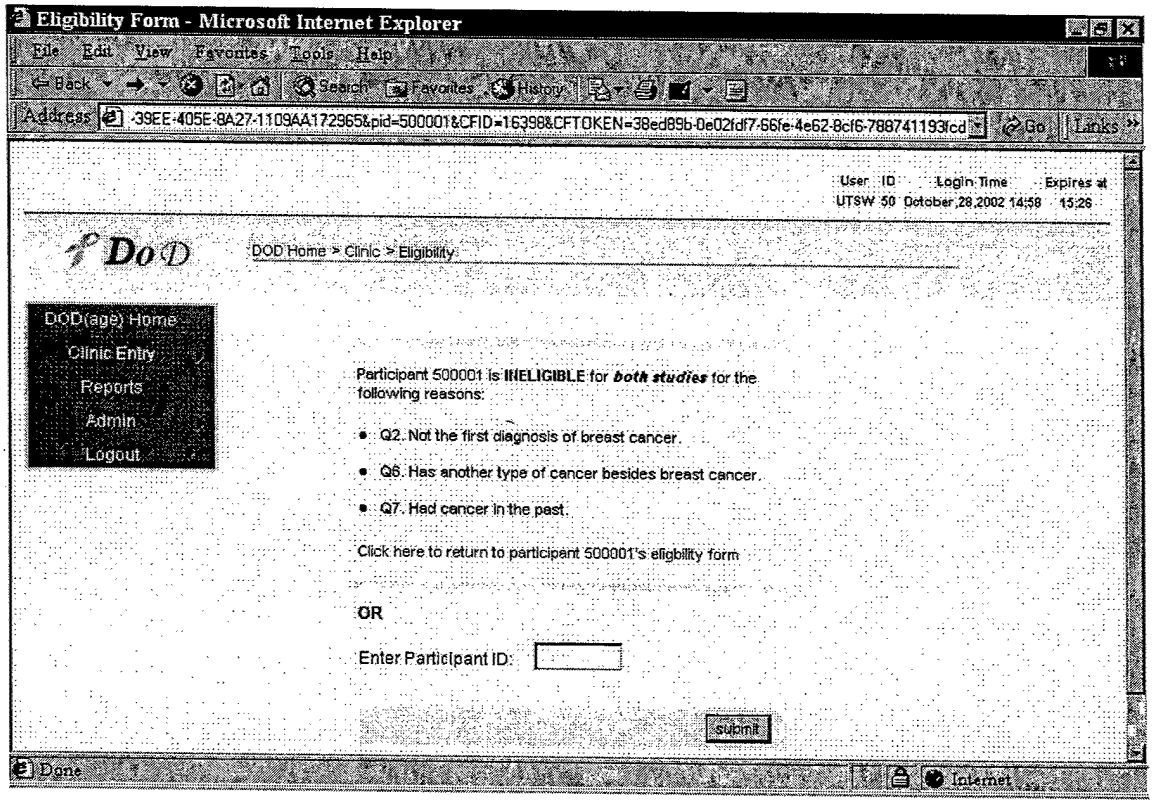
- If the participant is eligible, a screen will display to allow entry of the participant's name:



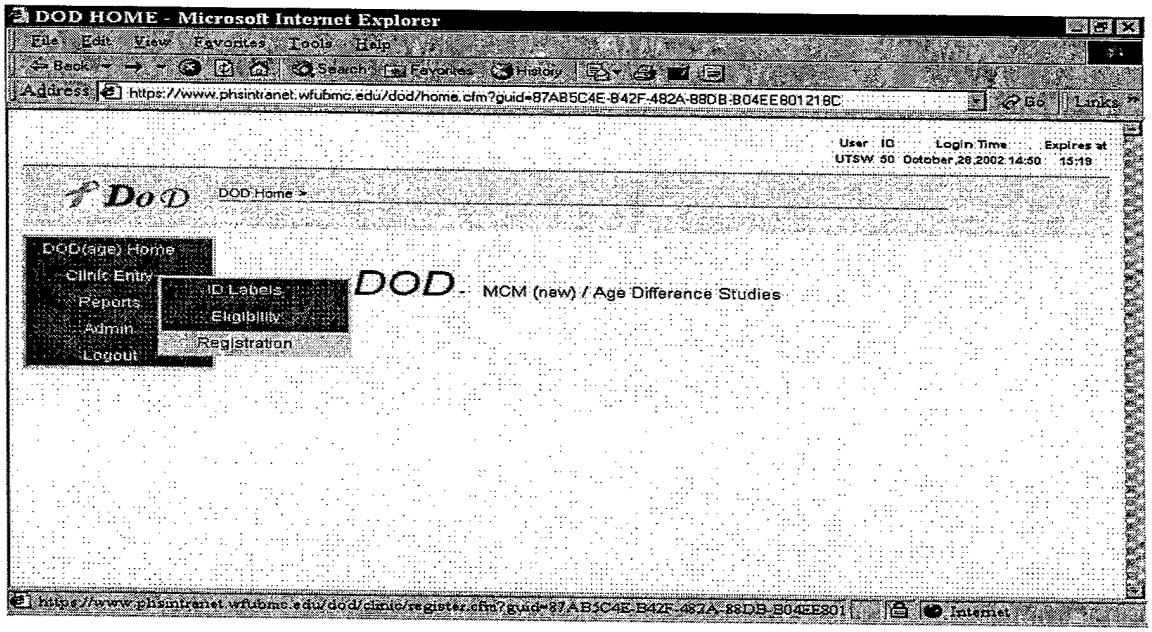
- After entering the name, click *'Submit'* to save the data and close the window. A summary page will then display the study the participant is eligible for and reasons for ineligibility on the other study.
  NOTE: Study B is Menstrual Cycle Maintenance, Study C is Age Differences.



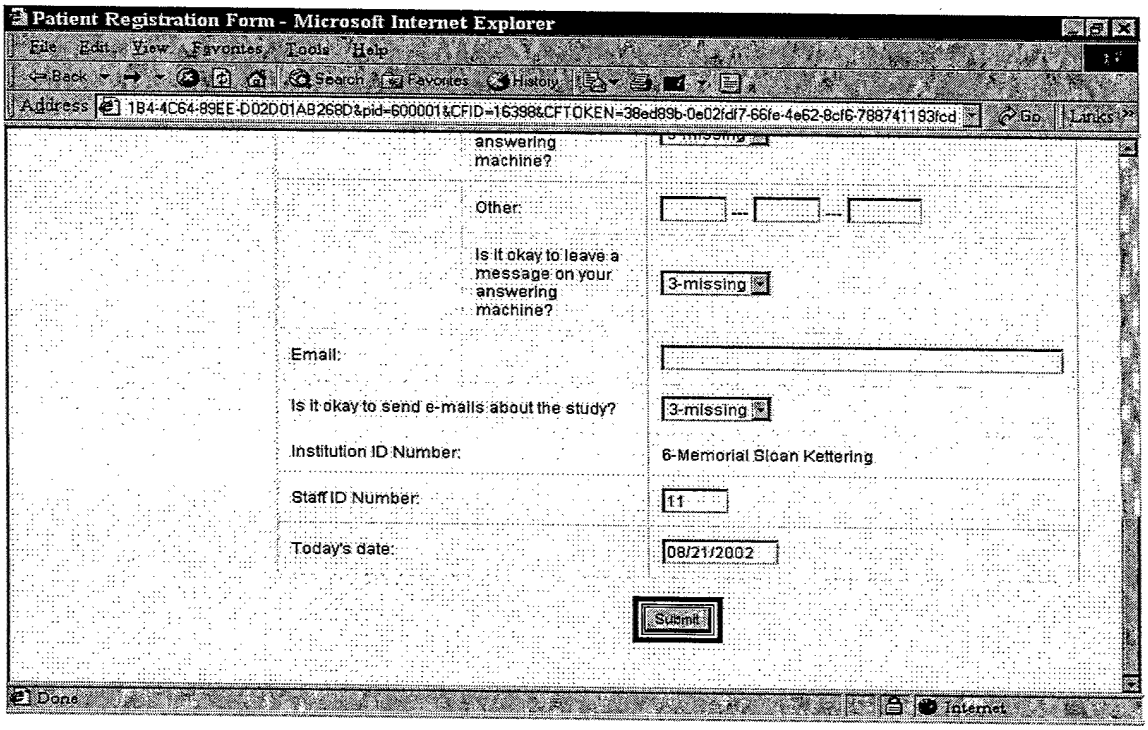
- If the participant is ineligible or eligibility cannot be determined because of missing data, a screen will display listing the questions with missing data or reasons for ineligibility. To return to the participant's eligibility form, click the link, *'Return to participant's eligibility form'* or enter their ID in the ID field and click *'Submit':*



- **To enter registration form data:**
  - From the menu on the left, choose *'Clinic'* then *'Registration':*



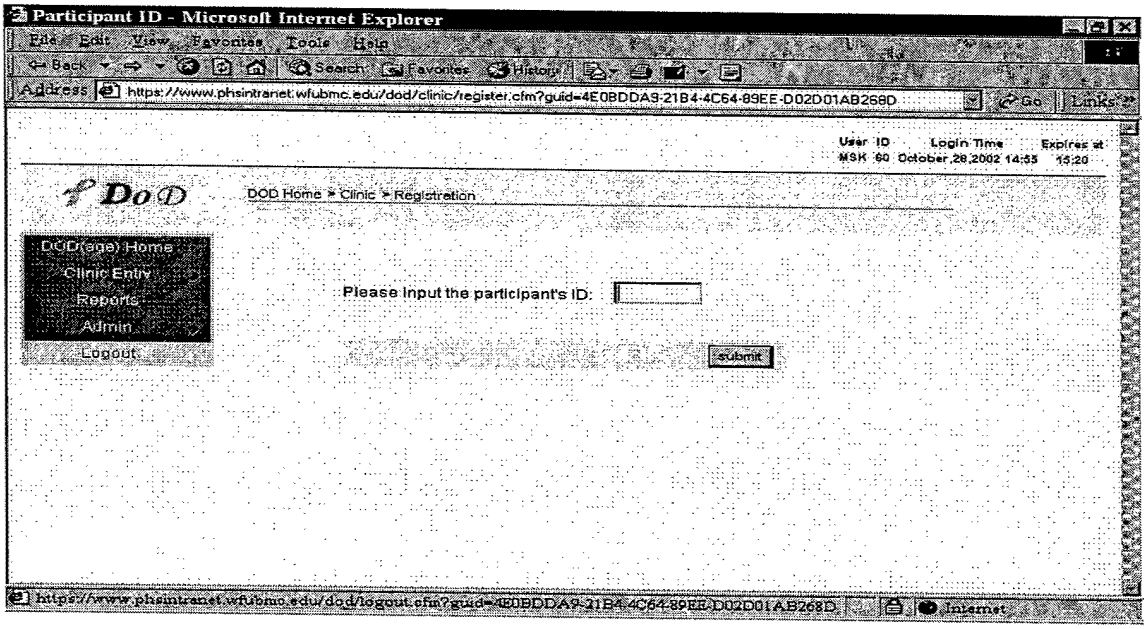
- After entering the form data, click *'Submit'* at the bottom of the page to save the data.



NOTE: An eligibility form must be entered before the registration form can be entered. Also, once the registration form has been entered, the eligibility form cannot be modified.

Logging off

To log off the web site, choose 'Logout' from the menu on the left. NOTE: The site will automatically log off if there is no activity for 15 minutes.



Example of Completing the Patient Eligibility Form

User ID Login Time Expires at
UTSW 50 October,28,2002 16:35 16:48

DOD > Clinic > Eligibility

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Eligibility Form

Patient I.D.__ 500001 Patient Name _ Jane J Doe Study __ B Lastupdate __ 10/28/2002 15:20:20

PART I. PATIENT ELIGIBILITY

Eligibility Questions:

1. Participant is female?	1-Yes
2. Is this your first diagnosis of breast cancer?	1-Yes
3a. On what date were you diagnosed with breast cancer. (Patient must be no greater than 6 months post-diagnosis.)	09/25/2002 (mm/dd/yyyy)
3b. For interviewers only: Is patient less than 6 months post-diagnosis?	1-Yes
4. Was the stage of your breast cancer at diagnosis stage 1,2, or 3?	1-Yes
Please write in stage of cancer here:	1
5a. Were you at least 18 years of age at the time of your diagnosis?	1-Yes
5b. What is your date of birth? (For MCM study, age must be 45 years or less at time of diagnosis.)	06/06/1966 (mm/dd/yyyy)
5c. For interviewers only: Was patient aged 18-45 at diagnosis?	1-Yes
6. Do you currently have another type of cancer besides breast cancer?(Exclude basal or squamous cell skin cancer or stage 0 cervical cancer.)	2-No
7. Have you had any form of cancer in the past?(Exclude basal or squamous cell skin cancer or stage 0 cervical cancer.)	2-No

8. Have you had a hysterectomy? 2-No

For interviewers only: For participants age 45 years or less at the time of diagnosis who answered "no" to question 8,please ask the following question.

9. Were you having regular menstrual cycles at the time you were diagnosed with breast cancer? This means were you having a period every 28 to 45 days, or whatever is normal for you? 1-Yes

If the patient indicates that her periods have never been regular or occurred roughly on a monthly basis, please check the "no" box.

PART II. PARTICIPANT RECRUITMENT

After you have discussed the purposes for each research study with the patient, please ask her the following questions.

1. Do you agree to participate in the study? 1-Yes

If no, may I know the reason why you have chosen not to participate?

- ☐ Not interested
- ☐ Lack of time
- ☐ Patient is already enrolled in another study.
- ☐ Don't feel well enough to participate.
- ☐ Family member refused or objected to patient's participation.
- ☐ Other
- ☐ No reason given

2. For my records, may I ask you of which ethnic or racial group you consider yourself to be a member: 1-White(Not Hispanic)

If Other,specify:

To be completed by staff following the interview:

1. Institution ID Number: 5-UT Southwestern

2. Staff ID Number: 11

3. Today's Date (mm/dd/yyyy): 10/10/2002

Submit

Example of Completing Patient Registration

User ID Login Time Expires at
UTSW 50 October,28,2002 16:35 16:49

DOD > Clinic > Registration

- DOD(age) Home
- Clinic Entry
- Reports
- Admin
- Logout

Registration Form

Patient I.D.__ 500001 Study __ B Lastupdate __

Please print the information in the spaces provided or mark the appropriate box. This form is to be faxed to the clinical coordinating center the same day as the participant's baseline forms have been completed.

Participant Identification Number: 500001 - B

Participant Acrostic: DOEJAJ

Participant's **enrollment/baseline visit date**: (mm/dd/yyyy)

Consent form has been signed and is in patient's file? 3-missing

Baseline forms have been completed? 3-missing

Menstrual Cycle Calendar Instructions have been completed? 4-missing

Patient was given 4 bleeding calendars? 4-missing

Participant's Name : First JANE MI J
Last DOE

Mailing Address: Street:

Address2:

City: State:

Country:

Zip Code: -

Telephone Numbers: Home: --- ---

Is it okay

to leave a message on your answering machine? 3-missing

Work: --- ---

Is it okay to leave a message on your answering machine? 3-missing

Other: --- ---

Is it okay to leave a message on your answering machine? 3-missing

Email:

Is it okay to send e-mails about the study? 3-missing

Institution ID Number: 5-UT Southwestern

Staff ID Number:

Today's date:

Submit

CHAPTER 3

BASELINE DATA COLLECTION VISIT

3.1 OVERVIEW

Those women who are eligible and willing to participate in the study will be invited to attend a baseline clinic visit. If a participant is unable to come to the clinic for the baseline visit, the requirements of the visit may be completed by mail. (Procedures for recruitment by mail are described below.) During the baseline visit, a clinical center staff person will meet with the prospective participants and explain the purpose of the research project and the study requirements in detail. If the participant decides to join the study officially, she will sign the Informed Consent Form and the Medical Release Form, and complete the baseline questionnaires. This chapter outlines the tasks to be performed during the baseline clinic visit.

3.2 INFORMED CONSENT

When the participant arrives at the clinical center, the staff person charged with explaining the study will describe: the purpose of the study, the study requirements, the schedule for follow-up contacts, the various measurements to be obtained, and the forms to be completed by the participant. The participant and staff person will then review the Informed Consent Form approved by their Institution's Internal Review Board.

In accordance with local institutional review board guidelines, informed consent procedures and consent forms will vary somewhat by clinical center. All consent forms will stress the voluntary and confidential nature of participation in this research investigation. The participant should be told that a decision against participating in the study will in no way influence their treatment or medical care. The participant must also be informed that they may drop out of the study at any time without penalty.

The staff person should answer any questions that the prospective participant may have. When all information has been provided and all questions have been answered satisfactorily, the participant should sign the Informed Consent Form and the Medical Release Form, if she agrees to join the study. A copy of the Informed Consent Form and the Medical Release Form should be given to the participant to take home with her, and the originals should be filed in the participant's study file. After obtaining informed consent and the medical record release, the participant can be given the packet of baseline forms to be completed

3.3 INSTRUCTIONS FOR COMPLETION IN CLINIC

The following study forms will be completed at the baseline clinic visit, which will be approximately 1 hour and 30 minutes in length. The baseline administration time for all study questionnaires is approximately 35-45 minutes. Participants can be provided with opportunities to rest during the completion of the study forms, if necessary. The study coordinators should also be available to assist the patients as needed.

3.3.1 Standard Items:

Prior to giving the forms to the participants, the clinical center staff will label the baseline forms with the 1) the Patient ID Number - six-digit patient ID Number, 2) the Acrostic- six-digit

letter identification, and 3) Visit Type/Number clearly marked "BV" or "Baseline" on all study forms.

Chapter 6 of this manual outlines the proper form for the patient ID number, acrostic, and visit type. Please refer to this chapter as necessary.

3.3.2 Baseline Questionnaires

The following information will be obtained at baseline. These questionnaires have been designed to be self-administered by the participants. Please provide a room free from distractions for participants to complete these forms. Remain in the vicinity to assist the participants with any questions that they might have about the study forms.

1) Demographics
2) Medical History
3) Family History
4) Reproductive History
5) Current Medications
6) Arm and Hand Swelling
7) Physical Symptoms Checklist
8) Health-Related Quality of Life
    a) SF-36 Health Status Profile
    b) Functional Assessment of Cancer Therapy - Breast (FACT-B).
    c) Ladder of Life
    d) Beck Depression Inventory
    e) Body Appearance Scale
    f) MOS Sexual Functioning Questionnaire
9) Spirituality Scale (FACIT-Sp)
10) Brief COPE Scale
11) Illness Intrusiveness Scale
12) Post-Traumatic Growth Inventory
13) Optimism
14) MOS Social Support Questionnaire
15) Contact Information

3.3.3 Review of Questionnaires

1. General Instructions

All data forms filled out at the baseline visit must be checked by the study coordinators before the patient leaves the clinic, (or after the forms have been mailed back to the clinical center, if recruitment was completed by mail). The clinical center staff person should review each form for completeness and consistency, check any skip patterns, and read any written responses to assure that

the answers are complete and understandable. Any missing items should be double-checked with the participants to inquire as to whether they intended to leave items blank or chose not to answer the questions. It is easier to ask questions and get clarification prior to the participant leaving the clinic.

2. Alert Values

Two procedures must be followed regarding the review of the Beck Depression Inventory. The first is to calculate the total score on this scale. The calculation of the total score is a simple sum of the 21 items. The values assigned to the response categories range from '0' (the least distressed response) to '3' (the most distressed response). Those participants who score 16 or higher on this scale should be referred to the coordinating center for a determination as to whether the Principal Investigator of the respective clinical center site need to take any action to assist the study participant.

Staff will also be asked to check the participants' responses to question #9 on the Beck Depression Inventory to see if the patient is strongly considering suicide. Patients who make a response of "3" on this question must be referred to the Principal Investigator of the respective clinical center for immediate physician follow-up.

3.3.4 Participant Follow-up

At the close of the baseline visit, the follow-up schedule of data collection must be reviewed with the participants. Participants need to be informed that:

- All follow-up questionnaires and diaries will be mailed to the participants' homes by staff persons from the Clinical Coordinating Center at the Wake Forest University School of Medicine in Winston-Salem, North Carolina. Participants should expect to receive a letter from the Coordinating Center welcoming them to the study within a week to 10 days of the baseline visit.

- At 3, 6, 12, and 18 months from the participants' date of enrollment, staff from the Clinical Coordinating Center will mail participants a packet of follow-up questionnaires. These forms are to be completed and returned to the Coordinating Center in an enclosed self-addressed, stamped envelope. Participants should be given their Schedule of Follow-Up Visits prior to leaving the clinic, so that they will know when these forms are to be mailed to them. (See Appendix)

3.3.5 Ending the Baseline Visit

1. Checklist for the Clinical Center Staff Persons:

Before the patient leaves the baseline visit, make sure that all the baseline activities have been completed. These include:

- Study requirements have been reviewed in detail.

- Informed Consent Form has been signed
- Medical Release Form has been signed
- All baseline forms/questionnaires have been completed
- All baseline forms have been checked for completeness, clarity, etc.
- The Beck Depression Inventory has been scored and participants referred if the score is 16 or greater.
- Item 9 on the Beck Depression Inventory has been checked for the participants' contemplation of suicide.
- Participant has been informed about follow-up data collection.
- Participants have been given their schedule for the 3, 6, 12, and 18-month follow-up contacts.

2. What the Participants Take Home:

The following items need to be provided to the participants to take home with them after the baseline visit has been completed. These are:

- Copy of the Informed Consent Form
- Copy of the Medical Release Form
- Schedule of Follow-Up Contacts

3.4 COMPLETING THE BASELINE VISIT BY MAIL

Many participants may need to be enrolled in the study through the mail instead of at a baseline clinic visit. For those participants who are not able to come to the clinical center, the following procedures should be followed.

All women should be identified and prescreened following the procedures outlined in Chapter 2. If a woman is willing to participate in the study, but is unable to travel to the clinical centers, please do the following:

1. Obtain the woman's address, phone number, and the times that it is good to reach her by telephone.

2. Tell the participant that you will mail the forms to her, and **before you end your conversation with the participant, schedule a brief telephone interview (approximately 15-20 minutes) to review the study materials** that you are going to send to her. It is very important that you go through the consent form and the study procedures with the participants. Schedule the telephone interview for 5-7 days after you send the first mailing of materials to the women.

3. Mail the following items to the participant:

- 2 Copies of the Informed Consent Form
- 2 Copies of the Medical Release Form
- Baseline Questionnaire Booklet
- Self-addressed stamped envelope

4. Hold the telephone interview with the participant to review the consent form and medical release form. Answer any questions that the participant may have about the study or baseline forms.

   Instruct the patients to send the questionnaires back to you as soon as possible, as well as 1 copy of the Consent Form and the Medical Release Form. The extra copies of the Consent Form and Medical Release Form are for her to keep.

5. Once the materials have been returned to the clinical center, review the materials to ensure that the:

   - Informed Consent Form has been signed
   - Medical Release Form has been signed
   - Baseline questionnaires have been completed

   Review the baseline forms:

   - Check the baseline forms for completeness, clarity, etc.
   - Score the Beck Depression Inventory and contact the clinical center PI if the score is 16 or greater.
   - Check item 9 on the Beck Depression Inventory for the participants' contemplation of suicide and notify the clinical center PI, if necessary.
   - Resolve any issues/questions about the forms with the participants.

6. If the Consent Form, Medical Release Form, and the Baseline questionnaires have been completed satisfactorily, complete the Registration Form online using the instructions outlined in Chapter 2. **Important: The date of enrollment to be listed on the Registration Form is the date that the participants completed the baseline questionnaires.**

7. After the Registration form has been completed, the following materials need to be mailed to the participants:

   - Thank you letter acknowledging receipt of the baseline questionnaires.
   - Schedule of Follow-Up Contacts

3.5 PARTICIPANT REGISTRATION FORM

After all of the requirements of the baseline clinic visit have been conducted, regardless of

whether it is completed in the clinic or by mail, the Participant Registration Form needs to be completed online by clinical center staff. This form will serve to register the participants in the study.

Please remember that a participant cannot be enrolled in the study officially unless the baseline forms have been completed. The date the baseline forms are completed is used as the participant's official date of enrollment in the study.

3.6 SHIPMENTS TO CLINICAL COORDINATING CENTER

All data forms and questionnaires completed by clinical center staff and/or the participants at baseline are to be mailed to the clinical coordinating center on roughly **the 15th and the 30th of each month**. This includes the packet of questionnaires completed by the participants, and a hard copy of the participant registration and eligibility forms. Questionnaires received at the Clinical Coordinating Center will be re-checked for clarity, completeness, etc., and clinical center staff may be contacted if questions arise regarding particular items and/or participants. Adherence to this mailing schedule is requested, so that study forms are received and entered into the centralized data bases efficiently.

APPENDIX MATERIALS

CHECKLIST FOR COMPLETION OF THE BASELINE CLINIC VISIT TASKS

Checklist for the Clinical Center Staff Persons:

___ Informed Consent Form has been signed

___ Medical Release Form has been signed

___ All baseline forms/questionnaires have been completed

___ All baseline forms have been checked for completeness, clarity, etc.

___ The Beck Depression Inventory has been scored and participants referred if the score is 16 or greater.

___ Item 9 on the Beck Depression Inventory has been checked for the participants' contemplation of suicide.

___ Participant has been informed about follow-up data collection.

___ Participants have been given their schedule for follow-up contacts.

Participants Have Been Given the Following to Take Home:

___ Copy of the Informed Consent Form

___ Copy of the Medical Release Form

___ Schedule of Follow-up Contacts

COMPLETION OF THE BASELINE VISIT TASKS BY MAIL

Procedures for Clinical Center Staff Persons:

1. Obtain the woman's address, phone number, and the times that it is good to reach her by telephone.

2. Schedule a telephone interview with the participant.

3. Mail the following items to the participant:

   - 2 Copies of the Informed Consent Form
   - 2 Copies of the Medical Release Form
   - Baseline Questionnaire Booklet
   - Self-addressed stamped envelope

4. Hold the telephone interview with the participant to review the consent form and medical release form.

5. Instruct the patients to send the questionnaires back to you as soon as possible, as well as 1 copy of the Consent Form and the Medical Release Form.

6. Once the materials have been returned to the clinical center, review the materials to ensure that the:
   - Informed Consent Form has been signed
   - Medical Release Form has been signed
   - Baseline questionnaires have been completed

   Review the baseline forms:

   - Check the baseline forms for completeness, clarity, etc.
   - Score the Beck Depression Inventory and contact the clinical center PI if the score is 16 or greater.
   - Check item 9 on the Beck Depression Inventory Form for the participants' contemplation of suicide and notify the clinical center PI, if necessary.
   - Resolve any issues/questions about the forms with the participants.

6. If the Consent Form, Medical Release Form, and the Baseline questionnaires have been completed satisfactorily, complete the Registration Form online using the instructions outlined in Chapter 3. **Important: The date of enrollment to be listed on the Registration Form is the date that the participants completed the baseline questionnaires.**

7. After the Registration form has been completed, the following materials need to be mailed to the participants:

- Thank you letter acknowledging receipt of the baseline forms
- Schedule of Follow-Up Contacts

Draft Letter to be Sent With First Mailed Packets

Date

Dear Ms. _____:

Thank you for your interest in participating in the clinical research study entitled: Investigating Mechanisms to Explain Age-Associated Differences in Quality of Life Among Breast Cancer Patients. I have enclosed the following materials for you:

2 copies of the Consent Form
2 copies of the Medical Release Form
Baseline Questionnaire Booklet
A self-addressed stamped envelope in which to return the materials to us.

Please review these materials prior to our telephone interview at (2:00 pm) on (Tuesday, June 5th). You have been sent 2 copies of the Consent Form and the Medical Release Form, so that you can sign one each of the copies of these forms, and keep the other copies for your records.

Please do not mail any of these items back to me until we have had our telephone interview. Thank you very much for your willingness to participate in this study.

Sincerely,

Lisa Loudon
Study Coordinator
Memorial Sloan-Kettering Cancer Center

enclosures

Draft Letter Sent to Participants After Forms Have Been Received at the Clinical Center

Date

Dear Ms. _____:

I received your Consent Form, Medical Release Form, and your Baseline Questionnaire in the mail. Thank you for returning them so promptly. Everything was filled out correctly, and we are delighted to have you in the study. I have included a sheet that will let you know when to expect the study questionnaires for the duration of the study. The follow-up questionnaires will take approximately 30-35 minutes to complete. These questionnaires will be mailed from the Coordinating Center at Wake Forest University in Winston-Salem, North Carolina, which will be contacting you about the study from now on. Within the next 2 weeks you will receive a letter from Carol Corum at the Coordinating Center welcoming you to the study, and letting you know how to get in touch with them if you should need assistance. They will also be sending you new bleeding calendars every three months and will let you know when it is time to mail these calendars back in.

It has been my pleasure to enroll you in this study, and I hope that you find it interesting.

Sincerely,

SCHEDULE OF FOLLOW-UP CONTACTS

Participant's Name: _____

Enrollment Date: _____

The following are the approximate dates when you will receive follow-up questionnaires from the study coordinating center at Wake Forest University in Winston-Salem, North Carolina. These forms will be mailed to you on the following dates.

3-month follow-up: _____

6-month follow-up: _____

12-month follow-up: _____

18-month follow-up: _____

If you ever have any questions about this schedule, please call Ms. Carol Corum at the Wake Forest University School of Medicine at 1-336-713-4268 or toll free 1-888-278-1486 or via e-mail at: ccorum@wfubmc.edu.

CHAPTER 4

BASELINE STUDY DATA FORMS AND QUESTIONNAIRES

4.1 OVERVIEW

This chapter briefly describes the questionnaires and forms to be used in this study. For organizational purposes, the forms have been divided into those completed prior to the completion of baseline forms, those completed at baseline, and those which are filled out after the baseline forms.

4.2. FORMS COMPLETED BY CLINIC STAFF AT BASELINE

4.2.1 Participant Eligibility Form

The Participant Eligibility Form is completed by clinical center staff on those patients who have been identified through cancer patient registries or referral as being potentially eligible for the protocol. This form is written in the form of a telephone or person interview script, to standardize the recruitment process. Eligibility at each step in the process is discussed. This screening form will be used for recruitment to both the Menstrual Cycle Maintenance and the Age Differences Questionnaires, as participants under the age of 46 years are eligible (potentially) to recruitment to both studies. **All participants must be prescreened for eligibility before they are recruited and before they complete the baseline forms.**

4.3 FORMS COMPLETED BY PARTICIPANTS AT BASELINE

The following forms are to be self-administered by the participants at baseline.

4.3.1 Demographic Form

Questions about the participants' background are very important. This information will help describe, in general terms, the women who participant in the study. This form will collect data on age, marital status, racial/ethnic identity, education completed, household income, number of persons in household, employment status, occupation, insurance status, and religious preference. This information will be used to describe the group of women in study reports and publications.

4.3.2 Medical History

Participants will be asked to indicate whether they currently have certain medical conditions or procedures, such as heart disease or diabetes.

4.3.3. Family History

Participants will identify female family members who have had breast cancer. A positive family history of breast cancer confers a somewhat increased risk. The risk is particularly high if both the mother and sister have been affected at a young age. Family history is also very

important to collect as it may support the belief that some families have a genetic susceptibility to develop breast cancer at a young age.

4.3.4 Reproductive History

Participants will be asked questions about their age of menarche, past pregnancies and births, surgeries of their reproductive organs, and hot flushes in the past month.

4.3.5 Current Medications

Participants will be asked to list the prescription and non-prescription medications and supplements they are taking currently, in addition to their cancer treatment-related drugs.

4.3.6 Swelling Form

This study form asks questions concerning problems with lymphedema or swelling in the arm and/or hand. Treatment-related swelling of the arm and hand is used to document the occurrence, duration, and circumstances surrounding arm and hand swelling. Little is known about lymphedema. This data will provide much needed information about the condition.

4.3.7 Symptoms Questionnaire

The occurrence and bothersomeness of symptoms associated with breast cancer treatment are assessed in this questionnaire. Participants are asked to indicate whether they had a particular symptom, and if yes, whether the symptom was mild, moderate, or severe.

4.3.8 Health-Related Quality of Life

The following instruments will be used to assess the participants' quality of life.

A) SF-36 Health Status Questionnaire. This questionnaire will be used as a generic measure of quality of life. This measure is included to provide a means of comparing HRQL of the cancer patients with the general population. The SF-36 is one of the most widely used measures of health status. It consists of 36 items measuring the following eight domains: general health, physical functioning, vitality, mental health, bodily pain, role limitations due to physical health, and role limitations due to emotional health.

B) Global Quality of Life. Because the SF-36 does not provide a global assessment of quality of life, we will also include three global assessments of current QOL: The Ladder of Life (1=lowest possible QOL, 10=highest possible QOL), Life Satisfaction (1=complete dissatisfaction, 7=complete satisfaction, and a 100 mm visual analogue scale (0=lowest possible QOL, 100= highest possible QOL). These 1-item measures are frequently used to assess global quality of life.

C) Functional Assessment of Cancer Therapy - Breast (FACT-B). This questionnaire is a multidimensional quality of life scale. This scale assesses the patients' physical well-being,

social/family well-being, emotional well-being, fulfillment/contentment, and concerns specific to breast cancer patients. Scores can be calculated for each of the 5 subscales, as well as a total score composed of all 5 subscales.

D) Beck Depression Inventory. This is a 21-item scale that is used to assess the depressive symptomatology/general distress of the participants in the study. This instrument has been used with a variety of clinical and non-clinical populations, and has been validated as a reliable screening tool for depression. A total score is calculated from this instrument. In general, scores above 15 are considered to indicate persons who need further evaluation to determine if clinical depression exists.

E) Body Appearance. These questions assess the participants' satisfaction with different areas of their body and their overall weight. Persons undergoing surgery for breast cancer may experience an alteration in their perception of their body image, which may affect their psychosocial status and intimate relationships. This scale is being assessed as a secondary HRQL endpoint.

F) MOS Sexual Functioning Questionnaire. The MOS Sexual Functioning scale will be used to measure sexual functioning. This is a 6-item measure tapping sexual interest, ability to relax and enjoy sex, difficulty becoming aroused, and difficulty having orgasm.

4.3.9 Spirituality

Spirituality (FACIT-Sp). Spiritual beliefs of the participants will be measured by the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale. This is a 12-item scale that was developed with input from cancer patients, psychotherapists and religious/spiritual experts. It was designed to measure a sense of meaning in one's life, harmony, peacefulness, and sense of strength and comfort from one's faith. Spiritual beliefs have been identified recently as an important predictor of patients' coping and hopefulness for the future when dealing with a serious illness.

4.3.10 Brief COPE Scale

Coping will be assessed with the 28-item Brief COPE scale. This scale measures 14 conceptually differentiable coping reactions and is based on the longer COPE inventory (Carver et al., 1989). Participants rate the extent to which each response was used in trying to deal with stresses associated with their cancer diagnosis and treatment. Response choices are on scale ranging from 1 ("I haven't been doing this at all") to 4 ("I have been doing this a lot"). The present study will examine the interaction between coping strategies and age to determine if effective coping strategies vary by age.

4.3.11 Illness Intrusiveness Scale

Illness intrusiveness is hypothesized to be greater for younger women and to contribute to lower quality of life. The Illness Intrusiveness Scale by Devins and colleagues measures perceptions of how much the diagnosis of breast cancer and its treatment have affected 13 life domains: health, diet, work, active recreation, passive recreation, relationship with spouse, sex life, family relations,

other social relations, self-expression, religious expression and community, and civic involvement.

4.3.12 Post-Traumatic Growth Inventory

A number of studies have found that women report experiencing various benefits from having cancer or other traumatic life events or illnesses. These benefits include such things as personal growth, improved relationships, and greater appreciation of life. Having a positive experience from a stressful event is predicted to be associated with higher quality of life., and to mediate the effect of disease and treatment factors on depression. To assess these possible benefits, we will use the Posttraumatic Growth Inventory (PTGI). The PTGI is a 21-item scale measuring new possibilities, relating to others, personal strength, spiritual change, and appreciation of life. In addition to these 5 subscales, an overall score is also computed.

4.3.13 Optimism

Optimism represents a cluster of constructs (perceived control, positive expectations, empowerment, lack of helplessness) that have been linked to depressive symptoms and to health outcomes. To measure optimism, an 8-item version of the self-report Life Orientation Test (LOT) will be used. Participants indicate on a 4-point scale ranging from 1 to 4 their degree of agreement or disagreement with statements. A high score reflects greater levels of optimism.

4.3.14 MOS Social Support Questionnaire

The social support questionnaire developed in conjunction with the Medical Outcomes Study (MOS), completed by the RAND Corporation, will be used to assess the amount of instrumental and emotional support available to the participants. Social support has been found to be an important predictor of adherence to treatment regimens, one's emotional health, and overall health-related quality of life. This 20-item measure produces a total score, as well as 4 subscale scores: tangible support, affectionate support, positive social interactions, emotional-informational support.

4.3.15 Contact Form

As a part of the study group, the participant will complete this form and provide her mailing address and telephone number(s), e-mail address (if applicable), and the names of her physicians (i.e., primary care, surgeon and/or oncologist and/or radiologist). In addition, the names and addresses of three friends or relatives who will always know how to reach the participant will also be obtained.

4.4 FORMS COMPLETED FOLLOWING COMPLETION OF BASELINE FORMS

The following group of forms is that which is completed following baseline.

4.4.1 Participant Registration Form

This form is to be completed by clinical center staff after the baseline forms have been completed by the participants. This form will serve to register the participants in the study, and contains information about the participants' name, address and phone number, race/ethnicity, stage of cancer, date of birth, date at enrollment/completion of baseline forms, and the participant's identification number and acrostic. This form is completed on-line, using the registration procedures outlined in Chapter 3.

4.4.2 Chart Review Form

At 12 months post-enrollment, a medical chart review will be completed by the study coordinators at the participating centers on all registered participants. The information to be obtained includes the: the date of breast cancer diagnosis, grade, location and size of tumor(s), number of nodes examined, number of positive lymph nodes, whether reconstructive surgery was performed, patient's height and weight, the treatment prescribed (e.g., surgery, radiation, and/or chemotherapy; hormonal therapy), dose and duration of treatment, estrogen and progesterone receptors (positive and negative) test results, and whether the patient had other surgery (i.e., hysterectomy, oophorectomy or ovarian ablation) as a result of her treatment.

Additional chart reviews may be required on participants who have a breast cancer recurrence and/or new breast cancer diagnosis.

CHAPTER 5

DOD FOLLOW-UP

5.1 PARTICIPANT FOLLOW-UP ASSESSMENT FORMS

All participant follow-up assessments will be completed centrally by staff persons at the Clinical Coordinating Center. Follow-up assessments for all participants will take place at 3, 6, 12, and 18 months from the date of patient enrollment. All participants will be followed for 18 months.

Participant follow-up data collection will consist of a packet of questionnaires that will be sent to the participants' to complete and return to the Coordinating Center. Each follow-up contact will be targeted for the corresponding anniversary date of when the participant completed the baseline data forms. For example, if a participant was enrolled on January 1, 1998, the target date for her six-month follow-up would be July 1, 1998. A computerized tracking system has been developed to assist coordinating center staff in mailing out forms to the participants on schedule. Study forms will be mailed two weeks prior to each target date, to provide time for the mail to be delivered and for the participants to complete the forms by their due dates.

In the event the participant does not return the completed forms within two weeks of the date of mailing, the Coordinating Center Project Manager or Assistant Project Manager will send the participant a reminder letter asking her to return her forms. If the Coordinating Center has not received the forms a week after mailing the reminder letter, the Coordinating Center Project Manager or Assistant Project Manager will call the participant to check on the status of the form and/or perform the data collection activities by telephone interview, if necessary.

The measures described below will be mailed to the participants at 6, 12, and 18 months post-enrollment:

1. Demographic Information Update
2. Medical History Update
3. Family History Update
4. Current Medications
5. Arm and Hand Swelling Form
6. Physical Symptoms Checklist
7. Health-Related Quality of Life Forms:
   - Functional Assessment of Cancer Therapy-Breast (FACT-B)
   - SF-36 Health Status Profile
   - Ladder of Life
   - Spirituality (FACIT-Sp)
   - Beck Depression Inventory
   - Body Appearance
   - MOS Sexual Functioning Questionnaire

9. Brief COPE Scale

10. Illness Intrusiveness Scale

11. Post-Traumatic Growth Inventory

12 Optimism

13 MOS Social Support Questionnaire

14. Life Events Checklist (12 month follow-up only)

15. Contact Information Update

At the 3 month data collection point, a limited assessment will be made and will include the following forms:

1. Current Medications

2. Physical Symptoms Checklist

3. Functional Assessment of Cancer Therapy-Breast (FACT-B)

4. Global Quality of Life Measure

5. Illness Intrusiveness Scale

6. Beck Depression Inventory

5.2. MEDICAL CHART REVIEW

Medical chart reviews will be performed during the follow-up period on patients who have serious complications resulting from treatment, and/or have a cancer recurrence or new diagnosis of breast cancer during the study period. Information to be obtained on these individuals includes the stage and grade of cancer, size and number of positive lymph nodes, estrogen and progesterone receptors, prescribed treatment, medications, and comorbidities.

5.3. FOLLOW-UP ALERT VALUES SAFETY MONITORING

During the course of the study the following safety monitoring procedure will be maintained to detect higher than average rates of depressive symptomatology. The Beck Depression Inventory

will be used, in part, as a screen for clinical depression. A cutoff score of 16 or greater is indicative of individuals who are experiencing higher than average depressive symptomatology, which could indicate the presence of clinical depression. Moreover, Item 9, response choice #3 on the Beck Depression Inventory concerns whether the person is considering suicide. Persons who mark response #3 ("I would kill myself if I had the chance.") will be referred for immediate consultation. The Principal Investigators of the clinical centers will be contacted should any of their participants have a Beck Depression Inventory score of 16 or greater and/or if the participant marked response "3" on question 9 of this form. The Principal Investigators will then be responsible for contacting the patients for further follow-up.

CHAPTER 6

DATA MANAGEMENT

6.1 DATA IDENTIFIERS

Certain items will appear on every form and will serve as unique identifiers for the participants. These items are the Participant Identification Number, the Participant Acrostic Code, the Study Code, and the Visit Code.

6.1.1 Participant Identification Number

The Participant identification number is composed of 6 digits, the first digit representing the clinic code. The participant identification number will be denoted as given below:

_____ - ____ ____ ____ ____ ____
clinic participant code

- Clinical Center Code: Each Clinical Center has been assigned a code number by the Coordinating Center. This number, the first digit of the participant's ID number, should be clearly entered in the space provided on all forms. Codes for each Clinical Center are listed below:

Clinical Center	Code
UT Southwestern	**5**
Memorial Sloan-Kettering Cancer Center (new)	**6**

- Participant Identification Code: The last 5 digits of the participants' identification number will be the participant identification code. As patients are screened/enrolled in the study, they will be assigned consecutive numbers, ranging from 0001 to as many as are needed to meet recruitment goals. These numbers are assigned by each clinic when they log in to the DOD web site and generate Participant ID labels as needed. These labels will be used on the eligibility and registration forms, and the ID will be used to enter these forms into the DOD database.

An example of a participant identification number for a participant at UT Southwestern would be:

500007

6.1.2. Participant Acrostic

This 6-letter alphabetic code will serve as a double-check of each participant's ID number. It will consist of the first three letters of the participant's last name, the first two letters of her first name, and her middle initial. For example, the acrostic for Myrtle Pauline Gooch would be GOOMYP. If a participant's last name is less than three letters, then a hyphen (-) will be used to fill in each blank space. Likewise, if the woman does not have a middle name, a hyphen (-) will appear in the last space. Even if a participant changes her name during the course of the trial, her acrostic will remain the same.

If an error is made in assigning the acrostic at the beginning of the trial and discovered later, it should not be corrected.

The acrostic code must be written on the top of the pages in the questionnaire booklet where indicated.

6.1.3 Visit Name

The type of visit is indicated on the front page of each form booklet and in the footer on every page of each booklet.

Visit Name Description	Code Used in Database
Baseline	**BV**
3 Month Follow-up	**F3**
6 Month Follow-up	**F6**
Etc....	**FN**

6.1.4 Study Code

Each participant will be assigned a study code after eligibility verification. The codes are as follows:

Study Code Description	Code
Menstrual Cycle Maintenance Only	**A**
Menstrual Cycle Maintenance and Age Difference Studies (Shared)	**B**
Age Difference Study Only	**C**

6.2. DATA TRACKING AND INVENTORY

In addition to the main study data, an inventory will be maintained at the Coordinating Center containing participant contact information, follow-up status information, and form completion date information. This inventory will form the core of the data and participant tracking system. Most study management reports, including recruitment reports, missed visit reports, and missing form reports will be generated from this inventory. Lists of participants due for mailings will also be generated from the tracking system.

6.3 MAINTAINING COMPUTER DATA FILES

6.3.1 Hardware and Software Components

The data management system will be implemented on a Sun SparcServer 1000E at the Department of Public Health Sciences at the Wake Forest University School of Medicine. The data entry application for the questionnaires will be developed using ColdFusion software and Microsoft SQL Server relational database management system. Quality assurance checks and routine study reports will also be dynamically displayed on the web utilizing both ColdFusion and SAS/IntrNet software. Statistical analyses will be done using SAS.

6.3.2 Data Security

Several levels of security have been implemented for access to the DOD project's web site and data entry areas. All data entered into the site is saved onto a server in the Department of Public Health Sciences. The server is located behind the medical school's firewall and the data is backed up to tape nightly (see 6.3.3 System Backups). The web site utilizes Secure Socket Layer Encryption software to encrypt data moving to and from each user's PC. In addition, each user is required to enter a username and password to access the web site. Access to different areas of the web site is determined by access privileges stored in a database.

6.3.3 System Backups

Each night, all data, programs, code, documents, etc. associated with the DOD project will be backed up to a DLT tape library. These tapes are kept indefinitely and are located in a fireproof cabinet that remains locked at all times. Periodically, copies of tapes are moved to an off-site location for storage. In the event that there is any loss of data, the information can be restored from tape in a matter of hours. The entire PHS computer facility is provided with conditioned power, UPS capability and environmental sensors with notification protocols.

CHAPTER 7

QUALITY CONTROL

7.1 CLINICAL CENTER ACTIVITIES

Specific quality control activities to be carried out by Clinical Center staff include:

- Recording of patient identifiers on the top of each questionnaire prior to their completion at the baseline clinic visit.
- Review of completed baseline questionnaires and forms for incomplete or inconsistent responses prior to shipment to the clinical coordinating center.
- Reporting of quality control concerns to the clinical coordinating center for prompt resolution.

The clinical center coordinator should regularly review this manual of procedures to be sure that activities are being carried out properly and with consideration for the participant. Corrective action should be taken immediately if problems are observed.

The clinical center coordinators are encouraged to communicate with the clinical coordinating center about quality control or other concerns.

7.2 DATA QUALITY

Each individual participating in the study will be assigned a participant identification number and a participant acrostic, (as described in Chapter 11). Form booklets are further identified on the front cover by the associated visit, (for example, baseline, 6 months, 18 months, etc.). The data entry system ensures that the participant identification number and participant acrostic are unique by permitting only one ID number and acrostic to be entered per participant for each questionnaire/form for each visit. In addition, the data entry system determines participant eligibility and assigns the appropriate study code upon entry of the eligibility form.

Clinical center staff are asked to review all of the participants' questionnaires at baseline, prior to ending the baseline clinic visit. Forms must be completed correctly, and every question should be answered. Written responses to any items on the questionnaires/forms should be legible.

Review of the completed forms will be done again at the coordinating center by the Project Manager or Assistant Project Manager. The Project Manager will verify that the forms are legible, and that they have been filled out correctly and completely. Any problems identified will be resolved before the data entry step. If necessary, the clinic or participant will be contacted to provide missing information or to correct invalid responses on the forms.

The data entry screens will be designed to mirror the paper data collection forms to allow smooth flow from item to item and thereby minimize errors with data entry. Verification of participant identifiers and visit and study codes will be incorporated into the data entry system, in addition to gross range checking of fields, skip pattern checks, validation of missing data and cross form checks. These quality control checks will be triggered upon saving each participant

form thereby facilitating early detection of data entry problems. Initially, a random 10% sample of study forms will be selected for duplicate data entry. Reports of data entry errors rates will be provided to the Principal Investigator of the coordinating center. The target error rates will be $\leq$ 0.5% per field. Error rates in excess of this level will support the need for additional training for data entry staff, double keying of all study data, or double entry of key study variables.

In addition to the quality control procedures during the data entry process, the clinical coordinating center will regularly perform internal comparisons of the entered data to detect missing records or suspicious or invalid data. These comparisons will include logical consistency checks of data within and across forms/questionnaires. Error reports will be generated and sent to the Principal Investigator and Project Manager of the coordinating center for resolution and for re-entry of corrected data.

7.3 COORDINATING CENTER ACTIVITIES

Quality assurance will be a major activity of the clinical coordinating center throughout the study. Activities will include:

- Training/retraining of clinical center staff in data collection procedures.
- Rechecking all completed questionnaires/forms sent by the clinical centers prior to data entry.
- Entering identifying patient and visit information on follow-up forms prior to mailing them to the participants.
- Data control (filing, manual editing, special coding efforts)
- Monitoring of data entry activities and error rates
- Documentation of data base changes.

Quality control and monitoring reports will also be generated by the clinical coordinating center. These reports will include:

- Recruitment yields at each Clinical Center
- Missed follow-up assessments, refusals, losses to follow-up
- Timeliness of data transmission
- Data error levels
- Deviations from protocol

The Coordinating Center personnel will be responsible for reviewing these reports in a timely basis and initiating actions needed to remedy any problems. If necessary, this may require performing site visits at the clinical centers, with follow-up evaluations of actions taken.

7.4 STUDY-WIDE REPORTS

During the recruitment period, monthly reports of recruitment activities by each clinical center will be provided to the principal investigators of the clinical centers.

During all phases, monitoring reports and analyses will be generated for each clinical center and for the whole study. These will be reported to all investigators and staff.

Quality control data will be summarized by the clinical coordinating center for annual reporting.

APPENDIX

DATA FORMS/QUESTIONNAIRES

PARTICIPANT ELIGIBILITY FORM - PHONE SCRIPT

Age-Associated Differences in Quality of Life Among Breast Cancer Patients and Menstrual Cycle Maintenance Study

PART I. PATIENT ELIGIBILITY

STAFF ONLY - Do not read to patient.

A telephone or clinic screen will be completed with all prospective patients. The purposes of this interview are to: 1) determine if the patient is eligible for either the age differences and/or the menstrual cycle maintenance studies; and 2) to invite eligible participant to participate in the research project(s) for which they are eligible.

READ TO PATIENT:

"Hello, my name is (your first and last names). I am a (job title) at the (clinical center name). I am calling about a research study we are conducting of women recently diagnosed with breast cancer. The purpose of this study is to see how treatment for breast cancer affects a woman's quality of life. This study has been funded by the US Army Department of Defense. You may have received a letter from (clinical center name) regarding this study in the past two weeks.

"I would like to talk with you about participating in this research study. May I talk with you about this study now? The call should take about 5-10 minutes to complete."

If patient is busy - - - > determine a better time to call the patient back.

If patient refuses to complete the call ----> Go to page 6, and answer question #1, if the patient is agreeable. Otherwise, thank the participant for her time, and end the call.

If patient agrees - - -> continue with the call.

"Before I talk about the specific details of the study, I need to make sure that you are eligible to participate. In order to do this, I need to ask you questions related to your diagnosis and treatment. Do I have your permission to ask you these questions?"

☐ **No ----> If the patient refuses to continue with the interview, thank her for her time and end the call.**

☐ **Yes ----> If patient agrees - - -> continue with the call.**

ELIGIBILITY QUESTIONS:

1. Are you a female? (Ask *only* if there is any ambiguity regarding the patients gender: e.g., ambiguous name.) ☐ Yes ☐ No

2. Is this your first diagnosis of breast cancer? ☐ Yes ☐ No

3a. On what date were you diagnosed with breast cancer ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year
(Patient must be no greater than 6 months post-diagnosis.)

((3 b. *For interviewers only*: Is patient less than 6 months post-diagnosis? ☐ Yes ☐ No

4. Was the stage of your breast cancer at diagnosis stage 1, 2, or 3? ☐ Yes ☐ No
(Please write the stage of cancer here: _____)

5a. Were you at least 18 years of age at the time of your diagnosis ? ☐ Yes ☐ No

5b. What is your date of birth? ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year
(Age must be 45 years or less at time of diagnosis for MCM study.)

((5c: *For interviewers only*: Was patient aged 18- 45 at diagnosis? ☐ Yes ☐ No

6. Do you currently have another type of cancer besides breast cancer? (Exclude basal or squamous cell skin cancer or stage 0 cervical cancer.) ☐ Yes ☐ No

7. Have you had any form of cancer in the past? (Exclude basal or squamous cell skin cancer or stage 0 cervical cancer.) ☐ Yes ☐ No

8. Have you had a hysterectomy? ☐ Yes ☐ No

(*For interviewers only*: For participants age 45 years or less at the time of diagnosis who answered 'no' to question 8, please ask the following question.)

9. Were you having regular menstrual cycles at the time you were diagnosed with breast cancer? This means were you having a period every 28 to 45 days, or whatever is normal for you? ☐ Yes ☐ No

(If the patient indicates that her periods have never been regular or occurred roughly on a monthly basis, please check the "no" box.)

STAFF ONLY - Do not read to patient.

Recruitment/Eligibility Criteria:

If the patient was ages 18-45 at diagnosis:

Eligible: If you checked all the boxes that were shaded in questions 1-8, the patient is eligible to participate in the **age differences study only**. Continue with the Age Differences Phone Script on page 4.

Eligible: If you checked all the boxes that were shaded in **questions 1-7 and** the patient has not had a hysterectomy (i.e., the answer to question #8 was "no") **and** she was having regular menstrual cycles at the time of diagnosis (i.e., the answer to question #9 was "yes"), the patient is eligible to participate in the **menstrual cycle maintenance study**. Continue with the Menstrual Cycle Maintenance Phone Script on page 5.

Ineligible: If you checked **any** box that was **not** shaded in **questions 1-7,** the patient is ineligible for either the age differences or the menstrual cycle maintenance study. Thank the patient for her time and terminate the call. However, you may answer any questions the participant may have about the study, in general terms.

If the patient was over the age of 45 years at diagnosis:

Eligible: If you checked **all the boxes that were shaded in questions 1-7, (excluding question 5c)**, the patient is eligible to participate in the **age differences study**. Continue with the Age Differences Phone Script on page 4.

Ineligible: If you checked **any** box that was **not** shaded in **questions 1-7, *(other than question 5c)*,** the patient is ineligible to participate in the age differences study. Thank the patient for her time and terminate the call. However, you may answer any questions the participant may have about the study in general terms.

PART II. PARTICIPANT RECRUITMENT

Script for Age Differences Study - (To be read to the patient.)

"Your answers to all of these questions mean that you are eligible to participate in this study. As I said earlier, the purpose of this study is to see how diagnosis and treatment for breast cancer affect a woman's quality of life. There are only a few requirements to participate in this study. You will have to sign a consent form, a medical release form, and fill out some questionnaires. It is required that you sign a consent form to participate in this study before completing any questionnaires. The consent form states the purposes of this research study, our research procedures, the risk and benefits of the study, and confidentiality. It also states that this research is entirely voluntary and you have the right to withdraw from the study at any time if you no longer choose to participate. No medical tests will be taken during your participation in this study. However, we do ask that you sign a medical release form in order for us to receive medical records from your doctors concerning your breast cancer diagnosis and treatment. It is necessary that we collect these records so that we can study how specific treatments may affect a woman's quality of life. After the consent form is signed, you will be asked to complete questionnaires regarding your medical history, treatment, and quality of life. After that, we will mail to your home similar quality of life questionnaires at 3, 6, 12, and 18 months. We will ask you to fill out and return these forms to us in a self-addressed stamped envelope at no cost to you. Are you interested in participating in this study? Are there any questions you have for me?"

Answer any questions the participant may have.

(If the patient has no questions, stress that she may call 1-877- 636-7562 with any questions in the future).

Script for Menstrual Cycle Maintenance Study - (To be read to the patient.)

"Your answers to all of these questions mean that you are eligible to participate in this study. As I said earlier, the purposes of this study are to see how treatment for breast cancer affects a woman's quality of life, and menstrual cycles. To participate in this study, you will need to sign a consent form, a medical history release form, and complete quality of life questionnaires and monthly menstrual bleeding calendars. You must sign a consent form to participate in this study before completing any questionnaires. The consent form states the purposes of this research study, our research procedures, the risk and benefits of the study, and confidentiality. It also states that this research is entirely voluntary and you have the right to withdraw from the study at any time if you no longer choose to participate. No medical tests will be taken during your participation in this study. However, we do ask that you sign a medical release form in order for us to receive medical records from your doctors concerning your breast cancer diagnosis and treatment. It is necessary that we collect these records so that we can study how specific treatments may affect a woman's quality of life and menstrual cycles. After the consent form is signed, you will be asked to complete a questionnaire booklet regarding your medical history, treatment, and quality of life. You will also be given 4 menstrual bleeding calendars to record you monthly menstrual bleeding over the next several months. In the future, we will mail to your home new bleeding calendars every 3 months, and quality of life questionnaires to complete every 6 months. We will ask you to fill out and return these forms to us in a self-addressed stamped envelope at no cost to you. Are you interested in participating in this study? Are there any questions you have for me?"

Answer any questions the participant may have.

(If the patient has no questions, stress that she may call 1-877- 636-7562 with any questions in the future).

STAFF ONLY - Do not read to patient.

After you have discussed the purposes for either research study with the patient, please ask her the following questions.

1. Do you agree to participate in the study? ☐ Yes ☐ No

If no: "May I know the reason why you have chosen not to participate? I am asked to record these reasons so that we can better understand patients' decisions to participate in research studies." (Mark all that apply.)

- ☐ Not interested
- ☐ Lack of time
- ☐ Patient is already enrolled in another study.
- ☐ Don't feel well enough to participate
- ☐ Family member refused or objected to patient's participation.
- ☐ Other: _____
- ☐ No reason given

(Staff only: If yes, patient was recruited to which study?

- ☐ Age Differences
- ☐ Menstrual Cycle Maintenance

2. For my records, may I ask you of which ethnic or racial group you consider yourself to be a member: *(Read all.)*

- ☐ White (Not Hispanic)
- ☐ Black or African-American
- ☐ Hispanic
- ☐ Asian or Pacific Islander
- ☐ American Indian or Alaskan Native Islander
- ☐ Other: _____
- ☐ Refused

STAFF ONLY:

If the patient agrees to participate in either study, schedule her for a baseline clinic visit, or obtain her mailing address to send the necessary forms to her home.

Date the baseline clinic visit is scheduled for: ☐☐/☐☐/☐☐☐☐
Month Day Year

or

Date the baseline forms and consent form were mailed to the participant: ☐☐/☐☐/☐☐☐☐
Month Day Year

Participant's Mailing Address:

_____

_____

_____

Closing Script to Patient:

"Thank you for talking with me about participating in this research study, *and for agreeing to participate in this study, (is applicable)*. I have enjoyed talking with you."

If the participant is coming into the clinic to complete the baseline forms: Remind her to bring all of her prescription and non-prescription medicine and supplement bottles to the baseline clinic visit. The names and dosages of these drugs/supplements will need to be recorded on the participant's medical history form.

********** *END OF INTERVIEW* **********

TO BE COMPLETED BY STAFF FOLLOWING THE INTERVIEW:

1: Institution ID Number:

☐ Memorial Sloan Kettering
☐ UT Southwestern

2.. Staff ID Number: ☐☐☐

3. Today's Date: ☐☐/☐☐/☐☐☐☐
Month Day Year

4. Please write any comments about the interview below.

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

DEMOGRAPHIC FORM

YOUR BACKGROUND

The following questions are about your background. This information will help us describe, in general terms, the women who are participating in the study. Please mark the appropriate box for each question.

1. What is your marital status?

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

2. What category below best describes your racial/ethnic background? If you are of mixed racial/ethnic background, choose the category with which you most closely identify yourself.

- ☐ **White (Not Hispanic)** (Persons having origins (ancestry) in any of the original people of Europe, North Africa, or the Middle East.)
- ☐ **Black or African American (Not Hispanic)** (Persons having origins (ancestry) in any of the Black racial groups of Africa.)
- ☐ **Hispanic** (Persons of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin (ancestry), regardless of race.)
- ☐ **Asian or Pacific Islander** (Persons from or having ancestors from the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, the Philippine Islands, Korea, Samoa, etc.)
- ☐ **American Indian or Alaskan Native** (Persons from or having ancestors from any of the original peoples of North America and who maintain cultural identification through tribal affiliation or community recognition.)

3. What is your date of birth?

☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

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

- ☐ No formal education
- ☐ Grade school (1st through 8th grade)
- ☐ Some high school (9th through 11th grade)
- ☐ High school diploma or G.E.D.
- ☐ Business or vocational training school after high school graduation
- ☐ Some college (but a college degree 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.)

5. How hard is it for you to pay for the very basics like food, housing, medical care, and heating? Would you say it is very hard, somewhat hard, or not very hard at all? (Check one box below).

- ☐ Very hard
- ☐ Somewhat hard
- ☐ Not very hard at all

6. 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

7. 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
- ☐ Medicare
- ☐ Disability Insurance
- ☐ None
- ☐ Other (Please list: _____)

8. What was your employment status prior to your diagnosis of breast cancer? (Check the box that describes you)

- ☐ Unemployed/Looking for work
- ☐ Retired
- ☐ Full-time Homemaker
- ☐ Employed - full-time
- ☐ Employed - part-time
- ☐ Disabled, unable to work
- ☐ Student
- ☐ Other (Please list: _____)

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

- ☐ Unemployed/Looking for work
- ☐ Retired
- ☐ Full-time Homemaker
- ☐ Employed - full-time (Including self-employment)
- ☐ Employed - part-time (Including self-employment)
- ☐ Disabled, unable to work
- ☐ Student
- ☐ Other (Please list: _____)

10. During the month just after your cancer diagnosis, about how many days did you miss work due to illness? If you were not employed, how many days did you miss other usual activities that you do during the day (such as caring for children, household work, volunteer work, etc.)?

☐☐ days

If you missed any days, what was the PRIMARY reason for missing these activities?

- ☐ Doctor appointments
- ☐ Recovering from surgery and other treatments
- ☐ Did not feel well enough
- ☐ Other: _____

11. If you are employed now, which category best describes your occupation? (If you are not employed currently, go to Question 10).

- ☐ **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 in 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): _____

12. Including yourself, what is the total number of persons who are living in your household currently?

☐☐ Persons

13. What is your religious preference?

- ☐ Catholic
- ☐ Jewish
- ☐ Protestant: (Indicate which denomination below:
  Baptist, Church of Christ, Episcopalian, Methodist, Moravian, Mormon, Presbyterian, Unitarian, etc., OR Inter-Denominational OR Non-Denominational)
  _____
- ☐ Muslim
- ☐ Hindu
- ☐ Greek Orthodox
- ☐ Russian Orthodox
- ☐ Buddhist
- ☐ Other: (Please specify: _____)
- ☐ None

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

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

MEDICAL HISTORY

1. Do you currently have any of the following conditions? **(Please check <u>all</u> that apply.)**

- ☐ None
- ☐ Amyotrophic Lateral Sclerosis (ALS, motor neuron disease, or Lou Gehrig's disease)
- ☐ Angina
- ☐ Arthritis
- ☐ Asthma
- ☐ Diabetes requiring pills
- ☐ Diabetes requiring insulin shots
- ☐ Diabetes treated with diet alone
- ☐ Diverticulitis
- ☐ Emphysema or chronic bronchitis
- ☐ Gallbladder disease or gallstones
- ☐ Glaucoma
- ☐ Heart disease:_____ (specify)
- ☐ High blood calcium
- ☐ High cholesterol requiring pills
- ☐ Hypertension or high blood pressure requiring pills
- ☐ Kidney or bladder stones (renal or urinary calculi)
- ☐ Kidney or renal failure requiring kidney dialysis of a kidney transplant
- ☐ Migraine headaches
- ☐ Multiple sclerosis
- ☐ Operation to remove gallbladder
- ☐ Overactive thyroid gland
- ☐ Pancreatitis (inflamed pancreas)
- ☐ Stomach or duodenal ulcer
- ☐ Systemic erythematosus ("lupus" or SLE)
- ☐ Ulcerative colitis or Crohn's disease
- ☐ Underactive thyroid gland
- ☐ Other

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

FAMILY HISTORY

Please answer the following questions 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 check **"Does Not Apply."** (MARK ONLY ONE BOX PER LINE.)

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

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

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 ages when certain things happened. If you are not sure about the exact date or age, please give your best estimate.

1. At what age did you have your first menstrual period?

☐☐ years old

2. Have you ever been pregnant (including full-term pregnancies, miscarriages, and abortions)?

☐ No ---> **(If no, go to Question 7)**

☐ Yes

3. How many times have you ever been pregnant?

☐☐ Pregnancies

4. How many full-term pregnancies (lasting at least six months) have you had? (If you have never had a full-term pregnancy, please write a "0" in the box.)

☐☐ Full-term pregnancies

5. Please list the date of birth of all your children:

Sons:

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐ Month Day Year

Daughters:

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

Date of Birth: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

6. How old were you at your first full-term pregnancy?

☐☐ Years old

7. Have you had any type of surgery involving your reproductive organs or pelvic region of the body? (For example, the removal of an ovary or uterine fibroids.)

☐ No
☐ Yes ----> (If yes, please describe below:)

Type of Surgery:

_____ Date: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

_____ Date: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

_____ Date: ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

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

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

☐☐☐ hot flashes/night sweats

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

CURRENT MEDICATIONS

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

Drug Name	Dosage

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

Drug Name	Dosage

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

SWELLING FORM

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

1. Since your diagnosis of breast cancer, has any swelling occurred in your arm or hand on the same side that you had your lumpectomy or mastectomy?

☐ No → (Go to question 13)
☐ Yes → (Go to question 2)
☐ Don't know → (Go to question 13)

2. How soon after your diagnosis did this swelling first occur? (Please write in the number of month(s) in the boxes below.)

☐☐ Month(s)

3. What best describes the pattern of swelling that you have had?

☐ Swelling occurred for several weeks or months, but has not happened since.
☐ Swelling has been constant since it began - no better or no worse.
☐ Swelling "comes and goes." Sometimes there is no swelling or mild swelling, and other times the swelling is moderate or severe.
☐ Other: _____

4. Do you have any swelling now?

☐ No --> **If no**, how long ago did you stop swelling? (Your best guess.) ☐☐ Month(s)

☐ Yes --> **If yes**, how long have you had this swelling? (Your best guess.) ☐☐ Month(s)

IF YOU DO NOT HAVE ANY SWELLING NOW, PLEASE GO TO QUESTION 13. IF YOU HAVE SWELLING NOW, PLEASE ANSWER QUESTIONS 5-12.

5. In the table below, please indicate where this swelling occurs, and whether the swelling is mild, moderate or severe.

	Swelling Did Not Occur	Mild Swelling	Moderate Swelling	Severe Swelling
Hand				
Upper Arm				
Lower Arm				
Arm Pit				
Other: _____ (Please specify.)				

6. Do you have any **pain** associated with the areas of your body in which the swelling occurs?

☐ No
☐ Yes

7. Do you have any **numbness** associated with the areas of your body in which the swelling occurs?

☐ No
☐ Yes

8. Do you have any **tingling** associated with the areas of your body in which the swelling occurs?

☐ No
☐ Yes

9. In general, how much does this swelling bother you?

- ☐ Not at all
- ☐ A little bit
- ☐ Somewhat
- ☐ Quite a bit
- ☐ Very much

10. Does the swelling interfere with any of the following: **(Check all that apply.)**

- ☐ Clothing that you wear
- ☐ Your ability to do routine activities such as household chores
- ☐ Your ability to pick up and carry objects
- ☐ Exercise
- ☐ Your appearance: (Describe: _____

  _____
- ☐ Other : _____

11. Does the swelling seem to get worse with any of the following? **(Check all that apply.)**

- ☐ Hot weather
- ☐ General use of your arm
- ☐ Housework or gardening
- ☐ Exercise
- ☐ Sauna/Jacuzzi/Hot bath
- ☐ Airplane travel
- ☐ Eating certain foods - (For example, salty or spicy foods)
- ☐ Drinking alcohol
- ☐ Emotional stress
- ☐ Other: Please describe: _____

12. Since your diagnosis, have you sought treatment for swelling?

☐ No → If no, why not?

- ☐ Swelling was not bad enough to seek treatment.
- ☐ Thought it was a common effect of breast cancer treatment.
- ☐ Did not know there were treatments for swelling.
- ☐ Other, please describe: _____

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

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

_____

13. Since your diagnosis, 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 14)
☐ Yes → (Continue to question 13a)
☐ Don't Know → (Continue to question 14)

13a. If yes, did you receive antibiotics?

- ☐ No
- ☐ Yes
- ☐ Don't know

14. Since your diagnosis, have you had any infection in the arm or hand on the same side that you had your lumpectomy or mastectomy?

- ☐ No
- ☐ Yes
- ☐ Don't Know

If yes, did you:

14a. receive antibiotics by mouth?

- ☐ No
- ☐ Yes
- ☐ Don't know

If yes, did you:

14b. receive antibiotics by injection (a shot)?

- ☐ No
- ☐ Yes
- ☐ Don't know

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

SYMPTOMS QUESTIONNAIRE

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

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

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

Symptom	Symptom did not occur	Symptom Occurred and Was:		
		Mild	Moderate	Severe
1. Fatigue or low energy level				
2. Nausea				
3. Restless sleep				
4. Sleeping too much				
5. Nervousness or shakiness inside				
6. Mood changes				
7. Feeling depressed				
8. Headaches				
9. Swelling of ankles or feet				
10. Diarrhea				
11. Constipation				
12. Abdominal pain/cramps				
13. Vaginal dryness				
14. Weight gain				
15. Weight loss				
16. General aches and pains				

Symptom	Symptom did not occur	Symptom Occurred and Was: Mild	Moderate	Severe
17. Hot flashes				
18. Joint pains				
19. Night sweats				
20. Forgetfulness				
21. Difficulty concentrating				
22. Increased appetite				
23. Short temper				
24. Decreased efficiency				
25. Loss of interest in work/activities				
26. Lowered work performance				
27. Breast sensitivity/tenderness				
28. Avoidance of social affairs				
29. Cold sweats				
30. Decreased appetite				
31. Bloating				

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

HEALTH STATUS QUESTIONNAIRE

1. Overall, how would you rate your quality of life? **(Check one box below.)**

1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Worst				Halfway					Best

As bad or worse than being dead

Best quality of life

2. How satisfied are you with your current quality of life? **(Check one box below.)**

1	2	3	4	5	6	7	8	9	10
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dissatisfied				Halfway					Satisfied

Not at all happy with quality of life now

Very happy with quality of life now

3. In general would you say your health is: **(Check one box.)**

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

4. **Compared to one year ago**, how would you rate your health in general now? **(Check one box.)**

- ☐ Much better now than 1 year ago
- ☐ Somewhat better now than 1 year ago
- ☐ About the same
- ☐ Somewhat worse now than 1 year ago
- ☐ Much worse than 1 year ago

The following are questions about a typical (or usual) day's activities. **Does your health now limit you in these activities,** and if so, how much? (Check one box for each question.)

		Yes, limited a lot	Yes, limited a little	No, not limited at all
5.	**Vigorous activities**, such as running, lifting heavy objects, or strenuous sports	☐	☐	☐
6.	**Moderate activities**, such as moving a table, vacuuming, bowling or golfing	☐	☐	☐
7.	Lifting or carrying groceries	☐	☐	☐
8.	Climbing **several** flights of stairs	☐	☐	☐
9.	Climbing **one** flight of stairs	☐	☐	☐
10.	Bending, kneeling, stooping	☐	☐	☐
11.	Walking **more than a mile**	☐	☐	☐
12.	Walking **several blocks**	☐	☐	☐
13.	Walking **one block**	☐	☐	☐
14.	Bathing or dressing yourself	☐	☐	☐

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

		Yes	No
15.	Cut down on the **amount of time** you spent on work or other activities	☐	☐
16.	**Accomplished less** than you would have liked	☐	☐
17.	Were limited in the **kind** of work or other activities you did	☐	☐
18.	Had **difficulty** performing work or other activities (it took extra effort)	☐	☐

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

		Yes	No
19.	You cut down on the amount of time spent on work or other activities	☐	☐
20.	You accomplished less than you would like	☐	☐
21.	You did work or other things less carefully than usual	☐	☐

22. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, neighbors, friends, or groups? **(Check one box.)**

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

23. During the **past 4 weeks**, how much body pain have you had? **(Check one box.)**

None	Very Mild	Mild	Moderate (Medium)	Severe	Very Severe
☐	☐	☐	☐	☐	☐

24. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)? **(Check one box.)**

Not at all	A little bit	Moderately (Medium)	Quite a bit	Extremely
☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 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 4 weeks...

		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
25.	Did you feel full of pep?	☐	☐	☐	☐	☐	☐
26.	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐

		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
27.	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
28.	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
29.	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
30.	Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
31.	Did you feel worn out?	☐	☐	☐	☐	☐	☐
32.	Have you been a happy person?	☐	☐	☐	☐	☐	☐
33.	Did you feel tired?	☐	☐	☐	☐	☐	☐

34. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends and relatives)?

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

How TRUE or FALSE is each of the following statements for you?

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
35.	I seem to get sick a little easier than other people ...	☐	☐	☐	☐	☐
36.	I am as healthy as anybody I know	☐	☐	☐	☐	☐
37.	I expect my health to get worse	☐	☐	☐	☐	☐
38.	My health is excellent	☐	☐	☐	☐	☐

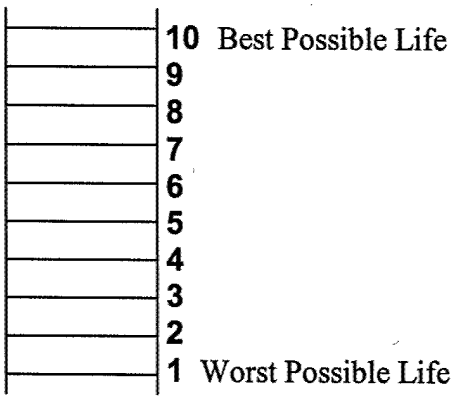
Patient I.D. __ __ - __ __ __ __

Patient Acrostic: __ __ __ __ __ __

The next set of questions are about your general quality of life.

1. Here is a picture of a stepladder. The top of the ladder represents the best possible life for you. The bottom of the ladder represents the worst possible life for you. On which of these 10 steps of the ladder do you feel you personally stand at the present time?

   (Circle one number from 1 to 10)



2. On a 7-point scale when "1" indicates complete dissatisfaction and "7" indicates complete satisfaction, which number comes closest to how you feel about your life as a whole these days?

   (Circle one number from 1 to 7)

1	2	3	4	5	6	7
Complete Dissatisfaction						Complete Satisfaction

3. Finally, please mark with an "X" the appropriate place within the bar below to indicate your rating of the quality of your life **in the past 4 weeks**:

Lowest Possible Quality		Highest Possible Quality

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

FACT - 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 *during the past 7 days*.

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

Social/Family Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
8. I felt distant from my friends.	1	2	3	4	5
9. I got emotional support from my family.	1	2	3	4	5
10. I got support from my friends and neighbors.	1	2	3	4	5
11. My family had accepted my illness.	1	2	3	4	5
12. 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 13-14. Otherwise, go to question 15.

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

Emotional Well-Being	**Not At All**	**A Little Bit**	**Some-what**	**Quite a bit**	**Very Much**
15. I felt sad	1	2	3	4	5
16. I was proud of how I'm coping with my illness.	1	2	3	4	5
17. I was losing hope in the fight against my illness.	1	2	3	4	5
18. I felt nervous.	1	2	3	4	5
19. I worried about dying.	1	2	3	4	5

Functional Well-Being	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
20. I was able to work (include work in home)	1	2	3	4	5
21. My work (include work in home) was fulfilling	1	2	3	4	5
22. I was able to enjoy life "in the moment."	1	2	3	4	5
23. I had accepted my illness	1	2	3	4	5
24. I was sleeping well	1	2	3	4	5
25. I enjoyed my usual leisure pursuits	1	2	3	4	5
26. I was content with the quality of my life right now	1	2	3	4	5

Additional Concerns	Not At All	A Little Bit	Some-what	Quite a bit	Very Much
27 I was short of breath	1	2	3	4	5
28. I was self-conscious about the way I dressed	1	2	3	4	5
29. My arms were swollen or tender	1	2	3	4	5
30. I felt sexually attractive	1	2	3	4	5
31. I was bothered by hair loss	1	2	3	4	5
32. I worried about the risk of cancer in other family members	1	2	3	4	5
33. I worried about the effect of stress on my illness	1	2	3	4	5
34. I was bothered by a change in weight	1	2	3	4	5
35. I was able to feel like a woman	1	2	3	4	5

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

EMOTIONAL FEELINGS

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

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

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

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

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

5. ☐ 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.

6.
- ☐ 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.

7.
- ☐ I don't feel disappointed in myself.
- ☐ I am disappointed in myself.
- ☐ I am disgusted with myself.
- ☐ I hate myself.

8.
- ☐ 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.

9.
- ☐ 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.

10.
- ☐ 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.

11.
- ☐ I am no more irritated now than I ever am.
- ☐ I get annoyed or irritated more easily than usual.
- ☐ I feel irritated all the time now.
- ☐ I don't get irritated at all by the things that used to irritate me.

12.
- ☐ 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.

13. ☐ 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.

14. ☐ 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.

15. ☐ 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.

16. ☐ 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.

17. ☐ 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.

18. ☐ 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.

19. ☐ 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.

20.
- ☐ 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.

21.
- ☐ I have not noticed any recent change in my interest in sex.
- ☐ I am less interested in sex than I used to be.
- ☐ I am much less interested in sex now.
- ☐ I have lost interest in sex completely.

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

Patient Acrostic: ___ ___ ___ ___ ___ ___ ___

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
1. Hair					
2. Breast area					
3. Arms					
4. Face					
5. Waist					
6. Hips					
7. Thighs					
8. Overall body					

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

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

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

10. I view myself as a:

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

The next questions have to do with how you feel about your body. To what extent do you agree or disagree with each of these statements? **(Check only one box for each statement).**

	Strongly agree	**Agree**	**Neither agree or disagree**	**Disagree**	**Strongly disagree**
11. I am attractive to others.					
12. My attractiveness has changed due to surgery.					
13. My attractiveness has changed due to weight change.					
14. I am afraid of being unattractive sexually.					
15. I am satisfied with the appearance of my breast area that was affected by cancer.					
16. I am satisfied with the texture of my breast area that was affected by cancer.					
17. I would describe my scar from breast cancer treatment as more beautiful than ugly.					

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

SEXUALITY

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

1. Have you been sexually active in the past month?

☐ No ----> (If no, go to the Social Support Form).
☐ Yes ----> (If yes, continue to Question 2).

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
2. Lack of sexual interest.					
3. Difficulty in becoming sexually aroused.					
4. Unable to relax and enjoy sex.					
5. Difficulty in having an orgasm.					
6. Partner lacking sexual interest.					

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

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
1. I felt peaceful.					
2. I had a reason for living.					
3. My life has been productive.					
4. I had trouble feeling peace of mind.					
5. I felt a sense of purpose in my life.					
6. I was able to reach down deep into myself for comfort.					
7. I felt a sense of harmony within myself.					
8. My life lacked meaning and purpose.					
9. I found comfort in my faith or spiritual beliefs.					
10. I found strength in my faith or spiritual beliefs.					
11. My illness strengthened my faith or spiritual beliefs.					
12. I know that whatever happens with my illness, things will be okay.					

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

COPING

These items deal with ways you've been coping with your diagnosis of breast cancer. There are many ways to try to deal with problems. These items ask what you've been doing to cope with this one. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know to what extent you've been doing what the item says. How much or how frequently. Do not answer on the basis of whether it seems to be working or not-just whether or not you're doing it. Use these response choices. Try to rate each item separately in your mind from the others. Make your answers as true FOR YOU as you can.

	Not doing at all	Doing a little bit	Doing a medium amount	Doing a lot
1. I've been turning to work or other activities to take my mind off things	1	2	3	4
2. I've been concentrating my efforts on doing something about the situation I'm in	1	2	3	4
3. I've been saying to myself "this isn't real."	1	2	3	4
4. I've been using alcohol or other drugs to make myself feel better	1	2	3	4
5. I've been getting emotional support from others.	1	2	3	4
6. I've been giving up trying to deal with it.	1	2	3	4
7. I've been taking action to try to make the situation feel better.	1	2	3	4
8. I've been refusing to believe that it has happened.	1	2	3	4
9. I've been saying things to let my unpleasant feelings escape.	1	2	3	4
10. I've been getting help and advice from other people.	1	2	3	4
11. I've been using alcohol or other drugs to hep me get through it.	1	2	3	4
12. I've been trying to see it in a different light, to make it seem more positive	1	2	3	4

	Not doing at all	Doing a little bit	Doing a medium amount	Doing a lot
13. I've been criticizing myself.	1	2	3	4
14. I've been trying to come up with a strategy about what to do.	1	2	3	4
15. I've been getting comfort and understanding from someone	1	2	3	4
16. I've been giving up the attempt to cope.	1	2	3	4
17. I've been looking for something good in what is happening.	1	2	3	4
18. I've been making jokes about it.	1	2	3	4
19. I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	1	2	3	4
20. I've been accepting the reality of the fact that it has happened.	1	2	3	4
21. I've been expressing my negative feelings.	1	2	3	4
22. I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4
23. I've been trying to get advice or help from other people about what to do.	1	2	3	4
24. I've been learning to live with it.	1	2	3	4
25. I've been thinking hard about what steps to take.	1	2	3	4
26. I've been blaming myself for things that happened.	1	2	3	4
27. I've been praying or meditating.	1	2	3	4
28. I've been making fun of the situation.	1	2	3	4
29. I've tried to keep my feelings to myself.	1	2	3	4
30. I've kept others from knowing how bad things were.	1	2	3	4
31. I've wished that the situation would go away or somehow be over with.	1	2	3	4
32. I've had fantasies or wishes about how things might turn out.	1	2	3	4

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

ILLNESS INTRUSIVENESS

The following items ask about how much your illness and/or its treatment interfere with different aspects of your life. **PLEASE CIRCLE THE ONE NUMBER THAT BEST DESCRIBES YOUR CURRENT LIFE SITUATION.** *If an item is not applicable, please circle the number one (1) to indicate that this aspect of your life is not affected very much.* Please do not leave any item unanswered. Thank you.

How much does your illness and/or its treatment interfere with your:

1. **HEALTH:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

2. **DIET** (i.e., the things you eat and drink)**:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

3. **PAID WORK:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

4. **ACTIVE RECREATION** (e.g., sports)**:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

5. **PASSIVE RECREATION** (e.g., reading, listening to music)**:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

6. **FINANCIAL SITUATION:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

7. **RELATIONSHIP WITH YOUR SPOUSE** (girlfriend or boyfriend if not married)**:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

8. **SEX LIFE:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

How much does your illness and/or its treatment interfere with your:

9. **FAMILY RELATIONS:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

10. **OTHER SOCIAL RELATIONS:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

11. **SELF-EXPRESSION/SELF-IMPROVEMENT:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

12. **RELIGIOUS EXPRESSION:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

13. **COMMUNITY AND CIVIC INVOLVEMENT:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

14. **FAMILY RESPONSIBILITIES:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

15. **SOCIAL ACTIVITIES:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

16. **WORK AROUND THE HOUSE:**

1 2 3 4 5 6 7
Not Very Much *Very Much*

17. **OTHER ACTIVITIES YOU LIKE TO DO (PLEASE SPECIFY ACTIVITY):**_____

1 2 3 4 5 6 7
Not Very Much *Very Much*

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

POST TRAUMATIC GROWTH INVENTORY

Indicate for each of the statements below the degree to which this change occurred in your life **as a result of your cancer**, using the following scale:

		Did not experience	Experienced, very small degree	Experienced, small degree	Experienced, moderate degree	Experienced, great degree	Experienced, very great degree
1.	My priorities about what is important in life.						
2.	An appreciation for the value of my own life.						
3.	I developed new interests.						
4.	A feeling of self-reliance.						
5.	A better understanding of spiritual matters.						
6.	Knowing that I can count on people in times of trouble.						
7.	I established a new path for my life.						
8.	A sense of closeness with others.						
9.	A willingness to express my emotions.						
10.	Knowing I can handle difficulties.						
11.	I'm able to do better things with my life.						
12.	Being able to accept the way things work out.						
13	Appreciating each day.						
14.	New opportunities are available which wouldn't have been otherwise.						
15.	Having compassion for others.						

		Did not experience	Experienced, very small degree	Experienced, small degree	Experienced, moderate degree	Experienced, great degree	Experienced, very great degree
16.	Putting effort into my relationships.						
17.	I'm more likely to try to change things that need changing.						
18.	I have a stronger religious faith.						
19.	I discovered that I'm stronger than I thought I was.						
20.	I learned a great deal about how wonderful people are.						
21.	I accept needing others.						

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

SOCIAL SUPPORT FORM

The following are questions about the <u>support</u> that is available to you.

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

☐☐ Number of close friends and close relatives

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

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

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

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: ___ ___ ___ ___ ___ ___

LIFE ORIENTATION FORM

The following statements have to do with your general outlook on life. To what extent do you agree or disagree with the following statements? (Please check one box for each statement)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. In uncertain times you usually expect the best.					
2. If something can go wrong for you, it will.					
3. You always look on the bright side of things.					
4. You're always optimistic about your future.					
5. You hardly ever expect things to go your way.					
6. Things never work out the way you want them to.					
7. You believe in the idea that "every cloud has a silver lining."					
8. You rarely count on good things happening to you.					

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

Patient Acrostic: __ __ __ __ __ __

CONTACT INFORMATION FORM

We would like some information about you and two relatives or friends so that we can keep in touch with you during the study. This information is very important, so please answer these questions completely. Please print the information in the space provided or mark the appropriate box.

1. Your full legal name: _____ _____ _____
   First MI Last

2. Name you prefer to use: (if different) _____

3. What is your maiden name? _____
   Last

4. What is your date of birth: ☐☐/☐☐/☐☐☐☐
   Month Day Year

5. Social Security Number: ___ ___ ___ - ___ ___ - ___ ___ ___ ___

6. Your Mailing Address:

   _____

   _____

   _____

7. Telephone Numbers: Home: Area Code (___) ___ ___ - ___ ___ ___ ___
   Is it okay to leave a message about the study on your answering machine?
   Yes ☐ No ☐

   Work: Area Code (___) ___ ___ ___ - ___ ___ ___ ___
   Is it okay to leave a message about the study on your answering machine?
   Yes ☐ No ☐

   Other: Area Code (___) ___ ___ ___ - ___ ___ ___ ___
   Is it okay to leave a message about the study on your answering machine?
   Yes ☐ No ☐

8. Email address: _____
   Is it okay to send you messages about the study at this email address?
   Yes ☐ No ☐

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

_____ _____ _____

First MI Last

10. 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 (__ __ __) __ __ __ - __ __ __ __

Name: _____

Address: _____

_____

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

11. Please provide the name of the physician you go to for most of your general health care needs. (For example, your family physician or a gynecologist.)

Name: _____

Address: _____

_____

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

12. Please provide the name of your oncologist.

Name: _____

Address: _____

_____

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

13. Please provide the name of your breast surgeon, (if applicable).

Name: _____

Address: _____

_____

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

14. Please provide the name of your radiologist, (if applicable).

Name: _____

Address: _____

_____

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

PATIENT REGISTRATION FORM

Please print the information in the spaces provided or mark the appropriate box. This form is to be faxed to the clinical coordinating center the same day as the participant's baseline forms have been completed.

Participant Identification Number: ☐☐-☐☐☐☐-☐

Participant Acrostic: ☐☐☐☐☐☐

Participants' **enrollment/baseline visit date**: ☐☐/☐☐/☐☐☐☐
Month Day Year

Consent form has been signed and is in patient's file? Yes ☐ No ☐

Baseline forms have been completed? Yes ☐ No ☐

Menstrual Cycle Calendar Instructions have been completed? Yes ☐ No ☐ N/A ☐

Patient was given 4 bleeding calendars? Yes ☐ No ☐ N/A ☐

Participant's Name: _____ _____ _____
First MI Last

Mailing Address: _____

_____

Country: _____

Zip Code: ☐☐☐☐☐-☐☐☐☐

Telephone Numbers: Home: ☐☐☐-☐☐☐-☐☐☐☐

Is it okay to leave a message on your answering machine? Yes ☐ No ☐

Work: ☐☐☐-☐☐☐-☐☐☐☐

Is it okay to leave a message on your answering machine? Yes ☐ No ☐

Other: ☐☐☐-☐☐☐-☐☐☐☐

Is it okay to leave a message on your answering machine? Yes ☐ No ☐

Email: _____

Is it okay to send e-mails about the study? Yes ☐ No ☐

Institution: Patient Recruited from:

☐ 5 Memorial Sloan Kettering

☐ 6 UT Southwestern

Staff ID Number: ☐☐☐

Today's date: ☐☐/☐☐/☐☐☐☐

Month Day Year

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

Patient Acrostic: ___ ___ ___ ___ ___ ___

CHART REVIEW FORM

1. Date of Breast Cancer Diagnosis ☐☐/☐☐/☐☐☐☐
   Month Day Year

2. Stage of Cancer ☐☐

3. Types of Definitive Surgery:
   A. Lumpectomy/excisional biopsy
   or quadrantectomy ☐ No ☐ Yes ☐☐/☐☐/☐☐☐☐
   Month Day Year

   Final Margins of Lumpectomy Surgery

   ☐ Negative
   ☐ Positive Intraductal
   ☐ Positive Invasive
   ☐ Positive Both
   ☐ Unknown

   B. Mastectomy ☐ No ☐ Yes ☐☐/☐☐/☐☐☐☐
   Month Day Year

   Final Margins of Mastectomy Surgery

   ☐ Negative
   ☐ Positive Intraductal
   ☐ Positive Invasive
   ☐ Positive Both
   ☐ Unknown

4. Did patient have immediate reconstructive surgery?

☐ No
☐ Yes, (see below)

If yes, what type:

☐ Expander / Implant
☐ TRAM
☐ Gluteal / Latissimus
☐ Other (Specify)_____
☐ Unknown

5. Initial primary tumor location:

☐ Right Breast
☐ Left Breast
☐ Both Breasts

6. Size of Invasive Tumor: **(Check all that apply. Use size of largest tumor.)**

☐ Micro invasive (< 1 mm)
☐ Actual size ☐☐☐.☐ cm
☐ Multicentric (multiple invasive tumors)
☐ Indeterminate
☐ Unknown

7. How was invasive tumor size determined?

☐ Measurement from pathology report
☐ Estimated by mammogram or ultra sound
☐ Clinically assessed
☐ Unknown

8. Histologic tumor type: **(Check all that apply. Use size of largest tumor.)**

- ☐ Infiltrating ductal carcinoma (NOS)
- ☐ Infiltrating lobular carcinoma
- ☐ Infiltrating duct and infiltrating lobular carcinoma
- ☐ Carcinoma (Not otherwise stated)
- ☐ Tubular
- ☐ Tubulo-lobular
- ☐ Colloid
- ☐ Medullary
- ☐ Metaplastic
- ☐ Papillary Disease
- ☐ Other: (specify)_____

9. Prognostic Features:

A. Histologic Grade (Invasive Ductal Only): **and/or** Nuclear Grade:

☐ Grade I	☐ Grade I
☐ Grade II	☐ Grade II
☐ Grade III	☐ Grade III
☐ Grade IV	☐ Unknown
☐ Unknown	☐ Not applicable
☐ Not applicable.	

B. Lymphatic invasion/Blood vessel invasion?

☐ No ☐ Yes ☐ Unknown

C. Extensive intraductal component (Greater than 25%)?

☐ No ☐ Yes ☐ Unknown

D. Chest wall invasion (Skeletal muscle)?

☐ No ☐ Yes ☐ Unknown

E. Skin invasion/Dermal lymphatic invasion?

☐ No ☐ Yes ☐ Unknown

F. Other Invasion? Please describe: _____

_____

10. Did Patient Have Axillary Node Dissection?

☐ No

☐ Yes ➜ If yes, date of dissection? ☐☐/☐☐/☐☐☐☐
Month Day Year

☐ Unknown

11. Was Sentinel lymph node technology used?

☐ No

☐ Yes ➜ If yes, date of sentinel procedure? ☐☐/☐☐/☐☐☐☐
Month Day Year

12. Across the two procedures (i.e. axillary and sentinel)
Number of nodes examined? ☐☐

13. Across the two procedures (i.e. axillary and sentinel)
Number of nodes positive? ☐☐

14. Extranodal Invasion?

☐ No

☐ Yes

☐ Unknown

15. Participant's Height at diagnosis: ☐ feet ☐.☐ inches

16. Participant's Weight at diagnosis: ☐☐☐ pounds

17. Participant's Height at last clinic visit ☐☐/☐☐/☐☐☐☐
Month Day Year

☐ feet ☐.☐ inches

18. Participant's Weight at last clinic visit ☐☐/☐☐/☐☐☐☐
Month Day Year

☐☐☐ pounds

ADJUVANT THERAPY

Radiation Therapy:

19. Did patient have radiation therapy? ☐ No ☐ Yes ----> **(If no, go to Question 25)**

If yes, date patient started radiation ☐☐/☐☐/☐☐☐☐
Month Day Year

20. Has patient completed radiation therapy? ☐ No

☐ Yes ----> If yes, enter date of last radiation treatment:

☐☐/☐☐/☐☐☐☐
Month Day Year

21. Radiation after breast conservation surgery (e.g., lumpectomy, quadratectomy)?

☐ No
☐ Yes

22. Radiation to chest wall after mastectomy ?

☐ No
☐ Yes
☐ Unknown

23. Number of treatments ☐☐

24. Total dose received (treatments & boosts) ☐☐☐☐ rads or cgy

Chemotherapy:

25. Did patient have chemotherapy? ☐ No ☐ Yes ----> **(If no, go to Question 28)**

If yes, date patient started chemotherapy: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

26. Has patient completed chemotherapy? ☐ No
☐ Yes ----> If yes, enter date of last chemotherapy treatment:
☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

27. Type of Chemotherapy:
Please list types, dosage and duration. Enter information for all drugs used.

	TYPE	TOTAL MG	# DOSES
☐	IV Cytoxan (Cyclophosphamide)	☐☐☐☐☐	☐☐
☐	Oral Cytoxan (Cyclophosphamide)	☐☐☐☐☐	☐☐
☐	Amethopterin (Methotrexate)	☐☐☐☐☐	☐☐
☐	5-FU (Fluorouracil)	☐☐☐☐☐	☐☐
☐	Adriamycin (Doxorubicin)	☐☐☐☐☐	☐☐
☐	Oncovin (Vincristine)	☐☐☐☐☐	☐☐
☐	Taxol (Paclitaxel)	☐☐☐☐☐	☐☐
☐	Taxotere (Docetaxel)	☐☐☐☐☐	☐☐
☐	Other	☐☐☐☐☐	☐☐

28. Was pre-operative neo-adjuvant chemotherapy given before definitive surgery? ☐ No ☐ Yes

Hormonal Therapy:

29. Did patient have hormonal therapy? ☐ No ☐ Yes -----> **(If no, go to Question 31)**

If yes, date patient started hormonal therapy: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

30. Please list type of hormone, dosage, and duration

Check "box" if patient received treatment	TYPE
☐	Tamoxifen (Nolvadex) ☐☐ mg daily Date of first treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year) Date of last treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year)
☐	Arimidex (Anastrozole) ☐ mg daily Date of first treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year) Date of last treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year)
☐	Megace (Megestrol Acetate) ☐☐☐ mg daily Date of first treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year) Date of last treatment: ☐☐/☐☐/☐☐☐☐ (Month Day Year)

Check "box" if patient received treatment

TYPE

☐ Raloxifene (Evista)

☐☐☐ mg/daily

Date of first treatment: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

Date of last treatment: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐ Lupron/Leuprolide — Date of treatment:

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐ Zoladex/Goserelin — Date of Treatment:

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

☐☐.☐ mg — ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

Check "box" if patient received treatment

TYPE

☐ Other Drug:_____
(Please specify)

☐☐☐ mg/daily

Date of first treatment: ☐☐/☐☐/☐☐☐☐
Month Day Year

Date of last treatment: ☐☐/☐☐/☐☐☐☐
Month Day Year

31. Is patient still on hormonal therapy? ☐ No ----> If no, enter date therapy was discontinued:

☐☐/☐☐/☐☐☐☐
Month Day Year

☐ Yes

32. Receptor test results:

a. Estrogen:

☐ positive→_____%
☐ negative→_____%

b. Progesterone:

☐ positive→_____%
☐ negative→_____%

c. Her - 2 neu receptors

☐ positive→_____%
☐ negative→_____%

33. Is the patient on a treatment trial? ☐ Yes ☐ Unknown

34. Did the patient have any of the following types of surgery/procedures following her breast cancer?

A. Hysterectomy: ☐ no ☐ yes -----> Date ☐☐/☐☐/☐☐☐☐ Month Day Year

B. Oophorectomy: ☐ no ☐ yes -----> Date ☐☐/☐☐/☐☐☐☐ Month Day Year

C. Ovarian Ablation: ☐ no ☐ yes -----> Date ☐☐/☐☐/☐☐☐☐ Month Day Year

D. Breast Reconstruction completed at a date later than the initial surgery: ☐ no ☐ yes ----> Date ☐☐/☐☐/☐☐☐☐ Month Day Year

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

36. Staff ID: ☐☐☐☐