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Abstract

Approximately 20-30% of women develop lymphedema (LE) following breast cancer treatment. Effective symptom management requires that women recognize early signs of lymphedema, and maintain precautionary practices over time. Data indicates that knowledge and use of symptom minimization precautions are poor. Little is known about how breast cancer survivors perceive their LE risk, and the cognitive-affective factors that promote the uptake and adherence to LE symptom minimization precautions. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we are conducting a longitudinal study, to assess barriers and facilitators associated with knowledge and adherence to LE symptom-minimization practices among breast cancer survivors. We are exploring the mediating role of cognitive–affective variables, and the moderating role of attentional style, on knowledge, uptake and adherence. Our preliminary analysis shows a correlation between high monitoring and more knowledge of lymphedema risks compared to low-monitoring styles. We are surveying levels of knowledge, and practice of symptom minimization precautions at baseline, 6-, and 12-month follow-up. Although many women are aware of LE minimization practices, data suggest that they are not incorporating the recommendations into their daily lives. Further, psychosocial factors play a role in the uptake of LE symptom-minimization practices, and sustained adherence over time.

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INTRODUCTION

Improvements in breast cancer treatments have greatly reduced mortality rates (Petrek 2000; Passik 1998; Erickson, 2001; Tasmuth 1996). The number of breast cancer survivors continues to increase due to improved methods of detection and treatment. Consequently, more women are dealing with the impact of lymphedema on their everyday lives and well-being (Armer, J.M. et al., 2005; Jeffs, 2005). Thus, it has been recognized that greater attention needs to be given to survivorship issues, such as the management of post-treatment side effects such as lymphedema (LE), that compromise physical and psychological functioning and quality of life (Passik & McDonald 1998; Erickson, Pearson, et al., 2001; Brenes, Mihalko, et al., 2001). Yet, little is currently known about women's knowledge and practice of precautionary behaviors to prevent or lessen the impact of this condition (Coward, 1999; Clark, Wasilewska, et al., 1997). Guided by the Cognitive-Social Health Information Processing (C-SHIP) model (Miller, Shoda, et al., 1996; Miller & Rodoletz, 1996; Miller & Diefenbach, 1998), the overarching objective of the present study is to explore the cognitive–affective factors associated with knowledge about LE symptom-minimization practices, their initiation, and the sustained maintenance of these practices among breast cancer survivors currently unaffected by LE.

The specific aims of this project are as follows:

Aim 1: To delineate the underlying cognitive-affective mediating mechanisms (i.e., women's self-construals, expectancies, values and goals, affects, and self-regulatory strategies) that facilitate or undermine the uptake of LE symptom-minimization practices, and their sustained adherence over time. These cognitive-affective patterns will be assessed and related to levels of knowledge and the practice of symptom minimization precautions, at three points in time: baseline (within 6 weeks post-surgery), and again at 6- and 12-month follow-up post-baseline. It is hypothesized that greater LE-knowledge, greater intent to establish practices and/or adhere to existing practices, as well as greater uptake of recommendations and sustained adherence will be associated with heightened risk perceptions; greater self-efficacy, greater perceived benefits of, and fewer barriers to, enacting symptom minimization practices; lower LE-related distress; and greater ability to perform self-regulatory strategies.

Aim 2: To assess the moderating role of stable differences in the individual's cognitive-emotional profile or "psychological signature" on the uptake and adherence of LE symptom minimization practices and personalized cancer threats and challenges, over time (Miller, 1995). Specifically, it is predicted that high monitors (who attend to, focus on, and personalize cancer threats) will show greater knowledge, uptake, and adherence than low monitors (who distract from and downplay the significance of cancer threats and challenges).

To accomplish these objectives, we are conducting a longitudinal study of LE symptom-free women who are in remission following sentinel or axillary node surgery for Stages I-IIIa, primary breast cancer (N = 178). From two recruitment sites, the Breast

Evaluation Clinic at Fox Chase Cancer Center and Virtua Memorial Hospital, a nurse educator and a primary site coordinator, Dr. Eric Miller, respectively, make potential participants aware of the study through the provision of a leaflet describing involvement in the study upon registration for their clinic appointment. A member of the FCCC research team reviews FCCC's electronic medical records, the Soarian Clinical Access Database to identify clinic patients and to determine patient eligibility (i.e., diagnosis, surgery status). The research staff then contacts eligible patients by telephone to describe the study, solicit participation and obtain verbal consent for participation. Eligible, consenting participants then completes psychosocial measures and a written informed consent at their next post-surgery follow-up appointment, usually within two weeks of initial contact and consent. Upon completion of the baseline questionnaire, each participant is given a copy of the American Cancer Society Lymphedema booklet containing hand and arm care following surgery or radiation therapy for breast cancer and the recommended precautionary actions that they can follow will be briefly summarized verbally. Relevant psychosocial and behavioral variables are reassessed by telephone at each of the follow-ups, 6- and 12-months post-baseline. Participants who experience a breast cancer recurrence are excluded from follow-up and will be replaced in the study design.

BODY

During year 1, the plan was to initiate Tasks 1 and 2 and complete Task 1, as outlined in our approved Statement of Work.

The specific aims of Task 1 were:

a. Modify provisional measures according to Institutional Review Board (Months 1-2)
b. Establish Recruitment Procedures/ Train Staff (Months 1-2)

Task 1 was accomplished according to schedule.

The aims of Task 2, are:

a. Recruit Participants, Conduct Longitudinal Study (Months 2-33)
b. Establish Database and Enter Data (Months 2-33)

Fox Chase Cancer Center (FCCC) sent a formal request to further extend the budget period for an additional 12-months to fully complete Task 2 and Task 3 on August 2nd, 2005. The extension would allow the continuation of recruitment in order to reach the original recruitment targeted sample numbers (N=178), and to complete data analysis and publications reporting upon the work. Further, several amendments to the protocol were submitted over the past year to address issues related to FCCC staff turnover and the for clarification of recruitment methods:

1) By request of the Department of Defense request, an amendment to clarify the participating physician's, Dr. Eric Miller's, role on the study protocol. We have thus added Dr. Eric Miller's name to the protocol, given him the title of "primary site coordinator". We received approval for this amendment in December, 2004.

2) In February, 2005, IRB approval was provided for personnel changes to consent form, and as per DOD's request, clarification of participation consent process and addition of lines to record the participant's address. Michelle Rodoletz, PhD and Kerry Sherman, PhD were removed from the protocol and consent forms as they were no longer FCCC staff on this study.

3) In May, 2005, IRB approval was provided for the new HIPAA form for an updated version of the form that is standard to the Population Science Department at FCCC.

4) Finally, in June, 2005, changes to the recruitment brochure was approved by FCCC IRB with the replacement of Melanie Glenn, the former project manager, for the addition of Jessica Eisenberg, the study's research assistant, as the contact person on the recruitment brochure.

The aims of Task 3, initiated in year 1 and continued in year 3 are:

a. Analyze Preliminary Data (baseline to 6-month and 12-month follow-ups) (Months 4-33)

b. Annual Reports Prepared (Months 4-33)

To date, preliminary baseline data have been entered and descriptive statistics have been performed. Since August 15, 2003 a total of 1154 patients have visited the Breast Evaluation Clinic at FCCC. Since August 2003, 268 of the 1154 clinic patients (23%) have been identified as eligible for the study (i.e., early stage at diagnosis, LE symptom free, receiving treatment at FCCC). To date, of the 268 eligible women, our research team has successfully contacted 111 (41%) by using a maximum of 20 attempts to contact women by telephone. Of the women contacted, 90 (81%) provided verbal consent to participate. Fifty-eight of the women contacted (52%) declined participation with 50 women stating that they were "not interested" with no additional explanation provided and 8 women cited non-study specific related factors (i.e., language/communication barriers, already participating in another research study, lack of transportation) as reasons for non-participation. To date, 65 of the 90 consenting eligible participants have completed baseline data. Seventeen originally consenting eligible participants have attrited from the study (15 participants through passive attrition [i.e., not showing up; not returning telephone calls], 2 participant through active attrition [i.e., changing their minds about participation.]). Collection of six-month follow-up questionnaires began in August 2003 and 52 questionnaires have been completed. To date, eight women will soon be due for their 6-month follow-ups. Five participants failed to complete their 6-month follow-up in the allotted time. Collection of 12-month follow-up questionnaires began in April 2004 and, to date, 34 of the expected 55 questionnaires

have been collected. Telephone calls are placed on a regular basis to collect the remaining follow-up questionnaires.

BACKGROUND CHARACTERISTICS OF STUDY PARTICIPANTS

To date, 65 participants have completed baseline measures. The following section provides an update of the baseline statistics as compared with the report from last year, which reflected only 20 participants. Sample characteristics from these preliminary data include: a mean age of 54 years (range 32-81 years), 92% Caucasian, 69% married or living with a partner, 84% have children, 41% have earned a college degree or higher, and 72% have an annual household income of $45,000 or greater. Approximately half the sample (53%) have been diagnosed with Stage 1 breast cancer and 36% have been diagnosed with Stage 2 breast cancer. With regard to treatment methods the majority of the sample (89%) received multiple treatment methods (lumpectomy and lymph node dissection 62%; lumpectomy, mastectomy, and dissection 11%; lumpectomy, dissection and radiation 24%; mastectomy and dissection 49%; mastectomy, dissection, and chemotherapy 17%). 52% of the lymph node dissections were sentinel node and 24% were axillary node. 6% of the sample received both a sentinel and axillary dissection.

Table 1: Patient Characteristics

Patient Demographics (N=65)		
Age, years (median (min, max)): 54 (32, 81)		
	N	**Percentage (%)**
Race		
White	50	77
Black	13	20
Asian	1	2
Missing/Refused	1	2
Ethnicity		
Hispanic or Latino	0	0
Non-Hispanic or Latino	61	94
Missing/Refused	4	6
Marital Status		
Single, never married	9	14
Married/Partnered	46	71
Separated	1	2
Divorced	6	9
Widowed	3	5
Education		
High School or Below	15	23
Vocational/Technical School	3	5
Undergraduate College/University	27	42
Graduate/Doctoral Degree	19	29
Treatment History		
Lumpectomy	46	71

Mastectomy	23	35
Lymph node dissection	62	95
Chemotherapy	22	34
Radiation	12	19

LYMPHEDEMA-RELATED KNOWLEDGE

At baseline, LE-related knowledge was moderate, with only 30% of the women answering the majority of questions (at least 17 out of 19) correctly. The mean knowledge score was 14 out of 19. At least 95% of the women were able to correctly identify that it is recommended to keep your LE affected arm very clean and well moisturized, 95% to avoid blood pressure readings and injections on the affected arm, and 92% to wear gloves when doing housework or gardening. The questions most frequently answered incorrectly were related to LE-related symptoms ("An inflammation or infection in the affected arm is a sign of LE", 52% incorrect), its onset ("LE can ONLY occur within the first month following surgery for breast cancer", 49%), BRCA treatment risk-related factors ("Breast cancer treatment increases your chances of developing LE", 18%; "Women who have axillary node surgery followed by radiation therapy have a higher risk of developing LE", 7%), and frequently performed risk-related behaviors ("It is advisable that you wear a well-fitted bra with wire support", 63%; "Only use an electric razor to remove hair from under your arm", 20%). Since early action to treat lymphedema is essential to managing this condition, a lack of awareness about typical symptoms and onset of lymphedema among this sample is concerning, and suggests a need for more effective patient education approaches regarding lymphedema risk. Following baseline assessment, all study participants were given an information booklet outlining lymphedema risk for breast cancer patients. Paired t-tests revealed a significant increase in levels of lymphedema knowledge at 6-months (mean = 17.2) compared with baseline (12.5) ($t=-10.1$, $df=36$, $p<.0001$).

Table 2: Lymphedema Related Knowledge

Lymphedema Knowledge Items	N= 65
It is recommended that you keep your affected arm very clean and well moisturized	95% Correct
It is advisable to avoid blood pressure readings and injections on the affected arm	95% Correct
It is advisable that you always wear gloves when doing housework or gardening	92% Correct
An inflammation or infection in the affected arm is not a sign of lymphedema	52% Incorrect
Lymphedema can only occur within the first month following surgery for breast cancer	49% Incorrect
It is advisable to wear a well-fitted bra with wire support	63% Incorrect

ADHERENCE TO LYMPHEDEMA MINIMIZATION PRACTICES

Using a dichotomous yes/no item format, preliminary baseline data show that adherence to certain LE-risk minimization strategies is high, especially those that entail more passive acceptance strategies. Specifically, 76% of the women are not cutting the cuticles of their affected arm (i.e., arm associated with the surgery); 87% are keeping their affected arm very clean and well moisturized; 81% are avoiding heavy lifting and carrying handbags with over the shoulder straps; 92% are avoiding tight jewelry around the affected fingers or arms; 76% are avoiding exposing the affected arm to the sun; and 90% of the women are currently avoiding blood pressure readings and injections on the affected arm. However, 55% of the sample are not currently using an electric razor to remove hair under their affected arm, 53% are not wearing gloves when doing housework or gardening, and 27% are not avoiding extreme temperature changes when bathing or washing dishes. These are three important, and rather routine, behaviors recommended to prevent LE that require more active strategies. Moreover, 21% report that they do not consult with the doctor if they have any slight increase of swelling in the affected arm, hand, fingers, or chest wall, possibly related to the participants' lack of awareness of lymphedema symptoms identified in the assessment of lymphedema-related knowledge. Paired t-tests revealed a significant increase in the number of preventive strategies practiced at 6-months (mean = 10.4) compared with baseline (9.4) ($t=2.82$, $df=36$, $p<.01$).

Table 3: Adherence to Lymphedema Minimization Practices

Lymphedema-related Adherence Items	N= 65
Avoid cutting cuticles when manicuring your nails	76%
Keeping their affected arm very clean and moisturized	87%
Avoid wearing tight jewelry around the affected fingers and arms	92%
Currently avoid blood pressure readings and injections on the affected arm	90%
Currently using an electric razor to remove hair from underarms	45%
Wearing gloves when doing housework or gardening	47%

PSYCHOSOCIAL PROFILE OF STUDY PARTICIPANTS

Attentional Style

Mean scores for the Monitor-Blunter Style Scale (MBSS) are comparable to those found in related research (Mean monitoring score=8.96, SD=2.76; Mean blunting score=3.93, SD=2.10).

Risk Perceptions

Overall, participants tended to underestimate their risk of developing LE. Specifically, when asked to rate their risk for developing LE on a 5 point Likert-type scale ranging from 1="much lower than average" to 5="much higher than average", 85% of the sample reported that they were at an average to lower than average risk for developing LE, despite the fact that in all cases the lymph node surgery they received placed them at an increased risk in comparison to breast cancer patients who do not have lymph node dissection or radiation. Moreover, of the women sampled who had received axillary node dissection, a treatment associated with an even higher risk for LE than sentinel surgery, 85% reported that they had an average to below average risk for LE despite the higher risk for LE development associated with this type of surgery. The actual risk of developing LE following axillary lymph node dissection increases to 38% to 56% when adjuvant radiation is provided, however no participants to date have had this treatment combination. There were no changes in perceptions of lymphedema risk from baseline to 6-months.

Expectancies

With respect to outcome related expectations, using a 5 point Likert-type scale ranging from 1="not at all" to 5="very much", a subset of women endorsed that LE is a serious condition (i.e., 32% "quite a bit"; 49% "very much"), that developing LE would interfere with their lives (i.e., 49% "quite a bit"; 21% "very much"), and that LE-related problems would last a long time (i.e., 30% "quite a bit"; 16% "very much"). A majority of the women endorsed a belief that there are measures they can take to prevent LE (i.e., 52% "quite a bit"; 12% "very much") and that practicing the recommended hand and arm procedures will minimize their chances of developing LE (i.e., 44% "quite a bit"; 26% "very much").

With regard to self-efficacy expectations, using the same Likert-type scale, a majority of the sample indicated that they did "not at all" believe that whether or not they developed LE was God's will (47%) or that the development of LE is just luck (55%), implying that they did not take a fatalistic view of LE development. A majority of the sample were certain that they can effectively adhere to recommended procedures to minimize LE risk (i.e., 43% "quite a bit"; 24% "very much") and that they will be regularly checking themselves for signs of LE (i.e., 33% "quite a bit"; 23% "very much"). The data indicate that although a majority of the women have positive expectations regarding LE preventive actions and a belief in their ability to carry them out, there is a large subset of individuals for whom this may not be the case. No differences in lymphedema-related expectancies and beliefs were reported from baseline to 6-month follow-up.

Table 4: LE- Related Expectancies N=65

	Not at all (%)	A little bit (%)	Somewhat (%)	Quite a bit (%)	Very much (%)
Do you believe that LE is a serious condition?		5	12	32	50
Do you believe that LE would interfere with life?	2	2	25	49	23
Do you believe LE-related problems would last a long time?	2	11	39	31	19
Do you believe practicing the recommended arm and hand precautions will minimize your chances of developing Lymphedema?	3	5	20	45	26
Do you believe that whether or not you develop lymphedema is god's will?	49	12	19	6	14
To what extent do you believe that you can effectively adhere to recommended arm and hand procedures to minimize lymphedema risk?	2	5	25	43	25

Distress

As measured by the Revised Impact of Events Scale (RIES), participants reported low to low-moderate LE risk-related distress, as defined by the presence of intrusive and avoidant risk-related ideation (Mean intrusion scale score=3.64, SD=5.46; Mean avoidance scale score=5.74, SD=7.87). There were no significant differences in levels of intrusive and avoidant ideation from baseline to 6-months.

Using a 5-point Likert-type scale ranging from 1="not at all" to 5="very much", women were asked to rate their LE-risk related affect. Overall, women reported low levels of risk-related affect. Specifically, a majority of women endorsed "not at all" or "a little bit" when asked if they were experiencing thoughts of LE that affected their mood or ability to perform daily activities (mood: 53% "not at all", 27% "a little bit"; ability to perform daily activities: 61% "not at all", 23% "a little bit"), or the experience of LE-risk related worry (32% "not at all", 44% "a little bit"), sadness/depression (38% "not at all", 36% "a little bit"), anxiety (35% "not at all", 38% "a little bit"), or anger (60% "not at all", 20% "a little bit"). However, despite this tendency to manage LE-risk related emotions, there is a subset of women for whom risk related affect was more present. For example, there is a group of women who endorse "somewhat", "quite a bit", or "very much" when asked if they have LE-related thoughts that have affected their mood (4% "somewhat", 12% "quite a bit") or daily activities (7% "somewhat", 4% "quite a bit", 1% "very much"), or feel worried (7% "somewhat", 10% "quite a bit", 3% "very much"), sad/depressed (13% "somewhat", 6% "quite a bit", 3% "very much), scared/anxious (15% "somewhat", 6% "quite a bit", 3% "very much"), or angry (13% "somewhat", 4% "very much") regarding their LE risk. Moreover, a number of women report that they are "somewhat" (23%), "quite a bit" (9%), or "very much" (1%) worried about knowing when to contact the doctor about any LE symptoms they experience. Paired t-tests revealed significant

decreases in levels of lymphedema-related worry from baseline (mean=2.08) to 6-months later (mean=1.63) (t=2.25, df=37, p<.05); feelings of sadness or depression in relation to lymphedema risk (baseline=1.84; 6-months=1.42)[t=2.59, df=37, p<.02]; lymphedema risk-related anxiety (baseline=1.97; 6-months=1.50) [t=2.90, df=37, p<.01]; and anger regarding lymphedema risk (baseline=1.66; 6-months=1.34) [t=2.78, df=37, p<.01]. In addition, compared with baseline, at 6-months participants reported fewer cases of having thoughts about lymphedema risk influence their mood (t=2.162, df=37, p<.05) or affecting their ability to perform daily activities (t=2.49, df=37, p<.02).

Table 5: LE-Related Distress N=65

	Not at all (%)	A little bit (%)	*Somewhat* (%)	Quite a bit (%)	Very much (%)
How after have thought about Lymphedema affected your mood?	54	28	5	14	0
How often have thought about Lymphedema affected your ability to perform your daily activities?	62	25	8	5	2
Have you been worried about you risk for lymphedema?	32	45	8	11	5
Have you felt sad or depressed when thinking about your risk for lymphedema?	39	37	15	6	3

Values and Goals

Overall, women reported placing a large degree of value on their physical appearance and physical functioning. Using a 5-point Likert-scale ranging from "not at all" to "very much," the entire sample reported "functioning well" to be "quite a bit" (10%) to "very much" (86%) important to them. Similarly, the entire sample reported "feeling well" to be "quite a bit" (12%) to "very much" (84%) important to them. In addition, the majority of the sample reported the following to be "quite a bit" to "very much" important to them: the way in which they perceive their own bodies (49% and 32%, respectively), feeling attractive (35% and 35%, respectively). Eight-seven percent of the baseline sample reports the way in which their partner perceives their body to be "somewhat" (23%), "quite a bit" (43%), or "very much" (21%) important to them.

Table 6: LE-Related Values and Goals N=65

	Not at all (%)	A little bit (%)	*Somewhat* (%)	Quite a bit (%)	Very much (%)
Importance of functioning well?	0	0	1.5	11	87
Importance of feeling well?	0	0	1.5	12	86
To what extent is the way you perceive your body important to you?	0	0	16.9	49	34
To what extent is the way your partner perceives your body important to you?	2	3	23	43	23

Self-Regulatory Strategies

Using a 5-point Likert-type scale ranging from 1="not at all" to 5="very much", women were asked to rate their ability to manage LE-related thoughts and strategic plans to reduce their risk of developing LE. Overall, women reported a positive sense of control over their ability to manage LE-related feelings and the behaviors in which they were able to engage. Specifically, the majority of the sample felt that they were "quite a bit" (36%) to "very much" (41%) able to make the necessary lifestyle changes in order to carry out recommended LE minimization precautions and that they were "quite a bit" (41%) to "very much" (36%) able to follow the recommended behaviors that may minimize LE symptoms. A majority of the sample felt that they are "quite a bit" (33%) to "very much" (38%) able to limit the amount of stress they experience when they perform the recommended symptom minimization practices, that they are "quite a bit" (32%) to "very much" (27%) able to limit the amount of stress they experience about their LE risk, and that they are "quite a bit" (30%) to "very much" (26%) able to calm themselves down when they experience anxiety or worry about developing LE. Paired t-tests revealed significant increases in self-regulatory skills from baseline to 6-months with participants reporting being better able to calm down when feeling anxious about lymphedema risk (baseline=3.58; 6-months=4.33)[t=-4.49, df=32, p<.0001], and to limit the amount of stress experienced when practicing lymphedema risk-minimization strategies (baseline=4.06; 6-months=4.57)[t=-2.60, df=34, p<.02].

Table 7: LE-Related Self-Regulatory Strategies N=65

	Not at all (%)	A little bit (%)	*Somewhat* (%)	Quite a bit (%)	Very much (%)
I am able to limit the amount of stress I experience about my lymphedema risk.	2	6	32	32	27
I am able to make necessary lifestyle changes to carry out recommended precautions to minimize lymphedema symptoms?	3	3	14	36	43

KEY RESEARCH ACCOMPLISHMENTS

- Continue to hold weekly project staff meetings.
- 39 new participants have completed baseline measures since August 2003. Forty-eight 6-month follow-up questionnaires and 34 12-month follow-up questionnaires have been collected since August 2003.
- Twice weekly, members of the research team have accessed the FCCC electronic Soarian Clinical Access Database to identify new patients attending the Breast Evaluation Clinic at either site. Approximately, 5-10 new potential participants are identified on a weekly basis. Potential participants are FCCC patients who are initiating their breast cancer treatment or women who have come to FCCC for an initial consultation or post-diagnosis/pre-treatment second opinion.
- Potentially eligible women were tracked on a regular basis until their full eligibility (i.e., cancer stage, post-surgery status, receiving treatment at FCCC) can be determined. Eligible patients are contacted by telephone to solicit participation in the study after their medical records indicate that they have completed their surgery.
- Members of the research team continue to enter data from all study questionnaires as they are collected.
- The research team maintains an Access database to track participant follow-up. After a participant completes the baseline survey they are entered into the Access database and monitored to coordinate their follow-up interview date.
- In order to clearly ascertain the course of adjuvant treatment breast cancer patients will receive, 2 questions have been added to the questionnaire to assess their anticipated treatment. This will allow for a more accurate report of perception of risk among participants who are aware of any upcoming adjuvant treatment.
- In an effort to enhance recruitment, we have extended recruitment to breast cancer patients receiving care at Virtua Memorial Hospital, in New Jersey.
- The FCCC IRB audited this study in February 2004 and found it to be in accordance with compliance regulations.

REPORTABLE OUTCOMES

We have compiled 5 papers that analyze literature on adherence and adjustment in breast cancer disease/risk context and integrated findings obtained with our guiding theoretical model.

- Miller, S.M. & Sherman, K.A. (2004). Cancer screening. In N. Anderson (Ed.) The Encyclopedia of Health and Behavior. CA: Sage Publications.

- Miller, S.M., Bowen, D. J., Campbell, M.K., Diefenbach, M.A., Gritz, E.R., Jacobsen, P.B., Stefanek, M., Fang, C.Y., Lazovich, D., Sherman, K.A., Wang, C. (2004). Current research promises and challenges in behavioral oncology: Report from the American Society of Preventive Oncology Annual Meeting. Cancer Epidemiology, Biomarkers and Prevention, 13, 171-180.

- Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Rayser, & Popa-Mabe, M. (in press) Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on Health Communication.

- Miller, S.M., Roussi, P., Daly, M.B., Buzaglo, J.S., Sherman, K.A., Godwin, A.K., Balshem, A., & Atchison, M.A. (in press) Enhanced counseling for women undergoing BRCA1/2 testing: Impact on subsequent decision making about risk prevention behaviors. Health Education and Behavior, Special Issue on Genetic Risk.

- Sherman, K.A., Miller, S.M., Gorin, S.S., et al. Psychosocial determinants of participation. Psychosocial determinants of participation in breast cancer risk counseling programs and screening regimens among African-American women. NY: Susan G. Komen Foundation and African American National Advisory Committee, in press.

- We are also preparing three volumes that will integrate our ongoing study with the larger field of behavior and oncology.

  - Miller, S.M., McDaniel, S., Rolland, J., & Feetham, S. (Eds.) Individuals, families, and the new genetics. New York: Norton Publications, in press.

  - Miller, S.M., Bowen, D., Croyle, R. & Rowland, J. (Eds.) Handbook of psychosocial approaches to cancer prevention. Washington, D.C.: American Psychological Association, in preparation.

  - Elk, R., Miller, S.M., & Daly, M.B. Cancer and the Ashkenazi Jewish Woman. McGraw-Hill Publications, in press.

CONFERENCE PRESENTATIONS AND DISTINGUISHED VISITORSHIPS

Miller, S.M., Fleisher, L., Rodoletz, M., Buzaglo, J.S., Glenn, M., Higman, S., Cornfeld, M., Schnoll, R.A., Balshem, A., & Engstrom, P.F. Implementation of a Worksite Cancer Control Program: Enhancing Cancer Prevention-related Intentions and Attitudes Among Worksite Employees. Paper presented at Translating Research Into Practice (TRIP): Advancing Excellence from Discovery to Delivery, Symposium on Innovation in TRIP for Prevention, Washington, D.C., July, 2004.

Miller, S. M. 8th International Congress of Behavioral Medicine. Paper on: Tailoring Monitoring vs. blunting in the preparation for stressful medical procedures. Part of Invited Symposium on: Psychological Preparation for Medical Intervention. Mainz, Germany. August, 2004.

Miller, S.M. University of Michigan School of Public Health. Invited Speaker on: Facilitating Risk Processing in at-risk populations as part of Symposium on The Challenge Ahead: Implications of Genomic Information in Public Health Education and Behavior Change. Ann Arbor, MI, October, 2004.

Miller, S.M. 29th Annual Meeting of the American Society of Preventive Oncology, San Francisco, CA. March, 2005.

Miller, S.M., Sponsored by American Associates, Ben-Gurion University, Philadelphia Chapter, and Fox Chase Cancer Center. Invited speaker on: Fighting Breast Cancer March , 2005.

Miller, S.M. Invited Speaker on: A Developmental Perspective Cancer Risk and Responses. University of the Sacred Heart, Tokyo, Japan, March 2005.

Miller, S.M. Invited Speaker: Psychosocial Factors in Cancer. Choju Medical Research Center, Mie, Japan, March, 2005.

Miller, S.M., Chair, Invited Symposium and Roundtable Session on Decision Making in the Cancer Context – Translation from Basic Science through Population Health. Annual Meeting of the Society of Behavioral Medicine. Boston, MA. April, 2005.

Miller, S.M. Invited Colloquium on Coping with Cancer Risk and Disease: Is There a Role for Behavioral Science? Sponsored by Case Western Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH. April 29, 2005.

Miller, S.M. University of Padova (sponsored by the Department of Pediatrics). Invited Speaker on Monitoring vs. Blunting Styles of Coping: To See or Not to See?, Padova, Italy, May 2005.

Miller, S.M. Invited Speaker, Presented as part of Invited Symposium on Educating Women about Risk Counseling/Genetic Testing Makes a Difference in Intended Use of Services, Especially among those at High-Risk: Results of a Randomized Trial Among Callers to the Cancer Information Service. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Co-Chair, Invited Symposium on People and Populations. The Department of Defense(DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Speaker on Tailored Communication to Enhance Adaptation across the Breast Cancer Spectrum. Presented as part of Invited Symposium on Behavioral Centers of Excellence: Treating More Than the Tumor. The Department of Defense (DOD) Fourth Era of Hope Meeting, Philadelphia, PA, June, 2005.

Miller, S.M. Invited Speaker. Stress and Anxiety Research Society (STAR). Crete, July, 2006.

CONCLUSIONS

Although the number of participants is lower than had been anticipated, we expect that the addition of a recruitment site and the requested extension of our recruitment period will improve accrual rates. Recruitment began at the additional site, but was unsuccessful due to the late approval, and we were not able to contact a number of women in time for them to still be eligible. Thus, an additional 12-months of continuous recruitment efforts would greatly increase accrual rates. Due to a change in the electronic medical records database at FCCC, research efforts were delayed for a short period of time while members of the research team were trained in the navigation of this system. However, as this training is completed and as recruitment continues, we anticipate no further obstacles in conducting our study as scheduled, and we expect no additional delays in the progress of this project.

With the addition of 18 participants over the past year, descriptive data continue to indicate that there is a need for increased LE education and improved adherence to LE-related behaviors. Although a number of women are aware of LE minimization practices and their potential benefits, preliminary data suggest that they are not incorporating all of the recommendations into their daily lives, especially those that may constitute active strategies. Additionally, preliminary descriptive data analysis shows a significant correlation between high monitoring styles with more accurate knowledge of lymphedema risk factors (e.g. knowledge of the fact that women who have axillary node surgery followed by radiation therapy have higher risk of developing lymphedema. Moreover, our early data suggest that promoting the maintenance of LE preventive/minimization behaviors and enhancing the management of LE risk-related emotions over time may be a worthwhile focus for a subset of individuals. Taken together, our preliminary findings support the importance of this study in increasing LE-related knowledge and improving health behaviors to reduce women's risk for developing LE.

This research will fill a void in the breast cancer literature with respect to lymphedema. Survivors of breast cancer need to attend to the types of precautionary measures they can employ to prevent and control the occurrence of symptoms. However, little is known about how individuals understand and make sense of these issues, and few resources have been developed to address this problem. Hence, it is important to explore the psychosocial factors that facilitate or undermine the uptake of preventive behaviors, as well as their sustained maintenance over time.

Through more systematic investigation of these factors, we will be able to develop a profile of the role of cognitive-emotional processing in the management of lymphedema. These data will ultimately be used to design and evaluate enhanced management protocols, tailored to the individual's cognitive-emotional signature.

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APPENDICES

Appendix 1

Meeting Report

Current Research Promises and Challenges in Behavioral Oncology: Report from the American Society of Preventive Oncology Annual Meeting, 2002

Suzanne M. Miller,[1] Deborah J. Bowen,[2] Marci K. Campbell,[8] Michael A. Diefenbach,[1] Ellen R. Gritz,[3] Paul B. Jacobsen,[4] Michael Stefanek,[5] Carolyn Y. Fang,[1] DeAnn Lazovich,[7] Kerry A. Sherman,[1] and Catharine Wang[6]

[1]Fox Chase Cancer Center, Philadelphia, Pennsylvania; [2]Fred Hutchinson Cancer Center; [3]The University of Texas M. D. Anderson Cancer Center; [4]Moffit Cancer Center; [5]National Cancer Institute; [6]University of Michigan; [7]University of Minnesota; and [8]University of North Carolina

Abstract

The Behavioral Oncology Interest Group of the American Society of Preventive Oncology held a Roundtable session on March 10, 2002, at the American Society of Preventive Oncology annual meeting in Bethesda, Maryland, to discuss the current state-of-the-science in behavioral approaches to cancer prevention and control and to delineate priorities for additional research. Four key areas were considered: (*a*) behavioral approaches to cancer genetic risk assessment and testing; (*b*) biological mechanisms of psychosocial effects on cancer; (*c*) the role of risk perceptions in cancer screening adherence; and (*d*) the impact of tailored and targeted interventions on cancer prevention and control research. The evidence reviewed indicates that behavioral approaches have made significant contributions to cancer prevention and control research. At the same time, there is a need to more closely link future investigations to the underlying base of behavioral science principles and paradigms that guide them. To successfully bridge the gap between the availability of effective new cancer prevention and control technologies and the participants they are meant to serve will require the development of more integrative conceptual models, the incorporation of more rigorous methodological designs, and more precise identification of the individual and group characteristics of the groups under study.

Introduction

Behavior has been shown to play a key role in many aspects of cancer prevention and control from disease risk through treatment through survivorship. Indeed, behavioral science has emerged as one of the key priorities at the National Cancer Institute and a rapidly growing area for funded research (1). Yet, behavioral science is not always well integrated with other research areas; for example, behavioral research is often not coordinated with the clinical research agenda of the nation's cancer centers and investigations. In 2000, we therefore established a Behavioral Oncology Interest Group, nested within the existing umbrella organization of the American Society of Preventive Oncology. To date, the Behavioral Oncology Interest Group Steering Committee, comprised of behavioral scientists, has brought together a group of ~200 investigators who all share ongoing interests and active research programs at the interface of behavioral science and oncology. The mission of this group is to provide a structured forum for behavioral interactions and collaborations, with a view to addressing basic unresolved issues in psychosocial assessment and intervention approaches to cancer prevention and control.

To further this mission, we arranged a preconference session at the March 2002 meeting of American Society of Preventive Oncology, held in Bethesda, Maryland, with the goal of conducting a state-of-the-science evaluation of current areas of research focus in behavioral oncology. Four areas of research interest were chosen by the Behavioral Oncology Steering Group via a series of telephone conference calls before the annual meeting. These areas were as follows: (*a*) behavioral approaches to cancer genetic risk assessment and testing; (*b*) biological mechanisms of psychosocial effects on cancer; (*c*) the role of risk perceptions on cancer screening adherence; and (*d*) the impact of tailored and targeted interventions on cancer prevention and control research. The four topics were judged to be sufficiently well established in the behavioral oncology field to have generated an impressive and tantalizing array of research findings. The overarching goal of the roundtables was to provide an overview of what is known, what is suspected, and what is still unknown or unexplained to delineate priorities for research concentration and collaboration.

Two behavioral science leaders were selected to lead each roundtable based on their expertise in the field. One recorder supported the work of each roundtable. Discussions lasted on average one and one-half hours and were tape recorded. Participants were comprised mainly of behavioral scientists and self-selected into a roundtable based on interest and/or expertise. The specific objective of each roundtable was to summarize the current state of the field and to recommend potential directions and areas for future research. In this article, we highlight the key conclusions of the four roundtable discussions. For each topic area, we present the conclusions in terms of: (*a*) key findings and goals of the research area; (*b*) strengths of the research area; (*c*) weaknesses of the research area; and (*d*) directions for future research.

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FACILITATING INFORMED DECISION MAKING ABOUT BREAST CANCER RISK AND GENETIC COUNSELING AMONG WOMEN CALLING THE NCI'S CANCER INFORMATION SERVICE

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Acknowledgements: This research was supported in part by the Department of Defense DAMD17-98-1-8306, DAMD17-01-1-0238 and DAMD17-02-1-0382 grants and the Fox Chase Cancer Center's Behavioral Research Core Facility (P30CA06927) and NIH grant R01HG01766. We thank the Atlantic Region CIS Information Specialists who provided important insights into the development of the interventions and who diligently implemented the interventions over two years; Nancy McKeown Conn and Lisa Brower for their superb

management of all aspects of the research project and Susan Echtermeyer and Jamie Rodriguez for manuscript production.

Abstract: Despite increased interest among the public in breast cancer genetic risk and genetic testing, there are limited services to help women make informed decisions about genetic testing. This study, conducted with female callers (N=279) to the NCI's Atlantic Region Cancer Information Service (CIS), developed and evaluated a theory-based, educational intervention designed to increase callers' understanding of: a) the kinds of information required to determine inherited risk; b) their own personal family history of cancer; and c) the benefits and limitations of genetic testing. Callers requesting information about breast/ovarian cancer risk, risk assessment services, and genetic testing were randomized to either: 1) standard care or 2) an educational intervention. Results show that the educational intervention reduced intention to obtain genetic testing among women at average risk and increased intention among high risk women at 6 months. In addition, high monitors who typically attend to and seek information, demonstrated greater increases in knowledge and perceived risk over the six-month interval, than low monitors, who typically distract from information. These findings suggest that theoretically designed interventions can be effective in helping women understand their cancer risk and appropriate risk assessment options and can be successfully implemented within a service program, like the CIS.

Running Head: DECISION MAKING IN *BRCA1/2* TESTING

Enhanced Counseling for Women Undergoing *BRCA1/2* Testing: Impact on Subsequent Decision Making About Risk Reduction Behaviors

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ABSTRACT

We evaluated the impact of an enhanced counseling intervention, designed to promote well-informed decision making for follow-up risk reduction options for ovarian cancer, among high-risk women undergoing *BRCA1/2* testing (N = 77). Following standard genetic counseling, participants received either an Enhanced Counseling session -- designed to help participants anticipate their reactions to possible test outcomes and plan for post-result consequences -- or a General Health Information control session. One week after disclosure of test results, women in the enhanced counseling group experienced a greater reduction in avoidant ideation, suggesting more complete processing of risk feedback. At the six month follow-up, intervention subjects reported seeking out more information about prophylactic oophorectomy, and were more likely to have actually undergone preventive surgery. The results indicate that the use of enhanced counseling can play an important role in decision making about risk reduction behaviors following *BRCA1/2* testing.

Keywords: *BRCA1/2* genetic *risk*, prophylactic ovarian surgery, enhanced counseling intervention

Appendix 2

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Suzanne M. Miller, Ph.D.	Senior Member

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
McGill University, Montreal, Canada	B.S.	1972	Psychology
University of London, Institute of Psychiatry, Maudsley Hospital, London, England	Ph.D.	1976	Psychology (Clinical)

POSITIONS AND EXPERIENCE

Assistant Professor, University of Western Ontario, Department of Psychology, Canada	1976-1977
Research and Clinical Fellow, University of Pennsylvania, Dept of Psychiatry, Phila., PA	1977-1979
Visiting Scholar, Stanford University, Department of Psychology, Stanford, CA	1978-1979
Assistant Professor, Temple University, Department of Psychology, Philadelphia, PA	1979-1983
Associate Professor, Temple University, Department of Psychology, Philadelphia, PA	1983-1993
Adjunct Professor, Temple University, Department of Medicine, Philadelphia, PA	1985-1993
Professor, Temple University, Department of Psychology, Philadelphia, PA	1993-1995
Associate Member, Institute for Health, Health Care Policy, and Aging Research, Rutgers University, New Brunswick, NJ.	1991-date
Adjunct Professor, University of Pennsylvania, Department of Psychiatry, Philadelphia, PA	1993
Adjunct Professor, Temple University, Department of Ob/Gyn, Philadelphia, PA	1993
Senior Member, Division of Population Science, Fox Chase Cancer Center, Philadelphia, PA	1995
Director, Psychosocial and Behavioral Medicine, Fox Chase Cancer Center, Philadelphia, PA	1995
Director, Behavioral Research Core Facility, Fox Chase Cancer Center, Philadelphia, PA	2000
Director, Behavioral Center of Excellence in Breast Cancer, Fox Chase Cancer Center, Philadelphia, PA	2001

SELECTED HONORS

Behavioral Medicine Study Section Chartered Member, National Institutes of Health	1991
Visiting Professor and Distinguished Lecturer, Psychology, Univ. of Amsterdam, Netherlands	1992
Fellow, American Psychological Association	1996-
Executive Committee Member, Division 38 (Health Psychology), American Psych. Assn.	1996-
Member, NIH Cancer Genetics Studies Consortium	1998-
Visiting Professor and Distinguished Fellow, Japanese Society for the Promotion of Science	1999
Member & Chair, Psychosocial, Behavioral, & Policy Research, ACS Peer Review Committee	1999
Founder & Chairperson, Oncology Special Interest Group, American Soc. of Prev. Oncology	2000-
Series Editor, Norton Books Genetics Series	2000-
Convenor of NCI Invitational Conference on Psychosocial Approaches to Cancer Prevention	2000
Executive Committee, American Society of Preventive Oncology	2000-
Member and Co-Chair of the Behavioral Working Group, NCI Early Lung Cancer Consortium	2001-
Scientific Advisor, Behavioral Program, Memorial Sloan-Kettering Cancer Center; Dartmouth College	2001-
Recipient, Cancer Information Service Atlantic Region Award for Partners in Research	2001
Invited Participant, Robert Wood Johnson Foundation Meeting on Shared Decision Making	2001-
Editorial Boards: Cancer Epidemiology, Biomarkers, & Prevention; J. of Women's Cancer	2001-
Member, NCI Cancer Information Service Advisory Committee on Health Commun Research	2001-
Recipient, Cancer Control Award, American Cancer Society	2002
Board of Directors, New Jersey Health Care Quality Institute	2002-
Visiting Professor and Distinguished Lecturer, University of Bologna, Bologna, Italy	2003

Visiting Scholar, Japanese Foundation for Aging Research, Tokyo, Japan 2004
Chair, Steering Committee, Cancer Special Interest Group, Society of Behavioral Medicine 2004-
Member, Cancer Epidemiology and Prevention Awards Committee, AACR 2004-
Member, Office of Cancer Information Service Advisory Panel on Strategic Direction for the CIS Research Program 2004-
Member, National Quality Forum Symptom Management/End of Life Care Technical Panel 2004-
Member, American Cancer Society, Science Council 2004-
Member, Steering Committee, Fox Chase Cancer Center Program on Medical Outreach and Minority Affairs 2005-
Advisor, Case Western Reserve University Cancer Center, Cleveland, OH 2005.
Advisor, James Graham Brown Cancer Center, University of Louisville, Kentucky 2005

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Appendix 3

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

10.26.04

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [X] CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:	**IRB# 01-851**

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other.
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.	**Suzanne M. Miller, PhD**

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA-00003846 , the expiration date 12/2/05 IRB Registration No. 00000050

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting _____ or [X] Expedited Review on 10/12/04 [ ] Facilitated Review on ____
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments: **This study expires 364 days from the date of approval.**

Amendment #13 – Clarification of participating Virtua physician's role in recruiting Virtua patients, as per DOD recommendation.

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	215-728-2204	Fox Chase Cancer Center 333 Cottman Avenue Philadelphia, PA 19111-2497
12. Fax No. *(with area code)*	215-214-4256	
13. Email:	W. T. London@fccc.edu	
14. Name of Official W. Thomas London, MD		15. Title Chairperson, Institutional Review Board
16. Signature W T London		17. Date **10/12/04**

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FOX CHASE CANCER CENTER

Memorandum

To: Institutional Review Board Coordinator
Through: Research Review Committee

From: Melanie Glenn, M.P.H.

Date: 9/30/03

Subject: Protocol Amendment

RE: **Protocol IRB# 01-851 PIs: Suzanne M. Miller, Ph.D, Michelle Rodoletz, Ph.D. & Kerry Sherman, Ph.D**
Amendment # 13
Title: Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.

The attached amendment has been received from the sponsoring agency, cooperative group, or principal investigator of the above referenced protocol. Review and approval is requested from the Research Review Committee (RRC) followed by the Institutional Review Board (IRB). Changes in the protocol as a result of this amendment require the following action to be taken by the IRB:

☒ ***No change in any patient risk factors relative to the originally approved version of this study. Please incorporate into the IRB file for purposes of compliance with Federal regulations.***

☐ ***Patient risk factors have been changed relative to the originally approved version of this study. Board approval of amendment and/or consent form revisions are required. Please incorporate into the IRB file for purpose of compliance with Federal regulations.***

Due to the scope of this amendment, the following action will be taken:

☒ ***Study will remain open to accrual.***

☐ ***Study accrual on hold pending IRB approval of this amendment.***

If this amendment is approved by the IRB, the principal investigator of this protocol will require the following documentation for continued patient accrual:

☐ ***No Further Action is required other than IRB notification.***

☒ ***Documentation of the IRB's approval of this amendment is needed. Please provide a signed HHS-310 form indicating the protocol and amendment number.***

☐ ***A new "stamped" consent form indicating the IRB has approved the revisions.***

****

Note: Per requirements of the IRB and Protocol Management Facility, documentation of Research Review Committee approval is required for all protocol amendments prior to IRB submission.

Reviewed and Approved by RRC: _____ 10-3-04
(Signature RRC Chairman or Designated Member) *(Date)*

For Internal Use Only After Approval:

☐ **Protocol File**	☐ **IRB (Original)**
☐ **Team**	☐ **Sponsor**
☐ **FCN**	☐ **Other:_____**

(form version: 2/9/2000)

FOX CHASE CANCER CENTER

To: IRB, RRC

From: Melanie Glenn, M.P.H.
Kerry Sherman, Ph.D
Michelle Rodoletz, Ph.D.
Suzanne M. Miller, Ph.D

Date: 9/30/04

Re: Amendment # 13 to IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors" (PIs: Suzanne M. Miller, Ph.D., Michelle Rodoletz, Ph.D., & Kerry Sherman, Ph.D.)

Dear RRC, IRB,

The purpose of this memo is to request review of the following amendment to the protocol for IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors." The amendment is as follows:

1. After submitting amendment materials to the DOD for approval of the addition of Virtua Memorial Hospital as a recruitment site, we were asked to clarify the participating physician's, Dr. Eric Miller, role on the study in the protocol. We have thus added Dr. Eric Miller's name to the protocol, given him the title of "primary site coordinator" and explained his exact role on the study. Since the original approval of this amendment did not explicitly state the site coordinator's name and role on the study, we revised the protocol and will now seek approval from the FCCC and Virtua IRB. Upon approval of this amendment, we will again go to the DOD for final approval. The exact change is listed below.

   Previously, the amendment to the protocol that was approved read, "**For patients receiving care at Virtua Memorial Hospital, the treating physician will introduce the LE study and distribute study brochures to all patients receiving care for Stage I, II, or IIIa breast cancer who have not previously opted out of research through HIPAA. The treating physician will then obtain the patient's consent to be contacted by a FCCC researcher. Upon obtaining consent from the patient to be**

solicited for recruitment, this physician will also obtain and forward the patient's medical history to FCCC staff, along with this consent form. Once this information is received, staff at FCCC will determine eligibility and contact any patients who are eligible and have provided consent to be contacted. Consenting patients will complete the study-specific informed consent form by mail and all measures by telephone."

The amendment now reads, **"For patients receiving care at Virtua Memorial Hospital, Dr. Eric Miller, the primary site coordinator, will be responsible for facilitating recruitment. Specifically, Dr. Miller will be responsible for introducing the study using the study brochure and explaining the study to all of his patients receiving care for Stage I, II, or IIIa breast cancer who have not previously opted out of research through HIPAA. He will also be responsible for obtaining consent from his patients to be contacted by a member of the Fox Chase Cancer Center (FCCC) research staff. Upon receiving this consent to be contacted, Dr. Miller will provide specific medical information (i.e., cancer stage, treatment type, date of surgery) by mail to the FCCC research staff, who will review this information to determine eligibility. After determining eligibility, a member of the FCCC research team will contact those patients who have provided consent to be contacted. Consenting patients will complete the study-specific informed consent form by mail and all measures by telephone. "**

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [X] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [X] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity Fox Chase Cancer Center		5. Name of Principal Investigator, Program Director, Fellow, or Other Eric Miller, MD

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00002656 the expiration date 6/5/2005 IRB Registration No. IRB00002494

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____ *(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations by:
- [X] Full IRB Review on (date of IRB meeting) 12/2/04 or [ ] Expedited Review on (date)
- [ ] If less than one year approval, provide expiration date _____
- [ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

AMENDMENT APPROVAL:

IRB 01-851, Cognitive-Affective Predictors of the Uptake of and Sustained Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors - *protocol amended, per DOD request, to clarify role of Eric Miller, MD*

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution VIRTUA HEALTH 94 BRICK ROAD MARLTON, NJ 08053
11. Phone No. *(with area code)* 609-267-0700 x 4190 12. Fax No. *(with area code)* 609-261-3542 13. Email:	
14. Name of Official Howard Press, DO	15. Title Chairperson, Oncology Institutional Review Board
16. Signature Howard Z. Press	17. Date December 2, 2004

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VIRTUA HEALTH

Patient Consent for Research Study

Cognitive-affective factors associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

I am being asked to take part in a research study of women who are at risk for developing lymphedema following surgery and treatment for breast cancer. Taking part in the study is entirely voluntary. The nature of the study, the risks, inconveniences, discomforts, and other pertinent information about the study are explained below. I am urged to discuss any questions I have about this study with my doctor and the staff members.

I have been invited to participate in this study because of my increased risk for lymphedema.

Why is this study being done?

The purpose of this study is to assess the patterns of adherence to lymphedema symptom minimization practices among women who have undergone treatment for primary breast cancer. This research is being done because it is not known what factors affect women's knowledge about lymphedema, and what factors affect the practice of precautionary measures designed to minimize lymphedema symptoms. The expected duration of my participation is 12 months, as described below. About 178 women will participate in this study.

What is involved in the study?

All women who participate in this study will initially be introduced to the study by a Nurse at either a weekly orientation session at FCCC, at the primary consultation at FCCC's Bryn Mawr offices, **or by the treating physician at Virtua Memorial Hospital**. The orientation session, conducted through the Social Services Department at FCCC, and the consultations held at FCCC's Bryn Mawr offices are attended by women who have been diagnosed with breast cancer but have not yet begun any further treatment or follow-up visits. Interested women can initiate participation in the study by contacting the Researcher at the phone number provided on the information brochure. Those who have not initiated participation will be contacted by the Researcher within three weeks of receiving the information brochure. Consenting, eligible **FCCC** participants will sign a consent form and complete psychosocial baseline measures at a subsequent, private meeting with the Researcher. **Virtua patients consenting to be contacted will be solicited for participation by telephone, will be asked to complete a consent form by mail, and will then complete psychosocial baseline measures during a subsequent telephone call with the Researcher upon receipt of the signed consent form.** 6-months and 12-months after the initial questionnaire, **all** participants will be contacted by the Researcher to conduct a telephone-based interview.

VIRTUA HEALTH
Patient Consent for Research Study

Cognitive-affective factors associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

As part of this study, I will be asked to complete questionnaires at the following points:

1) During the first 6 weeks following surgical treatment for breast cancer;
2) 6-months after my completion of the baseline questionnaires (telephone-based interview)
3) 12-months after my completion of the baseline questionnaire (telephone-based interview).

These questionnaires may take between 30 and 40 minutes to complete each time.

How long will I be on this study?
We think I will be in the study until I complete the final follow-up survey, which will entail a telephone interview approximately 12-months following completion of the baseline questionnaire. Thus, the entire duration of my participation in the study will be approximately 12-months.

What are the risks of the study?
There is very little risk associated with participating in this study. It is possible that talking about my lymphedema risk might make I anxious. In such an event I am encouraged to inform the health educator about my feelings. This individual is trained to help me cope with lymphedema-specific worries. In addition, in the event that I feel anxious, worried or uncomfortable about any of the questions, I can choose not to answer those questions without jeopardizing my participation in this program. There may also be other risks that we cannot predict. Significant new findings developed during the course of the research, which may relate to my willingness to continue participation will be provided to me. I am free to refuse to answer specific items on the questionnaires without consequence for my medical care. I am also free to withdraw from the study without consequence.

Are there benefits to taking part in the study?
If I agree to take part in this study, there may or may not be direct benefit to me. I will receive information that may benefit me, including knowledge of risk factors for lymphedema, ways to minimize my risk for lymphedema, and methods for early detection of lymphedema symptoms. We hope the information learned from this study will benefit other patients dealing with lymphedema risk in the future.

What other options are there?
Instead of being in this study, I have these options:

1) I can obtain information about lymphedema from the Nurse Educator or other information sources without participating in this study.

Please talk to the staff members about this and other options.

VIRTUA HEALTH
Patient Consent for Research Study

Cognitive-affective factors associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

What about confidentiality?

FCCC/Virtua Health will have access to my personal medical records; however, all efforts will be made to keep this and any other personal information confidential. The confidentiality of any central computer record will be carefully guarded and no information by which I can be identified will be released or published. FCCC/Virtua Health cannot guarantee absolute confidentiality. My personal information may be disclosed if required by law. Representatives of the Fox Chase Cancer Center, study's sponsor (Department of Defense), Virtua Health and other organizations may inspect and/or copy my research records for quality assurance and data analysis. Paper copies of the questionnaires will be kept in a locked file to which only the research staff will have access. Computerized data from the study will be password protected and accessible only to study personnel. Any reports or manuscripts about the study will contain no information by which I could be identified.

As previously mentioned, I am being asked to complete questionnaires for this study. These questionnaires will provide information about my demographics, medical history, and family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors relating to my lymphedema.

It will take 30-40 minutes to complete the questionnaires, and I will be asked to complete them on 3 different occasions either in person or via a telephone interview.

What are the costs?

I will receive no pay for taking part in this study of counseling sessions for women at risk for lymphedema. Any clinic visits or exams that I undergo at Fox Chase Cancer Center or Virtua Health that are not part of this study will be billed to my insurance company.

In the event of physical injury resulting from this study, medical treatments to the extent that it is available can be provided. The financial burden for this treatment may be my personal responsibility. No monetary compensation (pay) will be provided for wages lost or for any other reason because of injury resulting from this study.

Whom do I call if I have questions or problems?

I am free to ask questions at any time about these procedures and to ask for additional information from the investigator, the Researcher, or other designated representatives, or doctors involved in my care. If I have questions, I can reach the investigators of this project, **Dr. Eric Miller at (609) 267-7050.**

VIRTUA HEALTH
Patient Consent for Research Study

Cognitive-affective factors associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

Can I withdraw from the study? What are my rights as a participant?
Participation in this study is voluntary. I understand that I am free to withdraw my consent to participate in this study at any time without affecting my future care. Refusing to participate will involve no penalty or loss of benefits. I am free to seek care from a physician of my choice at any time. I will be told about new information that may affect my health, welfare, or willingness to stay in this study.

Can I be removed from the study?
My participation in the project may be removed by the investigator without my consent if participation is not appropriate to my case or for reasons at his/her discretion.

Where can I get more information about this study?
If I have questions about the research, or in the event of a research-related injury, I may contact the **Virtua Health Institutional Review Board,** Chairman Howard Press, DO. The IRB is a group of people charged with overseeing and protecting your rights as a research participant. I may reach the **Virtua Health Institutional Review Board** office by calling **(609) 276-0700 ext 44190.**

Participant statement and Signature:
I have read and received a copy of this consent form. I have been given an opportunity to discuss the information with my doctor/nurse, and all of my questions/concerns have been answered to my satisfaction. My signature below indicates my voluntary participation in this research.

I will receive a copy of this form.

_____ _____
Signature of Participant Date

_____ _____
Signature of Health Educator Date

IRB ACTIVITY

Jun 24, 2004 IRB Initial Approval – 12 Months
Dec 02, 2004 IRB Approval-Protocol Amendment, per DOD request, to clarify role of Eric Miller, MD

APPROVED
DEC - 2 2004
Virtua Health
Institutional Review Board

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

2.15.05

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [X] CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	**IRB # 01-851**

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other
Cognitive-affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.	Suzanne M. Miller, Ph.D., Kerry Sherman, Ph.D

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. M-1030, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] Expedited Review on (date) 11/21/05
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments: **Amendment #14**

- Clarification of participant consent process, as per DOD recommendation
- Personnel changes to consent form
- Addition of lines to record participant's address

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	215-728-2204	Fox Chase Cancer Center 7701 Burholme Avenue Philadelphia, PA 19111
12. Fax No. *(with area code)*	215-379-5722	
13. Email:	WT_London@fccc.edu	
14. Name of Official W. Thomas London, MD		15. Title Chairperson, Institutional Review Board
16. Signature WT London		17. Date 11/21/05

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FOX CHASE CANCER CENTER

Memorandum

To: Institutional Review Board Coordinator
Through: Research Review Committee

From: Melanie Glenn, M.P.H.

RECEIVED JAN 1 4 2005

Date: 1/12/05

Subject: Protocol Amendment

RE: **Protocol IRB# 01-851 PIs: Suzanne M. Miller, Ph.D. & Kerry Sherman, Ph.D**
Amendment # 14
Title: Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.

The attached amendment has been received from the sponsoring agency, cooperative group, or principal investigator of the above referenced protocol. Review and approval is requested from the Research Review Committee (RRC) followed by the Institutional Review Board (IRB). Changes in the protocol as a result of this amendment require the following action to be taken by the IRB:

☒ ***No change in any patient risk factors relative to the originally approved version of this study. Please incorporate into the IRB file for purposes of compliance with Federal regulations.***

☐ ***Patient risk factors have been changed relative to the originally approved version of this study. Board approval of amendment and/or consent form revisions are required. Please incorporate into the IRB file for purpose of compliance with Federal regulations.***

Due to the scope of this amendment, the following action will be taken:

☒ ***Study will remain open to accrual.***

☐ ***Study accrual on hold pending IRB approval of this amendment.***

If this amendment is approved by the IRB, the principal investigator of this protocol will require the following documentation for continued patient accrual:

☐ ***No Further Action is required other than IRB notification.***

☒ ***Documentation of the IRB's approval of this amendment is needed. Please provide a signed HHS-310 form indicating the protocol and amendment number.***

☒ ***A new "stamped" consent form indicating the IRB has approved the revisions.***

****

Note: Per requirements of the IRB and Protocol Management Facility, documentation of Research Review Committee approval is required for all protocol amendments prior to IRB submission.

Reviewed and Approved by RRC: RZ Hyde 1/19/05
(Signature RRC Chairman or Designated Member) ***(Date)***

For Internal Use Only After Approval:

☐	**Protocol File**	☐	**IRB (Original)**
☐	**Team**	☐	**Sponsor**
☐	**FCN**	☐	**Other:**_____

(form version: 2/9/2000)

OMB No 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [X] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [X] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity Fox Chase Cancer Center		5. Name of Principal Investigator, Program Director, Fellow, or Other **Eric Miller, MD**

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00002656 the expiration date 6/5/2005 IRB Registration No. IRB00002494

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations by:
- [X] Full IRB Review on (date of IRB meeting) 2/24/05 or [ ] Expedited Review on (date)
- [ ] If less than one year approval, provide expiration date _____
- [ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

AMENDMENT APPROVAL:

IRB 01-851, Cognitive-Affective Predictors of the Uptake of and Sustained Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors – *Amendment 14, clarification of Dr. Miller's role in recruiting and consenting patients*

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution VIRTUA HEALTH 94 BRICK ROAD MARLTON, NJ 08053
11. Phone No. *(with area code)* 609-267-0700 x 4190 12. Fax No. *(with area code)* 609-261-3542 13. Email:	
14. Name of Official Howard Press, DO	15. Title Chairperson, Oncology Institutional Review Board
16. Signature Howard Z. Press	17. Date February 24, 2005

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Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

You are being asked to take part in a study for women who are at risk of lymphedema as a side effect of surgery and treatment for breast cancer. Taking part in the study is your choice. The nature of the study and other important information about the study are explained below. You should ask your doctor and other staff members any questions you have about this study.

Why is this research study being done?
The reason for this study is to find out how much you know about lymphedema and what you are doing to lower your risk of lymphedema because the factors that affect your knowledge about lymphedema and your chances of practicing certain behaviors are not well known.

How many people will take part in this study?
About 178 people will take part in this study.

What is involved in the research study?
Your treating physician, Dr. Eric Miller, will tell you about this study before you have started any treatment for your breast cancer. If you choose to participate in this study, a member of the FCCC research team will contact you to complete a survey over the telephone. After you complete this first survey, you will be contacted by phone to complete a 6-month and 12-month follow-up survey.

As part of this study, you will be asked to complete surveys at these times:

1) during the first 6 weeks after breast cancer surgery;
2) 6-months after you complete the first survey (over the phone)
3) 12-months after you complete the first survey (over the phone).

These surveys may take between 30 and 40 minutes to complete each time.

Assigning groups:
Everyone who takes part in this study will get the same information. You will not be placed into separate groups.

How long will you be on this research study?
If you take part in the entire study, we expect that you will be on this study for twelve months.

What are the risks of the research study?
There is very little risk in taking part in this study. Talking about your lymphedema risk might make you uneasy. In such an event you are urged to tell your physicians about your feelings. This person is trained to help you deal with lymphedema-specific worries. Also, if you feel uneasy, worried or uncomfortable by any of the questions, you do not have to answer those questions. This will have no effect your treatment.

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

There may also be other risks that we do not know about. We will tell you about any new information that we find out about while you are in the study that may make you change your mind about taking part. You are also free to stop taking part in the study at any time.

Are there benefits to taking part in the research study?

If you decide to be in this study, there may or may not be direct benefit to you. You well get information that might help you, including education about risk factors for lymphedema, ways to lower your risk, and ways to identify lymphedema symptoms. We also hope that this information will help other women who are dealing with lymphedema.

What other options are there?

Instead of taking part in this study you can get information from your health care team without taking part in the study.

What about confidentiality?

FCCC/Virtua Health will have access to your personal medical records: However, all efforts will be made to keep this and any other information confidential. All information will be kept private. You have been assigned a code number, which will be used instead of your name to identify your surveys. Information that links your name to the code number and all completed surveys will be stored in a locked cabinet in the investigator's office. Information from the surveys will be entered and stored in a computer file to which only certain members of the study staff will have access. The results of the study will be presented in a summary manner. The results will not be included in any medical record, and will not be available to any other groups, such as insurance companies. Representatives of the Fox Chase Cancer Center, study's sponsor the U.S. Army Medical Research and Materiel Command, who fund this study, and Virtua Health can review our records to make sure that your rights are being upheld. All information, including audiotapes, which are stored in a password-protected computer database or in a locked cabinet to which only study staff will have access, will be kept for 7 years, after which it will be destroyed.

As mentioned above, you are being asked to complete surveys for this study. These surveys will provide information about your age, race, marital status, etc., medical history, family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors about your lymphedema.

It will take 30-40 minutes to complete the surveys, and you will be asked to complete them at 3 times over the telephone.

You do not have to answer any question. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the surveys in a locked file to protect your privacy.

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

What are the costs? Will I be compensated?
You will receive no pay for taking part in this study. Any clinic visits or exams that you have at Fox Chase Cancer Center or Virtua Health that are not part of this study will be billed to your insurance company.

In the event of physical injury from this study, medical treatments to the extent that it is available can be provided. The payment for this treatment may be your responsibility. No money will be provided for wages lost or for any other reason because of injury from this study.

Who do you call if you have questions or problems?
You are free to ask questions at any time about this study and to ask for more information from the investigator, the research team, or other staff or doctors involved in your care. If you have questions, you can reach the investigators of this project, Dr Suzanne Miller at 215-728-4069, or Eric Miller, M.D. at 609-267-7050.

Can you stop being on the research study? What are your rights as a participant?
Taking part in the study is your choice. You are free to change your mind and stop taking part in this study at any time without effecting you or your family's present or future medical care.

We will tell you about new information that may affect your health, well-being, or make you change your mind about being in this study.

Can you be removed from the research study?
Your doctors may remove you from the study without your permission for any of the following reasons:

- They feel that it will not benefit you to continue;
- The sponsor decides to end the study.

Who do you call if you have problems with the research study, or your rights as a research subject?
If you are not fully satisfied with how this study is being conducted, you may report (anonymously, if you so choose) any complaints to the Virtua Health Institutional Review Board by calling (609) 267-0700 ext 44190. For questions about this research, you may contact the principal investigator listed above.

By signing below, you tell us that you have read this form, that you understand what it means to take part in this study, that you have received clear answers to your questions, and that you agree to take part in the study. You will receive a copy of this form. You may also request a copy of the research plan.

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

_____ _____
Signature of Participant Date

_____

_____
Address of Participant

_____ _____
Signature of Treating Physician Date

IRB ACTIVITY:
June 24, 2004- IRB intial approval-12 months
December 2, 2004-Approval – Protocol Amendment, per DOD request, to clarify role of Eric Miller, M.D.
January 27, 2005- Protocol Amendment, per DOD request, to clarify role of Eric Miller, M.D.

APPROVED
FEB 2 4 2005
Virtua Health
Institutional Review Board

FOX CHASE CANCER CENTER

To: IRB, RRC

From: Melanie Glenn, M.P.H.
Kerry Sherman, Ph.D
Suzanne M. Miller, Ph.D

Date: 1/12/05

Re: Amendment # 14 to IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors" (PIs: Suzanne M. Miller, Ph.D., and Kerry Sherman, Ph.D.)

Dear RRC, IRB,

The purpose of this memo is to request review of the following amendments to the protocol for IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors." The amendments are as follows:

1. After closely reviewing the amendment materials to add Virtua Memorial Hospital as a recruitment site for the lymphedema study, the DOD requested clarification regarding what institution would be consenting participants into the study. Because a consent form had been approved by the Virtua IRB to consent patients into the study, which was discrepant with the protocol, there was confusion as to whether a Fox Chase researcher or Dr. Eric Miller would be obtaining consent from interested patients. To rectify this discrepancy we have modified the protocol to reflect that Dr. Eric Miller will be recruiting and consenting Virtua patients into the study.

   Previously, the amendment to the protocol that was approved read, **"For patients receiving care at Virtua Memorial Hospital, Dr. Eric Miller, the primary site coordinator, will be responsible for facilitating recruitment. Specifically, Dr. Miller will be responsible for introducing the study using the study brochure and explaining the study to all of his patients receiving care for Stage I, II, or IIIa breast cancer who have not previously opted out of research through HIPAA. He will also be responsible for obtaining consent from his patients to be contacted by a member of the Fox Chase Cancer Center (FCCC) research staff. Upon receiving this consent**

to be contacted, Dr. Miller will provide specific medical information (i.e., cancer stage, treatment type, date of surgery) by mail to the FCCC research staff, who will review this information to determine eligibility. After determining eligibility, a member of the FCCC research team will contact those patients who have provided consent to be contacted. Consenting patients will complete the study-specific informed consent form by mail and all measures by telephone. "

The protocol will now read, "For patients receiving care at Virtua Memorial Hospital, Dr. Eric Miller, the primary site coordinator, will be responsible for **recruiting and consenting participants into the study.** Specifically, Dr. Miller will be responsible for introducing the study using the study brochure and explaining the study to all of his patients receiving care for Stage I, II, or IIIa breast cancer who have not previously opted out of research through HIPAA. He will also be responsible for **reviewing his patients' medical records and obtaining informed consent and HIPAA authorization from his patients who agree to participate in the study. Upon obtaining informed consent to participate in the research study and HIPAA authorization, Dr. Miller will provide the names of consenting patients to the FCCC research staff, who will contact these patients to complete baseline and follow-up assessments via telephone. Dr. Miller will also provide a copy of the signed informed consent form and HIPAA authorization to the FCCC research staff."**

2. Dr. Michelle Rodoletz, Ph.D., is no longer an employee of FCCC and should be removed from the protocol and consent form.

3. Dr. Kerry Sherman has been removed as a contact person from the consent form and additional lines to record the participant's address have been added to the consent form, as per recommendations from the DOD.

FOX CHASE CANCER CENTER

To: IRB, RRC

From: Melanie Glenn, M.P.H.
Kerry Sherman, Ph.D
Suzanne M. Miller, Ph.D

Date: 1/12/05

Re: Amendment # 14 to IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors" (PIs: Suzanne M. Miller, Ph.D., and Kerry Sherman, Ph.D.)

Dear RRC, IRB,

The purpose of this memo is to request review of the following amendments to the protocol for IRB # 01-851, "Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors." The amendments are as follows:

1. After closely reviewing the amendment materials to add Virtua Memorial Hospital as a recruitment site for the lymphedema study, the DOD requested clarification regarding what institution would be consenting participants into the study. Because a consent form had been approved by the Virtua IRB to consent patients into the study, which was discrepant with the protocol, there was confusion as to whether a Fox Chase researcher or Dr. Eric Miller would be obtaining consent from interested patients. To rectify this discrepancy we have modified the protocol to reflect that Dr. Eric Miller will be recruiting and consenting Virtua patients into the study.

   Previously, the amendment to the protocol that was approved read, "**For patients receiving care at Virtua Memorial Hospital, Dr. Eric Miller, the primary site coordinator, will be responsible for facilitating recruitment. Specifically, Dr. Miller will be responsible for introducing the study using the study brochure and explaining the study to all of his patients receiving care for Stage I, II, or IIIa breast cancer who have not previously opted out of research through HIPAA. He will also be responsible for obtaining consent from his patients to be contacted by a member of the Fox Chase Cancer Center (FCCC) research staff. Upon receiving this consent**

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2. Dr. Michelle Rodoletz, Ph.D., is no longer an employee of FCCC and should be removed from the protocol and consent form.

3. Dr. Kerry Sherman has been removed as a contact person from the consent form and additional lines to record the participant's address have been added to the consent form, as per recommendations from the DOD.

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

You are being asked to take part in a study for women who are at risk of lymphedema as a side effect of surgery and treatment for breast cancer. Taking part in the study is your choice. The nature of the study and other important information about the study are explained below. You should ask your doctor and other staff members any questions you have about this study.

Why is this research study being done?
The reason for this study is to find out how much you know about lymphedema and what you are doing to lower your risk of lymphedema because the factors that affect your knowledge about lymphedema and your chances of practicing certain behaviors are not well known.

How many people will take part in this study?
About 178 people will take part in this study.

What is involved in the research study?
A Nurse in FCCC's Breast Evaluation Clinic or Bryn Mawr office will tell you about this study at your first visit, before you have started any treatment for your breast cancer. After this visit, you can choose to call the Researcher on your own to join the study. If you do not choose to call on your own, you will be contacted within the first three weeks after your visit. If you agree to participate, you will be asked to meet with a member of the study team (Health Educator) to complete a survey. After you complete this first survey, you will be contacted by phone to complete a 6-month and 12-month follow-up survey.

As part of this study, you will be asked to complete surveys at these times:

1) during the first 6 weeks after breast cancer surgery;
2) 6-months after you complete the first survey (over the phone)
3) 12-months after you complete the first survey (over the phone).

These surveys may take between 30 and 40 minutes to complete each time.

Assigning groups:
Everyone who takes part in this study will get the same information. You will not be placed into separate groups.

How long will you be on this research study?
If you take part in the entire study, we expect that you will be on this study for twelve months.

What are the risks of the research study?
There is very little risk in taking part in this study. Talking about your lymphedema risk might make you uneasy. In such an event you are urged to tell the Health Educator about your feelings. The Health Educator is trained to help you deal with lymphedema-specific worries. Also, if you feel uneasy, worried or uncomfortable by

any of the questions, you do not have to answer those questions. This will have no effect your treatment. There may also be other risks that we do not know about. We will tell you about any new information that we find out about while you are in the study that may make you change your mind about taking part. You are also free to stop taking part in the study at any time.

Are there benefits to taking part in the research study?
If you decide to be in this study, there may or may not be direct benefit to you. You well get information that might help you, including education about risk factors for lymphedema, ways to lower your risk, and ways to identify lymphedema symptoms. We also hope that this information will help other women who are dealing with lymphedema.

What other options are there?
Instead of taking part in this study you can get information from your health care team without taking part in the study.

What about confidentiality?
All information will be kept private. You have been assigned a code number, which will be used instead of your name to identify your surveys. Information that links your name to the code number and all completed surveys will be stored in a locked cabinet in the investigator's office. Information from the surveys will be entered and stored in a computer file to which only certain members of the study staff will have access. The results of the study will be presented in a summary manner. The results will not be included in any medical record, and will not be available to any other groups, such as insurance companies. Representatives of the U.S. Army Medical Research and Materiel Command, who fund this study, can review our records to make sure that your rights are being upheld. All information, including audiotapes, which are stored in a password-protected computer database or in a locked cabinet to which only study staff will have access, will be kept for 7 years, after which it will be destroyed.

As mentioned above, you are being asked to complete surveys for this study. These surveys will provide information about your age, race, marital status, etc., medical history, family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors about your lymphedema.

It will take 30-40 minutes to complete the surveys, and you will be asked to complete them at 3 times either in person or over the telephone.

You do not have to answer any question. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the surveys in a locked file to protect your privacy.

What are the costs? Will I be compensated?
You will receive no pay for taking part in this study. Any clinic visits or exams that you have at Fox Chase Cancer Center that are not part of this study will be billed to your insurance company.

In the event of physical injury from this study, medical treatments to the extent that it is available can be provided. The payment for this treatment may be your responsibility. No money will be provided for wages lost or for any other reason because of injury from this study.

Who do you call if you have questions or problems?
You are free to ask questions at any time about this study and to ask for more information from the investigator, the research team, or other staff or doctors involved in your care. If you have questions, you can reach the investigators of this project, Dr Suzanne M. Miller at (215) 728-4069.

Can you stop being on the research study? What are your rights as a participant?
Taking part in the study is your choice. You are free to change your mind and stop taking part in this study at any time without effecting you or your family's present or future medical care.

We will tell you about new information that may affect your health, well-being, or make you change your mind about being in this study.

Can you be removed from the research study?
Your doctors may remove you from the study without your permission for any of the following reasons:

- They feel that it will not benefit you to continue;
- The sponsor decides to end the study.

Who do you call if you have problems with the research study, or your rights as a research subject?
If you are not fully satisfied with how this study is being conducted, you may report (anonymously, if you so choose) any complaints to the Fox Chase Cancer Center Institutional Review Board by calling (215) 728-2518, 9:00 AM to 5:00 PM, Monday to Friday, or by writing a letter to the Fox Chase Cancer Center Institutional Review Board, in care of Dolores Eckert, Fox Chase Cancer Center, 333 Cottman Avenue, Philadelphia, PA 19111. For questions about this research, you may contact the principal investigator listed above.

By signing below, you tell us that you have read this form, that you understand what it means to take part in this study, that you have received clear answers to your questions, and that you agree to take part in the study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____
Signature of Participant Date

_____
_____
Participant's Address

_____ _____
Signature of Health Educator/Counselor Date

FOX CHASE CANCER CENTER
INSTITUTIONAL REVIEW BOARD
PROTOCOL # 01-851
APPROVED 1-21-05
EXPIRES 11-29-05

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

5.10.05

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [X] CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	**IRB # 01-851**
4. Title of Application or Activity **Cognitive-affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.**		5. Name of Principal Investigator, Program Director, Fellow, or Other Suzanne M. Miller, Ph.D., Kerry Sherman, Ph.D

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. M-1030, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [X] Expedited Review on (date) 4/29/05
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

- 8. Comments: **Amendment #15: New HIPAA form**

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	215-728-2204	Fox Chase Cancer Center 7701 Burholme Avenue Philadelphia, PA 19111
12. Fax No. *(with area code)*	215-379-5722	
13. Email:	WT_London@fccc.edu	
14. Name of Official W. Thomas London, MD		15. Title Chairperson, Institutional Review Board
16. Signature WT London		17. Date 4/29/05

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FOX CHASE CANCER CENTER

Institutional Review Board
HIPAA Authorization Review Standards

IRB #: 01-851 **Principal Investigator:** Suzanne Reiter Ph.D.
Kerry Sherman Ph.D.

Study Title: Cognitive - Affective Factors Associated - Uptake of + Adherence to Lymphedema Symptoms Management Practices in Breast Ca. Survivors

Core Elements for an Authorization	Reviewed	Comments
1. The name or specific identification of the person(s) or class of person(s) authorized to make the requested use or disclosure	✓	
2. The name or other specific identification of the person(s) or class of person(s) to whom the Covered Entity may make the requested use or disclosure	✓	
3. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion and be research study specific	✓	
4. An expiration date or event – "end of research study" or similar language or "none" that relates to the individual or the purpose of the use or disclosure. If no expiration date is expected, the authorization must state so.	✓	
5. A statement of the individual's right to revoke the authorization in writing and the exception to the right to revoke, (when the covered entity has acted in reliance on the authorization) together with a description of how the individual may revoke the authorization.	✓	
6. A statement that the information used or disclosed to the authorization may be subject to re-disclosure by the recipient and no longer protected by this rule.	✓	
7. Signature of the individual and date	✓	
8. If authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual.	✓	

The consent process is as important to the protection of human subjects as is the consent form. Potential subjects should be provided with an explanation of the study and be given an opportunity to ask questions and seek additional information during the consent process. Who will actually conduct the consent process?

Reviewer Name: NORA B. McCANN

Signature: Nora B. McCann Date: 4/25/05

FOX CHASE CANCER CENTER

Memorandum

To: Institutional Review Board Coordinator
Through: Research Review Committee

From: Melanie Glenn, M.P.H.

Date: 4/1/05

Subject: Protocol Amendment

RE: **Protocol IRB# 01-851 PIs: Suzanne M. Miller, Ph.D. & Kerry Sherman, Ph.D**
Amendment # 15
Title: Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.

The attached amendment has been received from the sponsoring agency, cooperative group, or principal investigator of the above referenced protocol. Review and approval is requested from the Research Review Committee (RRC) followed by the Institutional Review Board (IRB). Changes in the protocol as a result of this amendment require the following action to be taken by the IRB:

☒ ***No change in any patient risk factors relative to the originally approved version of this study. Please incorporate into the IRB file for purposes of compliance with Federal regulations.***

☐ ***Patient risk factors have been changed relative to the originally approved version of this study. Board approval of amendment and/or consent form revisions are required. Please incorporate into the IRB file for purpose of compliance with Federal regulations.***

Due to the scope of this amendment, the following action will be taken:

☒ ***Study will remain open to accrual.***

☐ ***Study accrual on hold pending IRB approval of this amendment.***

If this amendment is approved by the IRB, the principal investigator of this protocol will require the following documentation for continued patient accrual:

☐ ***No Further Action is required other than IRB notification.***

☒ ***Documentation of the IRB's approval of this amendment is needed. Please provide a signed HHS-310 form indicating the protocol and amendment number.***

☐ ***A new "stamped" consent form indicating the IRB has approved the revisions.***

****

Note: Per requirements of the IRB and Protocol Management Facility, documentation of Research Review Committee approval is required for all protocol amendments prior to IRB submission.

Reviewed and Approved by RRC: _____ 4/15/05
(Signature RRC Chairman or Designated Member) ***(Date)***

For Internal Use Only After Approval:

☐ **Protocol File**	☐ **IRB (Original)**
☐ **Team**	☐ **Sponsor**
☐ **FCN**	☐ **Other:_____**

(form version: 2/9/2000)

FOX CHASE CANCER CENTER

Authorization (Permission) to Use or Disclose (Release) Protected Health Information (PHI) for Research

IRB# and Protocol ID:	01-851
Study Title:	Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors
Principal Investigator:	Suzanne M. Miller, Ph.D.
Coordinating Group (or Center):	N/A
Other Sponsor(s):	N/A

1. What is the purpose of this form?

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

The Coordinating Group is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. What protected health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a research study, medical information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;

- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my protected health information?

Fox Chase Cancer Center will collect your protected health information and share it with the Coordinating Group Biostatistical Center and the Operations Center if you enter a research study. The centers will use your information in their cancer research study.

4. Who will be able to use my protected health information?

Fox Chase Cancer Center will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. Fox Chase Cancer Center may also permit these groups to come in to review your original records that are kept by Fox Chase Cancer Center so that they can monitor their research study.

- the Coordinating Group Operations Center;
- the Coordinating Group Biostatistical Center;
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute that supports the research of the Coordinating Group;
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with research efforts of the Coordinating Group or sponsor; and
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the five bullets above.

5. How will information about me be kept private??

The Coordinating Group will keep all patient information private to the extent possible, even though the Coordinating Group is not required to follow the federal privacy laws. Only researchers working with the Coordinating Group or sponsor will have access to your information. The Coordinating Group or sponsor will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Contact Name: Suzanne M. Miller, Ph.D.

Contact Address: 333 Cottman Avenue, Suite P1096, Philadelphia, PA 19111

Contact Phone and FAX: Telephone: 215.728.4069 Fax: 215.214.1651

9. How long will this permission last?

If you agree by signing this form that researchers can use your protected health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by Fox Chase Cancer Center. You do not have the right to review and/or copy records kept by the Coordinating Group or other researchers associated with the research study.

****

Signatures

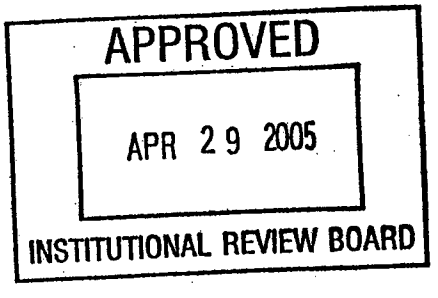
I agree that my protected health information may be used for the research purposes described in this form.

Patient Signature: _____ Date: _____

or Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

****



OMB No. 0990-0263
Approved for use through 07/31/2005

6.28.05

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [x] CONTINUATION [ ] EXEMPTION	[x] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:	**IRB# 01-851**

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other.
Cognitive-Affective Factors Associated with Uptake or and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.	**Suzanne M. Miller, PhD**

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA-00003846 , the expiration date 1/13/08 IRB Registration No. 00000050

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting or [x] Expedited Review on 6/15/05 [ ] Facilitated Review on ____
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments: This study expires 364 days from the date of approval.

Amendment #16: Addition of eligible participants attending Virtua Memorial Hospital will be recruited as needed.

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	215-728-2204	Fox Chase Cancer Center 333 Cottman Avenue Philadelphia, PA 19111-2497
12. Fax No. *(with area code)*	215-214-4256	
13. Email:	W. T. London@fccc.edu	
14. Name of Official W. Thomas London, MD		15. Title Chairperson, Institutional Review Board
16. Signature W T London		17. Date 6/15/05

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FOX CHASE CANCER CENTER

Memorandum

To: Institutional Review Board Coordinator
Through: Research Review Committee

From: Stephen La Monica
Date: 5/12/05
Subject: New recruitment material for Virtua participants
RE: **Protocol** IRB 01-851
PI: Suzanne M. Miller, Ph.D.
Title: Cognitive-Affective Factors Associated with Uptake of, and Adherence, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

The attached amendment has been received from the sponsoring agency, cooperative group, or principal investigator of the above referenced protocol. Review and approval is requested from the Research Review Committee (RRC) followed by the Institutional Review Board (IRB). Changes in the protocol as a result of this amendment require the following action to be taken by the IRB:

X ***No change in any patient risk factors relative to the originally approved version of this study. Please incorporate into the IRB file for purposes of compliance with Federal regulations.***

X ***Patient risk factors have been changed relative to the originally approved version of this study. Board approval of amendment and/or consent form revisions are required. Please incorporate into the IRB file for purpose of compliance with Federal regulations.***

Due to the scope of this amendment, the following action will be taken:

X ***Study will remain open to accrual.***

☐ ***Study accrual on hold pending IRB approval of this amendment.***

If this amendment is approved by the IRB, the principal investigator of this protocol will require the following documentation for continued patient accrual:

X ***No Further Action is required other than IRB notification.***

☐ ***Documentation of the IRB's approval of this amendment is needed. Please provide a signed HHS-310 form indicating the protocol and amendment number.***

☒ ***A new "stamped" consent form indicating the IRB has approved the revisions.***

****

Note: Per requirements of the IRB and Protocol Management Facility, documentation of Research Review Committee approval is required for all protocol amendments prior to IRB submission.

Reviewed and Approved by RRC: _____ 5-20-05
(Signature RRC Chairman or Designated Member) ***(Date)***

For Internal Use Only After Approval:

☐	**Protocol File**	☐	**IRB (Original)**
☐	**Team**	☐	**Sponsor**
☐	**FCN**	☐	**Other:**_____

(form version: 2/9/2000)

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

You are being asked to take part in a study for women who are at risk of lymphedema as a side effect of surgery and treatment for breast cancer. Taking part in the study is your choice. The nature of the study and other important information about the study are explained below. You should ask your doctor and other staff members any questions you have about this study.

Why is this research study being done?
The reason for this study is to find out how much you know about lymphedema and what you are doing to lower your risk of lymphedema because the factors that affect your knowledge about lymphedema and your chances of practicing certain behaviors are not well known.

How many people will take part in this study?
About 178 people will take part in this study.

What is involved in the research study?
A Nurse in FCCC's Breast Evaluation Clinic or Bryn Mawr office will tell you about this study at your first visit, before you have started any treatment for your breast cancer. After this visit, you can choose to call the Researcher on your own to join the study. If you do not choose to call on your own, you will be contacted within the first three weeks after your visit. If you agree to participate, you will be asked to meet with a member of the study team (Health Educator) to complete a survey. After you complete this first survey, you will be contacted by phone to complete a 6-month and 12-month follow-up survey.

As part of this study, you will be asked to complete surveys at these times:

1) during the first 6 weeks after breast cancer surgery;
2) 6-months after you complete the first survey (over the phone)
3) 12-months after you complete the first survey (over the phone).

These surveys may take between 30 and 40 minutes to complete each time.

Assigning groups:
Everyone who takes part in this study will get the same information. You will not be placed into separate groups.

How long will you be on this research study?
If you take part in the entire study, we expect that you will be on this study for twelve months.

What are the risks of the research study?
There is very little risk in taking part in this study. Talking about your lymphedema risk might make you uneasy. In such an event you are urged to tell the Health Educator about your feelings. The Health Educator is trained to help you deal with lymphedema-specific worries. Also, if you feel uneasy, worried or uncomfortable by

any of the questions, you do not have to answer those questions. This will have no effect your treatment. There may also be other risks that we do not know about. We will tell you about any new information that we find out about while you are in the study that may make you change your mind about taking part. You are also free to stop taking part in the study at any time.

Are there benefits to taking part in the research study?
If you decide to be in this study, there may or may not be direct benefit to you. You well get information that might help you, including education about risk factors for lymphedema, ways to lower your risk, and ways to identify lymphedema symptoms. We also hope that this information will help other women who are dealing with lymphedema.

What other options are there?
Instead of taking part in this study you can get information from your health care team without taking part in the study.

What about confidentiality?
All information will be kept private. You have been assigned a code number, which will be used instead of your name to identify your surveys. Information that links your name to the code number and all completed surveys will be stored in a locked cabinet in the investigator's office. Information from the surveys will be entered and stored in a computer file to which only certain members of the study staff will have access. The results of the study will be presented in a summary manner. The results will not be included in any medical record, and will not be available to any other groups, such as insurance companies. Representatives of the U.S. Army Medical Research and Materiel Command, who fund this study, can review our records to make sure that your rights are being upheld. All information, including audiotapes, which are stored in a password-protected computer database or in a locked cabinet to which only study staff will have access, will be kept for 7 years, after which it will be destroyed.

As mentioned above, you are being asked to complete surveys for this study. These surveys will provide information about your age, race, marital status, etc., medical history, family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors about your lymphedema.

It will take 30-40 minutes to complete the surveys, and you will be asked to complete them at 3 times either in person or over the telephone.

You do not have to answer any question. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the surveys in a locked file to protect your privacy.

What are the costs? Will I be compensated?
You will receive no pay for taking part in this study. Any clinic visits or exams that you have at Fox Chase Cancer Center that are not part of this study will be billed to your insurance company.

In the event of physical injury from this study, medical treatments to the extent that it is available can be provided. The payment for this treatment may be your responsibility. No money will be provided for wages lost or for any other reason because of injury from this study.

Who do you call if you have questions or problems?
You are free to ask questions at any time about this study and to ask for more information from the investigator, the research team, or other staff or doctors involved in your care. If you have questions, you can reach the investigator of this project, Dr Suzanne M. Miller at (215) 728-4069.

Can you stop being on the research study? What are your rights as a participant?
Taking part in the study is your choice. You are free to change your mind and stop taking part in this study at any time without effecting you or your family's present or future medical care.

We will tell you about new information that may affect your health, well-being, or make you change your mind about being in this study.

Can you be removed from the research study?
Your doctors may remove you from the study without your permission for any of the following reasons:

- They feel that it will not benefit you to continue;
- The sponsor decides to end the study.

Who do you call if you have problems with the research study, or your rights as a research subject?
If you are not fully satisfied with how this study is being conducted, you may report (anonymously, if you so choose) any complaints to the Fox Chase Cancer Center Institutional Review Board by calling (215) 728-2518, 9:00 AM to 5:00 PM, Monday to Friday, or by writing a letter to the Fox Chase Cancer Center Institutional Review Board, in care of Dolores Eckert, Fox Chase Cancer Center, 333 Cottman Avenue, Philadelphia, PA 19111. For questions about this research, you may contact the principal investigator listed above.

By signing below, you tell us that you have read this form, that you understand what it means to take part in this study, that you have received clear answers to your questions, and that you agree to take part in the study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____
Signature of Participant Date

_____ _____
Signature of Health Educator/Counselor Date

FOX CHASE CANCER CENTER
INSTITUTIONAL REVIEW BOARD
PROTOCOL # 01-851
APPROVED 6:15-05
EXPIRES 11-29-05

Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

Virtua Memorial Hospital

You are being asked to take part in a study for women who are at risk of lymphedema as a side effect of surgery and treatment for breast cancer. Taking part in the study is your choice. The nature of the study and other important information about the study are explained below. You should ask your doctor and other staff members any questions you have about this study.

Why is this research study being done?
The reason for this study is to find out how much you know about lymphedema and what you are doing to lower your risk of lymphedema because the factors that affect your knowledge about lymphedema and your chances of practicing certain behaviors are not well known.

How many people will take part in this study?
About 178 people will take part in this study.

What is involved in the research study?
You are being contacted to participate in this Fox Chase Cancer Center study because you have been identified as an eligible patient at Virtua Memorial Hospital. If you agree to participate, you will be asked to complete the enclosed survey. After you complete this first survey, you will be contacted again by phone to complete a 6-month and 12-month follow-up survey.

As part of this study, you will be asked to complete surveys at these times:

1) during the first 6 weeks after breast cancer surgery;
2) 6-months after you complete the first survey (by phone)
3) 12-months after you complete the first survey (by phone)

These surveys may take between 30 and 40 minutes to complete each time.

Assigning groups:
Everyone who takes part in this study will get the same information. You will not be placed into separate groups.

How long will you be on this research study?
If you take part in the entire study, we expect that you will be on this study for twelve months.

What are the risks of the research study?
There is very little risk in taking part in this study. Talking about your lymphedema risk might make you uneasy. In such an event you are urged to tell the Health Educator about your feelings. The Health Educator is trained to help you deal with lymphedema-specific worries. Also, if you feel uneasy, worried or uncomfortable by any of the questions, you do not have to answer those questions. This will have no

effect your treatment. There may also be other risks that we do not know about. We will tell you about any new information that we find out about while you are in the study that may make you change your mind about taking part. You are also free to stop taking part in the study at any time.

Are there benefits to taking part in the research study?
If you decide to be in this study, there may or may not be direct benefit to you. You well get information that might help you, including education about risk factors for lymphedema, ways to lower your risk, and ways to identify lymphedema symptoms. We also hope that this information will help other women who are dealing with lymphedema.

What other options are there?
Instead of taking part in this study you can get information from your health care team without taking part in the study.

What about confidentiality?
All information will be kept private. You have been assigned a code number, which will be used instead of your name to identify your surveys. Information that links your name to the code number and all completed surveys will be stored in a locked cabinet in the investigator's office. Information from the surveys will be entered and stored in a computer file to which only certain members of the study staff will have access. The results of the study will be presented in a summary manner. The results will not be included in any medical record, and will not be available to any other groups, such as insurance companies. Representatives of the U.S. Army Medical Research and Materiel Command, who fund this study, can review our records to make sure that your rights are being upheld. All information, including audiotapes, which are stored in a password-protected computer database or in a locked cabinet to which only study staff will have access, will be kept for 7 years, after which it will be destroyed.

As mentioned above, you are being asked to complete surveys for this study. These surveys will provide information about your age, race, marital status, etc., medical history, family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors about your lymphedema.

It will take 30-40 minutes to complete the surveys, and you will be asked to complete them at 3 times either in person or over the telephone.

You do not have to answer any question. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the surveys in a locked file to protect your privacy.

What are the costs? Will I be compensated?
You will receive no pay for taking part in this study. Any clinic visits or exams that you have at Virtua Memorial Hospital that are not part of this study will be billed to your insurance company.

In the event of physical injury from this study, medical treatments to the extent that it is available can be provided. The payment for this treatment may be your

responsibility. No money will be provided for wages lost or for any other reason because of injury from this study.

Who do you call if you have questions or problems?
You are free to ask questions at any time about this study and to ask for more information from the investigator, the research team, or other staff or doctors involved in your care. If you have questions, you can reach the investigator of this project, Dr Suzanne M. Miller at (215) 728-4069.

Can you stop being on the research study? What are your rights as a participant?
Taking part in the study is your choice. You are free to change your mind and stop taking part in this study at any time without effecting you or your family's present or future medical care.

We will tell you about new information that may affect your health, well-being, or make you change your mind about being in this study.

Can you be removed from the research study?
Your doctors may remove you from the study without your permission for any of the following reasons:

- They feel that it will not benefit you to continue;
- The sponsor decides to end the study.

Who do you call if you have problems with the research study, or your rights as a research subject?
If you are not fully satisfied with how this study is being conducted, you may report (anonymously, if you so choose) any complaints to the Fox Chase Cancer Center Institutional Review Board by calling (215) 728-2518, 9:00 AM to 5:00 PM, Monday to Friday, or by writing a letter to the Fox Chase Cancer Center Institutional Review Board, in care of Dolores Eckert, Fox Chase Cancer Center, 333 Cottman Avenue, Philadelphia, PA 19111. For questions about this research, you may contact the principal investigator listed above.

By signing below, you tell us that you have read this form, that you understand what it means to take part in this study, that you have received clear answers to your questions, and that you agree to take part in the study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____
Signature of Participant Date

_____ _____
Signature of Health Educator/Counselor Date

FOX CHASE CANCER CENTER
INSTITUTIONAL REVIEW BOARD
PROTOCOL # 01-851
APPROVED 6-15-05
EXPIRES 11-29-05

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[X] ORIGINAL [ ]CONTINUATION [ ] EXEMPTION	[X] GRANT [ ] CONTRACT [ ] FELLOWSHIP [] COOPERATIVE AGREEMENT [ ] OTHER:	**01-851**

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other.
Cognitive-Affective Predictors of the Uptake of, and Sustained Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors	Suzanne Miller PhD

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA-00003846 , the expiration date 1/13/08 IRB Registration No. 00000050

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting _____ or [X] Expedited Review on 7/28/08 [ ] Facilitated Review on _____
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments
Brochure recommended for approval by recruitment subcommittee

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	215-728-2204	Fox Chase Cancer Center 333 Cottman Avenue Philadelphia, PA 19111
12. Fax No. *(with area code)*	215-214-4256	
13. Email:	WT_London@fccc.edu	
14. Name of Official W. T. London, MD		15. Title Chairperson, Institutional Review Board

16. Signature	17. Date
W T London	7/28/08

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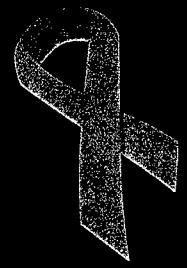
What is Lymphedema?

Lymphedema is a build up of excess fluid that causes swelling in an arm or chest wall that may occur in some women following the removal of a lymph node during breast cancer surgery.



ognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

FOX CHASE CANCER CENTER

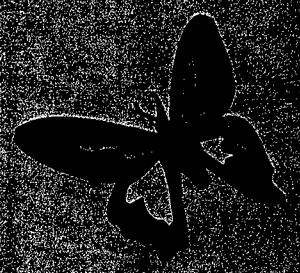
Fox Chase Cancer Center
333 Cottman Avenue
Phone: 215-728-4336
Fax: 215-214-1651
Email: Jessica.Eisenberg@fccc.edu

Fox Chase Cancer Center

Invites you to take part in the...

Lymphedema Awareness Project

You are being asked to take part in a research study of women who are at risk for developing lymphedema following surgery and treatment for breast cancer.



Why is this study being done?

The purpose of this study is to assess the different ways that women who have undergone treatment for breast cancer may or may not adhere to practices aimed at minimizing the symptoms associated with lymphedema.

What is involved in the study?

You will be asked to complete questionnaires at the following points:

- **6 weeks** following surgical treatment for breast cancer (in-person interview at Fox Chase or at our Bryn Mawr location).
- **6-months** after your completion of the baseline questionnaire (telephone-based interview).
- **12-months** after your completion of the baseline questionnaire (telephone-based interview).

Each questionnaire may take 30 to 40 minutes to complete.

Who is eligible to participate ?

Women who have been diagnosed with Stage I, II, or III breast cancer and are currently undergoing chemotherapy or radiation therapy are eligible to participate (participants must be able to communicate readily in English).

If you are interested in participating or if you would like more information, please contact

Jessica Eisenberg, at

215-728-4336

Thank you!

FOX CHASE CANCER CENTER

AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH APPROVED BY FOX CHASE CANCER CENTER [IRB]

IRB #: 01-851

Study Title: Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors.

Principal Investigator: Suzanne M. Miller, PhD

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulations (HIPAA) permit the research investigators listed above to use and disclose health information about you and/or your family for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

1. You authorize Fox Chase Cancer Center, your physician and/or administrative and/or clinical staff to use protected health information collected about you and for research purposes and/or disclose that protected health information to:

   - The Principal Investigator, Dr. Suzanne M. Miller, and the Investigator's study team;
   - The Fox Chase Cancer Center Institutional Review Board, the committee charged with overseeing research on human subjects;
   - The Fox Chase Cancer Center Office for Data Management, which collects, and stores study data;
   - The Department of Defense, the agency which provides funding for this study;
   - US Army Medical Research and Materiel Command.

2. Specific description of the health information to be used and/or disclosed:
   - Names;
   - Addresses;
   - Telephone numbers;
   - Dates (e.g., births, deaths, diagnoses)
   - Personal medical history;
   - Family medical history;
   - Current and past cancer screening and lifestyle practices, medications, therapies, diagnostic tests, surgeries, and/or biopsies;
   - Any information collected in the Health History Questionnaire and/or other survey instruments completed during the course of the study.

3. This protected health information is being used and/or disclosed for the following purposes:

- To contact you during the study.
- To assess the patterns of adherence to lymphedema symptom minimization practices among women who have undergone treatment for primary breast cancer and to determine what factors affect women's knowledge about lymphedema and what factors affect the practice of precautionary measures designed to minimize lymphedema symptoms.

4. This authorization shall be in force and in effect indefinitely.

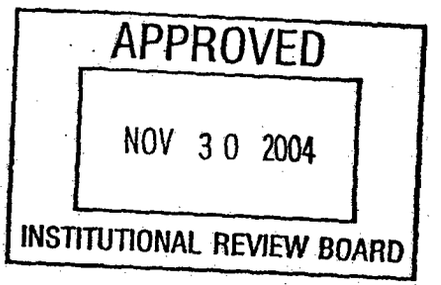
5. You understand that you have the right to withdraw this authorization, in writing, at any time, by sending such written notification to Dr. Suzanne M. Miller, the Principal Investigator of this study. You understand that a revocation is not effective to the extent that your physician has relied on the use or disclosure of the protected health information.

6. You understand that if the person(s) who receives your health information is not a health care provider or health plan covered by federal privacy regulations, your health information could no longer be protected under this authorization.

7. Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. The use or disclosure requested under this authorization will not result in direct or indirect compensation to your physician from a third party.

Participant Signature _____ Date _____



Informed Consent to Participate in Research Studies
Cognitive-Affective Factors Associated with Uptake of, and Adherence to, Lymphedema Symptom Minimization Practices in Breast Cancer Survivors

You are being asked to take part in a study for women who are at risk of lymphedema as a side effect of surgery and treatment for breast cancer. Taking part in the study is your choice. The nature of the study and other important information about the study are explained below. You should ask your doctor and other staff members any questions you have about this study.

Why is this research study being done?
The reason for this study is to find out how much you know about lymphedema and what you are doing to lower your risk of lymphedema because the factors that affect your knowledge about lymphedema and your chances of practicing certain behaviors are not well known.

How many people will take part in this study?
About 178 people will take part in this study.

What is involved in the research study?
A Nurse in FCCC's Breast Evaluation Clinic or Bryn Mawr office will tell you about this study at your first visit, before you have started any treatment for your breast cancer. After this visit, you can choose to call the Researcher on your own to join the study. If you do not choose to call on your own, you will be contacted within the first three weeks after your visit. If you agree to participate, you will be asked to meet with a member of the study team (Health Educator) to complete a survey. After you complete this first survey, you will be contacted by phone to complete a 6-month and 12-month follow-up survey.

As part of this study, you will be asked to complete surveys at these times:

1) during the first 6 weeks after breast cancer surgery;
2) 6-months after you complete the first survey (over the phone)
3) 12-months after you complete the first survey (over the phone).

These surveys may take between 30 and 40 minutes to complete each time.

Assigning groups:
Everyone who takes part in this study will get the same information. You will not be placed into separate groups.

How long will you be on this research study?
If you take part in the entire study, we expect that you will be on this study for twelve months.

What are the risks of the research study?
There is very little risk in taking part in this study. Talking about your lymphedema risk might make you uneasy. In such an event you are urged to tell the Health Educator about your feelings. The Health Educator is trained to help you deal with lymphedema-specific worries. Also, if you feel uneasy, worried or uncomfortable by

any of the questions, you do not have to answer those questions. This will have no effect your treatment. There may also be other risks that we do not know about. We will tell you about any new information that we find out about while you are in the study that may make you change your mind about taking part. You are also free to stop taking part in the study at any time.

Are there benefits to taking part in the research study?
If you decide to be in this study, there may or may not be direct benefit to you. You well get information that might help you, including education about risk factors for lymphedema, ways to lower your risk, and ways to identify lymphedema symptoms. We also hope that this information will help other women who are dealing with lymphedema.

What other options are there?
Instead of taking part in this study you can get information from your health care team without taking part in the study.

What about confidentiality?
All information will be kept private. You have been assigned a code number, which will be used instead of your name to identify your surveys. Information that links your name to the code number and all completed surveys will be stored in a locked cabinet in the investigator's office. Information from the surveys will be entered and stored in a computer file to which only certain members of the study staff will have access. The results of the study will be presented in a summary manner. The results will not be included in any medical record, and will not be available to any other groups, such as insurance companies. Representatives of the U.S. Army Medical Research and Materiel Command, who fund this study, can review our records to make sure that your rights are being upheld. All information, including audiotapes, which are stored in a password-protected computer database or in a locked cabinet to which only study staff will have access, will be kept for 7 years, after which it will be destroyed.

As mentioned above, you are being asked to complete surveys for this study. These surveys will provide information about your age, race, marital status, etc., medical history, family history of cancer, knowledge of lymphedema, and thoughts, feelings, and behaviors about your lymphedema.

It will take 30-40 minutes to complete the surveys, and you will be asked to complete them at 3 times either in person or over the telephone.

You do not have to answer any question. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the surveys in a locked file to protect your privacy.

What are the costs? Will I be compensated?
You will receive no pay for taking part in this study. Any clinic visits or exams that you have at Fox Chase Cancer Center that are not part of this study will be billed to your insurance company.

In the event of physical injury from this study, medical treatments to the extent that it is available can be provided. The payment for this treatment may be your responsibility. No money will be provided for wages lost or for any other reason because of injury from this study.

Who do you call if you have questions or problems?
You are free to ask questions at any time about this study and to ask for more information from the investigator, the research team, or other staff or doctors involved in your care. If you have questions, you can reach the investigators of this project, Dr Suzanne M. Miller at (215) 728-4069.

Can you stop being on the research study? What are your rights as a participant?
Taking part in the study is your choice. You are free to change your mind and stop taking part in this study at any time without effecting you or your family's present or future medical care.

We will tell you about new information that may affect your health, well-being, or make you change your mind about being in this study.

Can you be removed from the research study?
Your doctors may remove you from the study without your permission for any of the following reasons:

- They feel that it will not benefit you to continue;
- The sponsor decides to end the study.

Who do you call if you have problems with the research study, or your rights as a research subject?
If you are not fully satisfied with how this study is being conducted, you may report (anonymously, if you so choose) any complaints to the Fox Chase Cancer Center Institutional Review Board by calling (215) 728-2518, 9:00 AM to 5:00 PM, Monday to Friday, or by writing a letter to the Fox Chase Cancer Center Institutional Review Board, in care of Dolores Eckert, Fox Chase Cancer Center, 333 Cottman Avenue, Philadelphia, PA 19111. For questions about this research, you may contact the principal investigator listed above.

By signing below, you tell us that you have read this form, that you understand what it means to take part in this study, that you have received clear answers to your questions, and that you agree to take part in the study. You will receive a copy of this form. You may also request a copy of the research plan.

_____ _____
Signature of Participant Date

_____
_____
Participant's Address

_____ _____
Signature of Health Educator/Counselor Date

FOX CHASE CANCER CENTER
INSTITUTIONAL REVIEW BOARD
PROTOCOL # 01-851
APPROVED 1-21-05
EXPIRES 11-29-05

Appendix 4

COGNITIVE-AFFECTIVE FACTORS ASSOCIATED WITH UPTAKE OF, AND ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

BASELINE MEASURES

For Office Use Only	
Participant ID	
Date	

COGNITIVE-AFFECTIVE FACTORS ASSOCIATED WITH UPTAKE OF, AND ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

Directions

Thank you for participating in this study. This questionnaire will take about 20 - 40 minutes to complete. Some questions are about your thoughts, feelings, and behaviors in general. Some questions are about your thoughts, feelings, and behaviors pertaining to breast cancer. Please read the directions carefully on each page. Unless otherwise indicated, answer each question as it applies to you right now. If a question is difficult to answer, please give your best answer based on the information, thoughts, and feelings that you have right now, although you may leave questions unanswered if you do not feel comfortable answering the question(s). Your answers are strictly confidential and will be used for research and program evaluation purposes only. Your name will never appear in any publication of findings from this study. You will be assigned a study ID number that will be used to track your questionnaires instead of your name. **If you have any questions about how to complete this packet of questionnaires, please contact Dr. Kerry Sherman at (215) 214 1645. Dr. Sherman's contact information is provided on your copy of the consent form for this study.**

Thank you.

COGNITIVE-AFFECTIVE FACTORS ASSOCIATED WITH UPTAKE OF, AND ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

Directions. **Please answer each of the following questions.**

1. What is your ethnic group?	❑ Hispanic or Latino or Spanish origin ❑ Not Hispanic or Latino or Spanish origin		
2. What is your racial group? (check all that apply)	❑ American Indian or Alaska Native ❑ Asian ❑ Black or African American ❑ Native Hawaiian or Other Pacific Islander ❑ White ❑ Other (specify): _____		
3. Marital Status	❑ Single, never married ❑ Married, or living with partner ❑ Separated ❑ Divorced ❑ Widowed		
4. Number of Children	_____Sons _____Daughters		
5. Annual Household Income (in Dollars)	❑ $0-$15,000	❑ $15,001-30,000	❑ $30,001-45,000
	❑ $45,001-60,000	❑ $60,001-75,000	❑ $75,000 +
6. Highest amount of education completed (check one)	❑ Less than 8 years ❑ 8-11 years ❑ High school Graduation/ G.E.D. ❑ Vocational/Tech School ❑ Some college or university ❑ Bachelor's degree ❑ Graduate degree ❑ Doctoral		

7. Have you ever been diagnosed with cancer other than breast cancer?	❑ Yes. (Please complete this table, then continue)		❑ No. (Please go to question 8 below.)		
	When Diagnosed (MM/YY)	What type	Treatments	In treatment	In remission
First Cancer				❑	❑
Second Cancer				❑	❑
Third Cancer				❑	❑

8. When were you diagnosed with breast cancer?			MM/YY _____
9. At what clinical stage were you diagnosed?	❑ Stage 0	❑ Stage 1	❑ Stage II
	❑ Stage III	❑ Stage IV	❑ Don't know
10. Did you undergo a lumpectomy?	❑ Yes	❑ No	Date: _____mm/yy
11. Did you have a mastectomy?	❑ Yes	❑ No	Date: _____mm/yy
12. Did you have a lymph node dissection?	❑ Yes	❑ No	Date: _____mm/yy
If yes, please indicate whether it was sentinel or axillary.	❑ Sentinel	❑ Axillary	
13. Did you have chemotherapy?	❑ Yes	❑ No	Start Date: _____ mm/yy
14. Did you have radiation therapy?	❑ Yes	❑ No	Start Date: _____ mm/yy
14a. If no, will you be receiving radiation therapy as part of your breast cancer treatment in the future?	❑ Yes	❑ No	❑ Don't know
14b. If yes, when will you begin your radiation therapy?	Start Date: _____ mm/yy		

15. Are you currently taking tamoxifen/raloxifene?	❑ Yes	❑ No	

16 Did you have any problems with infection or wound healing after your treatment for breast cancer?	❑ Yes	❑ No	
17 After surgery, did you have fluid develop in your armpit (a hematoma or seroma)?	❑ Yes	❑ No	
18 Will you be taking tamoxifen /raloxifene post-treatment?	❑ Yes	❑ No	
19 Please check the box beside the word that best describes you.	❑ Pre-menopausal	❑ Post-menopausal	
20. When was your last pelvic exam?	_____mm/yy	❑ I never had a pelvic exam	
21. When did you last perform a breast self exam?	_____mm/yy	❑ Don't perform	

22. Please answer the following questions regarding mammograms.
(If you have never had a mammogram please check here: _____)

a. How old were you when you had your first mammogram? _____years old
b. How many mammograms have you had in the past 5 years? _____
c. When was the last time you had a mammogram? _____mm/yy

23. Do you have any blood relatives who have had breast cancer?	❑ Yes	❑ No
24. Do you have any relatives or friends who have developed breast cancer-related lymphedema?	❑ Yes	❑ No
25. Have you experienced lymphedema in your arm? If yes, how long after initial treatment for breast cancer did your lymphedema symptoms begin?	❑ Yes _____months	❑ No

Do you have any idea what may have triggered your lymphedema symptoms?

_____

_____

_____

_____

CES-D

Directions: Please indicate how often you felt each of the following ways during the past week by circling the number that corresponds to how often you felt that way.

	Rarely/ Not at all	Sometimes	Quite often	Almost always
I did not feel like eating; my appetite was poor.	0	1	2	3
I felt depressed.	0	1	2	3
I felt everything I did was an effort.	0	1	2	3
My sleep was restless.	0	1	2	3
I was happy.	0	1	2	3
I felt lonely.	0	1	2	3
People were unfriendly.	0	1	2	3
I enjoyed life.	0	1	2	3
I felt sad.	0	1	2	3
I felt that people disliked me.	0	1	2	3
I could not "get going".	0	1	2	3

RIES

Directions: Below is a list of comments made by people during various life events. We are interested in knowing how you feel about the possibility of developing lymphedema. Please check the box corresponding to the statement that indicates how frequently each comment was true for you in the past week regarding your risk for lymphedema. If any of these responses do not occur, mark the "not at all" column with an X.

In the past week, regarding my risk for lymphedema...	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.				
2. I avoided letting myself get upset when I thought about it or was reminded of it				
3. I tried to remove it from memory				
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind				
5. I had waves of strong feelings about it				
6. I had dreams about it				
7. I stayed away from reminders of it				
8. I felt as if it hadn't happened or it wasn't real				
9. I tried not to talk about it				
10. Pictures about it popped into my mind				
11. Other things kept making me think about it				
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them				
13. I tried not to think about it				
14. Any reminder brought back feelings about it				
15. My feelings about it were kind of numb				

STAI

Directions: A number of statements which people use to describe themselves are given below. Read each statement and then circle the number corresponding to the statement that indicates how you GENERALLY FEEL. There are no right or wrong answers. Do not spend too much time on any statement but give the answer which seems to describe how you generally feel.

	Not at All	Very Little	Moderately	Very Much
I feel pleasant.	1	2	3	4
I feel nervous and restless.	1	2	3	4
I feel satisfied with myself.	1	2	3	4
I wish I could be as happy as others seem to be.	1	2	3	4
I feel like a failure.	1	2	3	4
I feel rested.	1	2	3	4
I am "calm, cool, and collected ".	1	2	3	4
I feel that difficulties are piling up so that I cannot overcome them.	1	2	3	4
I worry too much over something that really doesn't matter.	1	2	3	4
I am happy.	1	2	3	4
I have disturbing thoughts.	1	2	3	4
I lack self-confidence.	1	2	3	4
I feel secure.	1	2	3	4
I make decisions easily.	1	2	3	4
I feel inadequate.	1	2	3	4
I am content.	1	2	3	4
Some unimportant thought runs through my mind and they bother me.	1	2	3	4
I take disappointments so keenly that I can't put them out of my mind.	1	2	3	4
I am a steady person.	1	2	3	4
I get in a state of tension or turmoil as I think over my recent concerns and interests.	1	2	3	4

MBSS

Directions: Next are four scenarios followed by statements describing what you might do in each situation. You can pick as many or as few statements as you like.

1. Vividly imagine that you are **afraid** of the dentist and have to get some dental work done. Which of the following would you do? Check **all** of the statements that might apply to you.

___ I would ask the dentist exactly what he was going to do.
___ I would take a tranquilizer or have a drink before going.
___ I would try to think about pleasant memories.
___ I would want the dentist to tell me when I would feel pain.
___ I would try to sleep.
___ I would watch all the dentist's movements and listen for the sound of the drill.
___ I would watch the flow of water from my mouth to see if it contained blood.
___ I would do mental puzzles in my mind.

2. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check **all** statements that might apply to you.

___ I would sit by myself and have as many daydreams and fantasies as I could.
___ I would stay alert and try to keep myself from falling asleep.
___ I would exchange life stories with the other hostages.
___ If there was a radio, I would stay near it and listen to the bulletins about what the police were doing.
___ I would watch every movement of my captors and keep an eye on their weapons.
___ I would try to sleep as much as possible.
___ I would think about how nice it's going to be when I get home.
___ I would make sure I knew where every possible exit was.

3. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check **all** the statements that might apply to you.

___ I would talk to my coworkers to see if they knew about what the supervisor's evaluation of me said.
___ I would review the list of duties for my present job and try to figure out if I had fulfilled them all.
___ I would go to the movies to take my mind off things.
___ I would try to remember any arguments or disagreements I might have had with the supervisor that would have lowered his opinion of me.
___ I would push all thoughts of being laid off out of my mind.
___ I would tell my spouse that I'd rather not discuss my chances of being laid off.
___ I would try to think of employees in my department the supervisor might think have done the worst job.
___ I would continue doing my work as if nothing special was happening.

4. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check **all** of the statements that might apply to you.

___ I would carefully read the information provided about safety features in the plane and make sure I knew where the emergency exits were.
___ I would make small talk with the passenger beside me.
___ I would watch the end of the movie, even if I had seen it before.
___ I would call for the stewardess and ask her exactly what the problem was.
___ I would order a drink or tranquilizer from the stewardess.
___ I would listen carefully to the engines for unusual noises and would watch the crew to see if their behavior was out of the ordinary.
___ I would talk to the passenger beside me about what might be wrong.
___ I would settle down and read a book or magazine or write a letter.

Cognitive-Affective Mediating Units

Directions: The following questions assess the your thoughts and feelings in relation to the possibility of developing lymphedema. Please answer each question by inserting the appropriate figure or by circling your response using the scale provided.

[SELF-CONSTRUALS/ENCODINGS]

1. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in the next year?

   _____%

2. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in your lifetime?

   _____%

3. Overall, how would you rate your risk for developing lymphedema? (circle one)

1	2	3	4	5
very low	a bit lower than average	about average	a little higher than average	much higher than average

4. Do you feel as though you are the kind of person who is likely to develop lymphedema?

1	2	3	4	5
not at all	a little bit	moderately	quite a bit	very much

[EXPECTANCIES/BELIEFS]

1. In general, to what extent, do you believe there are things you can do to prevent developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent, do you believe practicing the recommended arm and hand precautions will minimize your chances of developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. How serious would you say lymphedema is?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent do you feel that developing lymphedema would interfere with life?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent do you feel that problems you would experience from lymphedema would last a long time?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. To what extent do you believe that whether or not you develop lymphedema is God's will?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. To what extent do you believe that whether or not you develop lymphedema is just luck?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

8. To what extent do you anticipate that you will be regularly checking yourself for signs of lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

9. In general, to what extent do you believe that you can effectively adhere to recommended arm and hand precautions to minimize lymphedema risk?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[VALUES/GOALS]

1. To what extent is feeling attractive important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent is the way your partner perceives your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. To what extent is the way you perceive your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent is feeling well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent is functioning well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[AFFECT]

1. During the past month, how often have thoughts about lymphedema affected your mood?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. During the past month, how often have thoughts about lymphedema affected your ability to perform your daily activities?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. During the past month, have you been worried about your risk for lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. When thinking about your risk for lymphedema, do you feel sad or depressed?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. When thinking about your risk for lymphedema, do you feel scared or anxious?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. When thinking about your risk for lymphedema, do you feel angry?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. Do you worry that you won't know when to contact the doctor about any lymphedema symptoms you experience?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[SELF-REGULATORY STRATEGIES]

We are interested in how you feel and what you plan to do in response to your risk for lymphedema following your breast cancer treatment. The following items pertain to your thoughts and behaviors regarding your risk status and subsequent recommendations, or practices you can follow, to minimize lymphedema symptoms. **Please respond to each statement by circling the number that best reflects how you feel.**

1. I am able to make the necessary lifestyle changes to carry out recommended precautions (e.g., wearing gloves when doing housework, keeping your arm very clean and well moisturized, avoiding sun exposure to the affected arm) to minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. I am able to limit the amount of stress I experience about my lymphedema risk.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. I am able to calm myself down when I am anxious and worried about developing lymphedema.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. I am able to follow the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. I am able to limit the amount of stress I experience when I practice the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
Not at all	a little bit	somewhat	quite a bit	very much

Lymphedema Knowledge Scale

Lymphedema is a build up of fluid that causes swelling in an arm or the chest wall after breast cancer surgery that includes removal of lymph nodes and/or radiation therapy to the underarm area. Before or after your breast surgery, you were given information about recommended "arm and hand" precautions that you can take to reduce the risk of developing lymphedema.

The following statements represent beliefs that women may have regarding lymphedema and lymphedema "arm and hand" precautions. Please place an "X" in the appropriate box to indicate whether you believe that the statement is true (Yes) or false (No).

	Yes	No
1. Breast cancer treatment increases your chances of developing lymphedema.		
2. Women who have axillary node surgery followed by radiation therapy have a higher risk of developing lymphedema.		
3. Lymphedema can only occur within the first month following surgery for breast cancer.		
4. Lymphedema can occur at any time following breast cancer surgery.		
5. It is advisable to avoid blood pressure readings and injections on the affected arm.		
6. Consult with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall.		
7. When manicuring your nails, it is recommended that you always cut the cuticles.		
8. It is recommended that you keep your affected arm very clean and well moisturized.		
9. It is recommended that you avoid traveling by air.		
10. It is advisable that you always wear gloves when doing housework or gardening.		
11. It is recommended that you regularly expose your affected arm to the sun.		
12. It is recommended that you avoid heavy lifting and carrying handbags with over-the-shoulder straps.		
13. It is acceptable to wear tight jewelry around the affected fingers or arm.		

	Yes	No
14. Try to avoid extreme temperature changes when bathing, washing dishes, etc.		
15. An inflammation or infection in the affected arm is not a sign of lymphedema.		
16. Try to avoid any trauma in the affected arm (bruising, cuts, sunburn or other burns, sports injuries, insect bites, cat scratches).		
17. It is advisable that you wear a well-fitted bra with wire support.		
18. It is recommended that you only use an electric razor to remove hair from under your arm.		
19. If you cut or puncture your affected arm, wash the area immediately and cover with a gauze dressing.		

Uptake of, and Adherence to, Lymphedema-related Arm and Hand Precautions

⇒ Below is a list of recommended "arm and hand" precautions for reducing lymphedema risk. Please place an "X" in the appropriate box to indicate whether you are currently practicing the precaution (Yes) or you are not practicing the precaution (No).

*If you **are currently practicing a precaution**, please indicate how likely it is that you will be able to continue practicing this precaution for the rest of your life.

*If you are **NOT currently practicing the precaution**, please indicate how likely it is that you will establish this practice within the next 6 months.

1. Are you currently avoiding blood pressure readings and injections on the affected arm?

_____ Yes **_____ No**

If YES,

What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

2. Are you consulting with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall?

_____ Yes **_____ No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

3. **When manicuring your nails, do you avoid cutting your cuticles?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

4. **Are you keeping your affected arm very clean and well moisturized?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

5. **Are you always wearing gloves when doing housework or gardening?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

6. **Are you avoiding exposing your affected arm to the sun?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

7. **Are you avoiding heavy lifting and carrying handbags with over-the-shoulder straps?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

8. **Are you avoiding wearing tight jewelry around the affected fingers or arm?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

9. **Are you avoiding extreme temperature changes when bathing, washing dishes, etc.?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

10. **Are you avoiding any trauma in the affected arm (bruising, cuts, burns, sports injuries, insect bites, cat scratches)?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

11. **Are you wearing loose dresses or shirt/blouse sleeves?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

12. **Are you only using an electric razor to remove hair from under your arm?**

_____ Yes **_____ No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

Lymphedema Symptom Measurement Scale

SECTION A:

Please answer the following background questions.

1. Are you right-handed, left-handed, or do you use both hands to the same extent?

(Please choose one)

_____Right-Handed

_____Left-Handed

_____Use both hands to the same extent

2. What is your date of birth? _____(month/day/year)

3. In what month and year was your breast cancer diagnosed?
_____(month/year)

4. Which breast was affected?

(Please choose one)

_____Left _____Right _____Both

If both breasts were affected, please answer the following:

a. Was the breast cancer in both breasts diagnosed at the same time or at different times?

_____Same _____Different

b. Which side was diagnosed first?

_____Left Side _____Right Side

c. When was the *first* breast cancer diagnosed?

_____(month) _____(year)

d. When was the *second* breast cancer diagnosed?

_____(month) _____(year)

5. Was there any time before the date of your (first) diagnosis when your right and left hands or arms looked different to you?

_____YES _____NO ⇨ Please go to SECTION B on the next page.

a. How did the hands or arms appear different?
(Please check all that apply)

_____Size _____Shape

_____Feel of skin _____Something else
Please specify: _____
_____

b. Which side appeared larger, your right side or your left side?

_____Right Side ____Left Side

If you placed a check next to "size" in question 5a, please continue with question 6 below.

If you did not place a check next to "size" in question 5a, please go to SECTION B on page 26.

6. Did this difference appear suddenly, gradually, or was it something that was always there?

___Suddenly ____Gradually ____Always there ⇨ Please go to **SECTION B** on the next page.

a. In what month and year did you first notice this?
_____(month) _____(year)

b. Did the difference in size involve the:

(1) Hand: _____YES _____NO
(2) Lower Arm: _____YES _____NO
(3) Upper Arm: _____YES _____NO

c. Did any of the following happen that made one side larger than the other? (Please check all that apply)

_____Injury _____Infection _____Illness

_____Exercise _____Something else,
please specify: _____

SECTION B:

Please answer the following questions about your arms.

1. During the past three months, did your right and left **hands** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 2 on the next page.

a. Which **hand** appeared larger?
_____ right hand _____ left hand

b. In what month and year did you first notice this difference in size?
_____ (month) _____ (year)

c. Did this difference in hand size appear suddenly or gradually?
_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **hands** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **hands** change from day to day, or was it pretty steady?
_____ Changes
_____ Steady

f. Is the one **hand** still larger than the other?
_____ Yes
_____ No

If no, in what month and year did your **hands** return to being the same size?

_____ (month) _____ (year)

2. During the past three months, did your right and left **lower arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 3 on the next page.

a. Which **lower arm** appeared larger, your right lower arm or your left lower arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **lower arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **lower arms** was: (Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **lower arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **lower arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **lower arms** return to being the same size?

_____ (month) _____ (year)

3. During the past three months, did your right and left **upper arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to SECTION C on the next page

a. Which **upper arm** appeared larger, your right upper arm or your left upper arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **upper arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **upper arms** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **upper arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **upper arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **upper arms** return to being the same size?

_____ (month) _____ (year)

SECTION C

The following are ways that people notice that their hands or arms are different from each other. From the choices given, please indicate the extent you noticed each in the past three months.

1. Your rings got too tight on one side.

_____YES _____NO ⇨ Go to Question 2 below.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

2. Your watch got too tight.

_____YES _____NO ⇨ Go to Question 3 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

3. Your bracelets got too tight on one side.

_____YES _____NO ⇨ Go to Question 4 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

4. Your clothing was too tight on one side.

_____YES _____NO ⇨ Go to Question 5 next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

5. One side was puffy compared to the other.

_____YES _____NO ⇨ Go to Question 6 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

6. You couldn't see the knuckles of the hand on one side.

_____YES _____NO ⇨ Go to Question 7 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

7. You couldn't see the veins in the hand on one side.

_____YES _____NO ⇨ Go to Question 8 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

8. Your skin felt different on one side; for example firmer or "leathery" or some other way.

_____YES _____NO ⇨ Go to Question 9 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

9. Your hand or arm felt tired, thick, or heavy on one side.

_____YES _____NO ⇨ Go to Question 10 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

10. You had pain in your hand or arm on one side.

_____YES _____NO ⇨ Go to Question 11 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

11. You noticed indentations in the skin of your hand or arm on one side when you leaned against something.

_____YES _____NO ⇨ Go to Question 12 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

12. After exercise, your hand or arm swelled on one side.

_____YES _____NO ⇨ Go to Question 13 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

13. You had difficulty writing.

_____YES _____NO ⇨ Go to Question 14 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

14. You noticed the difference in some other way.

_____YES _____NO ⇨ Go to **SECTION D** on the next page.

Please explain:

_____

_____

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

IF YOU ANSWERED YES TO AT LEAST ONE OF THE QUESTIONS IN SECTION C ABOVE, PLEASE GO TO SECTION D (BELOW).

IF YOU ANSWERED NO TO ALL QUESTIONS IN SECTION C ABOVE, YOU HAVE COMPLETED THE QUESTIONNAIRE.

We greatly appreciate the time and effort you gave in helping us with our study and look forward to calling you and talking with you in approximately six months in order to complete a similar, follow-up, questionnaire. Best wishes for a continued healthy recovery!

SECTION D

Please indicate your answers from the choices given.

1. Did you ever talk to a doctor, nurse, physical therapist or other health professional about your **hands** being different sizes from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

a. What type or types of health professionals did you talk with? (Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **hands** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **hands** were different from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have?
(Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

2. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **lower arms** being different sizes from each other?

_____YES _____NO ⇨ Go to Question 3 on the next page.

a. What type or types of health professionals did you talk with?
(Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **lower arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **lower arms** were different from each other?

_____YES _____NO ⇨ Go to Question 3 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have?
(Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

3. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **upper arms** being different sizes from each other?

_____YES _____NO ⇨ Go to SECTION D on the next page.

a. What type or types of health professionals did you talk with?
(Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **upper arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **upper arms** were different from each other?

_____YES _____NO ⇨ Go to SECTION D on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have? (Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

YOU HAVE COMPLETED THE QUESTIONNAIRE.

We greatly appreciate the time and effort you gave in helping us with our study and look forward to calling you and talking with you in approximately six months in order to complete a similar, follow-up, questionnaire. Best wishes for a continued healthy recovery!

COGNITIVE-AFFECTIVE FACTORS ASSOCIATED WITH UPTAKE OF, AND ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

SIX-MONTH MEASURES

For Office Use Only	
Participant ID	
Date	

COGNITIVE-AFFECTIVE PREDICTORS OF THE UPTAKE OF, AND SUSTAINED ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

6- MONTH FOLLOW-UP PROVISIONAL MEASURES

Directions. Please answer each of the following questions.

1. In the past 6 months, have you been diagnosed with breast cancer, or had a recurrence of previously diagnosed breast cancer?	☐ Yes	☐ No
2. In the past 6 months, since completing the last questionnaire, have you experienced lymphedema in your arm?	☐ Yes	☐ No
If yes, how long after initial treatment for breast cancer did your lymphedema symptoms begin?	_____: Months	
Do you have any idea what may have triggered your lymphedema symptoms?		

RIES

Directions: Below is a list of comments made by people during various life events. We are interested in knowing how you feel about the possibility of developing lymphedema. Please check the box corresponding to the statement that indicates how frequently each comment was true for you in the past week regarding your risk for lymphedema. If any of these responses do not occur, mark the "not at all" column with an X.

In the past week, regarding your risk for lymphedema...	Not at all	Rarely	Sometimes	Often
1. You thought about it when you didn't mean to.				
2. You avoided letting yourself get upset when you thought about it or was reminded of it				
3. You tried to remove it from memory				
4. You had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind				
5. You had waves of strong feelings about it				
6. You had dreams about it				
7. You stayed away from reminders of it				
8. You felt as if it hadn't happened or it wasn't real				
9. You tried not to talk about it				
10. Pictures about it popped into your mind				
11. Other things kept making you think about it				
12. You were aware that you still had a lot of feelings about it, but you didn't deal with them				
13. you tried not to think about it				
14. Any reminder brought back feelings about it				
15. Your feelings about it were kind of numb				

Cognitive-Affective Mediating Units

Directions: The following questions assess the your thoughts and feelings in relation to the possibility of developing lymphedema. Please answer each question by inserting the appropriate figure or by circling your response using the scale provided.

[SELF-CONSTRUALS/ENCODINGS]

1. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in the next year?

   _____%

2. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in your lifetime?

   _____%

3. Overall, how would you rate your risk for developing lymphedema? (circle one)

1	2	3	4	5
very low	a bit lower than average	about average	a little higher than average	much higher than average

4. Do you feel as though you are the kind of person who is likely to develop lymphedema?

1	2	3	4	5
not at all	a little bit	moderately	quite a bit	very much

[EXPECTANCIES/BELIEFS]

1. In general, to what extent, do you believe there are things you can do to prevent developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent, do you believe practicing the recommended arm and hand precautions will minimize your chances of developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. How serious would you say lymphedema is?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent do you feel that developing lymphedema would interfere with life?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent do you feel that problems you would experience from lymphedema would last a long time?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. To what extent do you believe that whether or not you develop lymphedema is God's will?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. To what extent do you believe that whether or not you develop lymphedema is just luck?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

8. To what extent do you anticipate that you will be regularly checking yourself for signs of lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

9. In general, to what extent do you believe that you can effectively adhere to recommended arm and hand precautions to minimize lymphedema risk?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[VALUES/GOALS]

1. To what extent is feeling attractive important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent is the way your partner perceives your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. To what extent is the way you perceive your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent is feeling well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent is functioning well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[AFFECT]

1. During the past month, how often have your thoughts about your lymphedema affected your mood?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. During the past month, how often have your thoughts about lymphedema affected your ability to perform your daily activities?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. During the past month, have you been worried about your risk for lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. When thinking about your risk for lymphedema, do you feel sad or depressed?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. When thinking about your risk for lymphedema, do you feel scared or anxious?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. When thinking about your risk for lymphedema, do you feel angry?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. Do you worry that you won't know when to contact the doctor about any lymphedema symptoms you experience?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[SELF-REGULATORY STRATEGIES]

We are interested in how you feel and what you plan to do in response to your risk for lymphedema following your breast cancer treatment. The following items pertain to your thoughts and behaviors regarding your risk status and subsequent recommendations, or practices you can follow, to minimize lymphedema symptoms. **Please respond to each statement by choosing the response that best reflects how you feel.**

1. You are able to make the necessary lifestyle changes to carry out recommended precautions (e.g., wearing gloves when doing housework, keeping your arm very clean and well moisturized, avoiding sun exposure to the affected arm) to minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. You are able to limit the amount of stress you experience about your lymphedema risk.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. You are able to calm yourself down when you are anxious and worried about developing lymphedema.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. You are able to follow the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. You are able to limit the amount of stress you experience when you practice the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

Lymphedema Informational Brochure Satisfaction

At the time you completed the baseline questionnaire, we gave you a booklet with information about lymphedema. The following questions are in reference to this booklet.

1. Did you read this booklet? _____ YES _____ NO

2. Did you keep the booklet? _____ YES _____ NO

3. How useful did you find the booklet?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. How satisfied were you with the information provided in the booklet?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. Was there any information about lymphedema that was not covered in the booklet, but you felt should have been?

YES_____ NO _____

If YES, what was it? _____

Lymphedema Knowledge Scale

Lymphedema is a build up of fluid that causes swelling in an arm or the chest wall after breast cancer surgery that includes removal of lymph nodes and/or radiation therapy to the underarm area. Before or after your breast surgery, you were given information about recommended "arm and hand" precautions that you can take to reduce the risk of developing lymphedema.

The following statements represent beliefs that women may have regarding lymphedema and lymphedema "arm and hand" precautions. Please indicate whether you believe that the statement is true (Yes) or false (No).

	Yes	No
1. Breast cancer treatment increases your chances of developing lymphedema.		
2. Women who have axillary node surgery followed by radiation therapy have a higher risk of developing lymphedema.		
3. Lymphedema can only occur within the first month following surgery for breast cancer.		
4. Lymphedema can occur at any time following breast cancer surgery.		
5. It is advisable to avoid blood pressure readings and injections on the affected arm.		
6. Consult with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall.		
7. When manicuring your nails, it is recommended that you always cut the cuticles.		
8. It is recommended that you keep your affected arm very clean and well moisturized.		
9. It is recommended that you avoid traveling by air.		
10. It is advisable that you always wear gloves when doing housework or gardening.		
11. It is recommended that you regularly expose your affected arm to the sun.		
12. It is recommended that you avoid heavy lifting and carrying handbags with over-the-shoulder straps.		
13. It is acceptable to wear tight jewelry around the affected fingers or arm.		

	Yes	No
14. Try to avoid extreme temperature changes when bathing, washing dishes, etc.		
15. An inflammation or infection in the affected arm is not a sign of lymphedema.		
16. Try to avoid any trauma in the affected arm (bruising, cuts, sunburn or other burns, sports injuries, insect bites, cat scratches).		
17. It is advisable that you wear a well-fitted bra with wire support.		
18. It is recommended that you only use an electric razor to remove hair from under your arm.		
19. If you cut or puncture your affected arm, wash the area immediately and cover with a gauze dressing.		

Uptake of, and Adherence to, Lymphedema-related Arm and Hand Precautions

⇒ Below is a list of recommended "arm and hand" precautions for reducing lymphedema risk. Please indicate whether you are currently practicing the precaution (Yes) or you are not practicing the precaution (No).

*If you **are currently practicing a precaution**, please indicate how likely it is that you will be able to continue practicing this precaution for the rest of your life.

*If you are **NOT currently practicing the precaution**, please indicate how likely it is that you will establish this practice within the next 6 months.

1. Are you currently avoiding blood pressure readings and injections on the affected arm?

_____ **Yes** _____ **No**

If YES,

What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

2. Are you consulting with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall?

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

3. **When manicuring your nails, do you avoid cutting your cuticles?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

4. **Are you keeping your affected arm very clean and well moisturized?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

5. **Are you always wearing gloves when doing housework or gardening?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

6. **Are you avoiding exposing your affected arm to the sun?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

7. **Are you avoiding heavy lifting and carrying handbags with over-the-shoulder straps?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

8. **Are you avoiding wearing tight jewelry around the affected fingers or arm?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

9. **Are you avoiding extreme temperature changes when bathing, washing dishes, etc.?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

10. **Are you avoiding any trauma in the affected arm (bruising, cuts, burns, sports injuries, insect bites, cat scratches)?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

11. **Are you wearing loose dresses or shirt/blouse sleeves?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

12. **Are you only using an electric razor to remove hair from under your arm?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

Lymphedema Symptom Measurement Scale

SECTION A:

Please answer the following background questions.

1. Are you right-handed, left-handed, or do you use both hands to the same extent?
   (Please choose one)

   _____Right-Handed

   _____Left-Handed

   _____Use both hands to the same extent

2. What is your date of birth? _____(month/day/year)

3. In what month and year was your breast cancer diagnosed?
   _____(month/year)

4. Which breast was affected?
   (Please choose one)

   _____Left _____Right _____Both

   If both breasts were affected, please answer the following:

   a. Was the breast cancer in both breasts diagnosed at the same time or at different times?
      _____Same _____Different

   b. Which side was diagnosed first?
      _____Left Side _____Right Side

   c. When was the *first* breast cancer diagnosed?
      _____(month) _____(year)

   d When was the *second* breast cancer diagnosed?
      _____(month) _____(year)

5. Was there any time <u>before</u> the date of your (first) diagnosis when your right and left hands or arms looked different to you?

_____YES _____NO ⇨ Please go to SECTION B on the next page.

a. How did the hands or arms appear different?
(Please check <u>all</u> that apply)

_____Size _____Shape

_____Feel of skin _____Something else
Please specify: _____

b. Which side appeared larger, your right side or your left side?

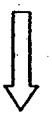
_____Right Side _____Left Side

<u>If you placed a check next to "size" in question 5a</u>, please continue with question 6 below.

<u>If you did not place a check next to "size" in question 5a</u>, please go to SECTION B on the next page.

6. Did this difference appear suddenly, gradually, or was it something that was always there?

___Suddenly ___Gradually ___Always there ⇨ Please go to **SECTION B** on the next page.



a. In what month and year did you first notice this?
_____(month) _____(year)

b. Did the difference in size involve the:

(1) Hand: _____YES _____NO
(2) Lower Arm: _____YES _____NO
(3) Upper Arm: _____YES _____NO

c. Did any of the following happen that made one side larger than the other?
(Please check <u>all</u> that apply)

_____Injury _____Infection _____Illness

_____Exercise _____Something else,
please specify: _____

SECTION B:

Please answer the following questions about your arms.

1. During the past three months, did your right and left **hands** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 2 on the next page.

a. Which **hand** appeared larger?
_____ right hand _____ left hand

b. In what month and year did you first notice this difference in size?
_____ (month) _____ (year)

c. Did this difference in hand size appear suddenly or gradually?
_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **hands** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **hands** change from day to day, or was it pretty steady?
_____ Changes
_____ Steady

f. Is the one **hand** still larger than the other?
_____ Yes
_____ No

If no, in what month and year did your **hands** return to being the same size?

_____ (month) _____ (year)

2. During the past three months, did your right and left **lower arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 3 on the next page.

a. Which **lower arm** appeared larger, your right lower arm or your left lower arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **lower arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **lower arms** was: (Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **lower arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **lower arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **lower arms** return to being the same size?

_____ (month) _____ (year)

3. During the past three months, did your right and left **upper arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to SECTION C on the next page

a. Which **upper arm** appeared larger, your right upper arm or your left upper arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **upper arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **upper arms** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **upper arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **upper arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **upper arms** return to being the same size?

_____ (month) _____ (year)

SECTION C

The following are ways that people notice that their hands or arms are different from each other. From the choices given, please indicate the extent you noticed each in the past three months.

1. Your rings got too tight on one side.

_____YES _____NO ⇨ Go to Question 2 below.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

2. Your watch got too tight.

_____YES _____NO ⇨ Go to Question 3 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

3. Your bracelets got too tight on one side.

_____YES _____NO ⇨ Go to Question 4 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

4. Your clothing was too tight on one side.

_____YES _____NO ⇨ Go to Question 5 next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

5. One side was puffy compared to the other.

_____YES _____NO ⇨ Go to Question 6 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

6. You couldn't see the knuckles of the hand on one side.

_____YES _____NO ⇨ Go to Question 7 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

7. You couldn't see the veins in the hand on one side.

_____YES _____NO ⇨ Go to Question 8 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

8. Your skin felt different on one side; for example firmer or "leathery" or some other way.

_____YES _____NO ⇨ Go to Question 9 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

9. Your hand or arm felt tired, thick, or heavy on one side.

_____YES _____NO ⇨ Go to Question 10 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

10. You had pain in your hand or arm on one side.

_____YES _____NO ⇨ Go to Question 11 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

11. You noticed indentations in the skin of your hand or arm on one side when you leaned against something.

_____YES _____NO ⇨ Go to Question 12 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

12. After exercise, your hand or arm swelled on one side.

_____YES _____NO ⇨ Go to Question 13 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

13. You had difficulty writing.

_____YES _____NO ⇨ Go to Question 13 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

14. You noticed the difference in some other way.

_____YES _____NO ⇨ Go to **SECTION D** on the next page.

Please explain:

_____

_____

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

IF YOU ANSWERED YES TO AT LEAST ONE OF THE QUESTIONS IN SECTION C ABOVE, PLEASE GO TO SECTION D (BELOW).

IF YOU ANSWERED NO TO ALL QUESTIONS IN SECTION C ABOVE, YOU HAVE COMPLETED THE QUESTIONNAIRE.

We greatly appreciate the time and effort you gave in helping us with our study and look forward to calling you and talking with you in approximately six months in order to complete the final, follow-up, questionnaire. Best wishes for a continued healthy recovery!

SECTION D

Please indicate your answers from the choices given.

1. Did you ever talk to a doctor, nurse, physical therapist or other health professional about your **hands** being different sizes from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

a. What type or types of health professionals did you talk with? (Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify: _____

b. In what month and year did you first talk with a health professional about your **hands** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **hands** were different from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have?
(Please check all that apply)

_____ Exercise _____ Elevation

_____ Wrap _____ Medication

_____ Sleeve _____ Massage

_____ Pump _____ Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____ YES _____ NO

2. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **lower arms** being different sizes from each other?

_____ YES _____ NO ⇨ Go to Question 3 on the next page.

a. What type or types of health professionals did you talk with?
(Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **lower arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **lower arms** were different from each other?

_____YES _____NO ⇨ Go to Question 3 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have? (Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

3. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **upper arms** being different sizes from each other?

_____YES _____NO ⇨ Go to SECTION D on the next page.

a. What type or types of health professionals did you talk with? (Please check all that apply)

_____ Doctor _____ Physical Therapist

_____Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **upper arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **upper arms** were different from each other?

_____YES _____NO ⇨ Go to SECTION D on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have? (Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

YOU HAVE COMPLETED THE QUESTIONNAIRE.

We greatly appreciate the time and effort you gave in helping us with our study and look forward to calling you and talking with you in approximately six months in order to complete the final, follow-up, questionnaire. Best wishes for a continued healthy recovery!

COGNITIVE-AFFECTIVE FACTORS ASSOCIATED WITH UPTAKE OF, AND ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

TWELVE-MONTH MEASURES

For Office Use Only	
Participant ID	
Date	

COGNITIVE-AFFECTIVE PREDICTORS OF THE UPTAKE OF, AND SUSTAINED ADHERENCE TO, LYMPHEDEMA SYMPTOM MINIMIZATION PRACTICES IN BREAST CANCER SURVIVORS

12-MONTH FOLLOW-UP PROVISIONAL MEASURES

Directions. Please answer each of the following questions.

1. In the past 6 months, have you been diagnosed with breast cancer, or had a recurrence of previously diagnosed breast cancer?	❑ Yes	❑ No
2. In the past 6 months, since completing the last questionnaire, have you experienced lymphedema in your arm?	❑ Yes	❑ No
If yes, how long after initial treatment for breast cancer did your lymphedema symptoms begin?	_____: Months	

Do you have any idea what may have triggered your lymphedema symptoms?

RIES

Directions: Below is a list of comments made by people during various life events. We are interested in knowing how you feel about the possibility of developing lymphedema. Please check the box corresponding to the statement that indicates how frequently each comment was true for you in the past week regarding your risk for lymphedema. If any of these responses do not occur, mark the "not at all" column with an X.

In the past week, regarding my risk for lymphedema...	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.				
2. I avoided letting myself get upset when I thought about it or was reminded of it				
3. I tried to remove it from memory				
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about it that came into my mind				
5. I had waves of strong feelings about it				
6. I had dreams about it				
7. I stayed away from reminders of it				
8. I felt as if it hadn't happened or it wasn't real				
9. I tried not to talk about it				
10. Pictures about it popped into my mind				
11. Other things kept making me think about it				
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them				
13. I tried not to think about it				
14. Any reminder brought back feelings about it				
15. My feelings about it were kind of numb				

Cognitive-Affective Mediating Units

Directions: The following questions assess the your thoughts and feelings in relation to the possibility of developing lymphedema. Please answer each question by inserting the appropriate figure or by circling your response using the scale provided.

[SELF-CONSTRUALS/ENCODINGS]

1. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in the next year?

   _____%

2. From 0% (no chances at all) to 100% (absolutely certain), what are your overall chances of developing lymphedema in your lifetime?

   _____%

3. Overall, how would you rate your risk for developing lymphedema? (circle one)

1	2	3	4	5
very low	a bit lower than average	about average	a little higher than average	much higher than average

4. Do you feel as though you are the kind of person who is likely to develop lymphedema?

1	2	3	4	5
not at all	a little bit	moderately	quite a bit	very much

[EXPECTANCIES/BELIEFS]

1. In general, to what extent, do you believe there are things you can do to prevent developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent, do you believe practicing the recommended arm and hand precautions will minimize your chances of developing lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. How serious would you say lymphedema is?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent do you feel that developing lymphedema would interfere with life?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent do you feel that problems you would experience from lymphedema would last a long time?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. To what extent do you believe that whether or not you develop lymphedema is God's will?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. To what extent do you believe that whether or not you develop lymphedema is just luck?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

8. To what extent do you anticipate that you will be regularly checking yourself for signs of lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

9. In general, to what extent do you believe that you can effectively adhere to recommended arm and hand precautions to minimize lymphedema risk?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[VALUES/GOALS]

1. To what extent is feeling attractive important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. To what extent is the way your partner perceives your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. To what extent is the way you perceive your body important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. To what extent is feeling well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. To what extent is functioning well important to you?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[AFFECT]

1. During the past month, how often have your thoughts about your lymphedema affected your mood?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. During the past month, how often have your thoughts about lymphedema affected your ability to perform your daily activities?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. During the past month, have you been worried about your risk for lymphedema?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. When thinking about your risk for lymphedema, do you feel sad or depressed?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. When thinking about your risk for lymphedema, do you feel scared or anxious?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. When thinking about your risk for lymphedema, do you feel angry?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

7. Do you worry that you won't know when to contact the doctor about any lymphedema symptoms you experience?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

[SELF-REGULATORY STRATEGIES]

We are interested in how you feel and what you plan to do in response to your risk for lymphedema following your breast cancer treatment. The following items pertain to your thoughts and behaviors regarding your risk status and subsequent recommendations, or practices you can follow, to minimize lymphedema symptoms. **Please respond to each statement by choosing the response that best reflects how you feel.**

1. You are able to make the necessary lifestyle changes to carry out recommended precautions (e.g., wearing gloves when doing housework, keeping your arm very clean and well moisturized, avoiding sun exposure to the affected arm) to minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. You are able to limit the amount of stress you experience about your lymphedema risk.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. You are able to calm yourself down when you are anxious and worried about developing lymphedema.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. You are able to follow the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. You are able to limit the amount of stress you experience when you practice the recommended behaviors that may minimize lymphedema symptoms.

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

Lymphedema Informational Brochure Satisfaction

At the time you completed the baseline questionnaire, we gave you a booklet from the American Cancer Society with information about lymphedema. The following questions are in reference to this.

1. Do you still have this booklet? _____ YES _____ NO

If YES, please answer questions 2, 3, 4, and 5 below.

2. Over the past six months, have you referred to the Lymphedema information booklet that was provided to you upon completion of the baseline questionnaire?

_____ YES _____ NO

3. How useful did you find the booklet?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. How satisfied were you with the information provided in the booklet?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. Was there any information about lymphedema that was not covered in the booklet, but you felt should have been?

YES_____ NO _____

If YES, what was it?

_____

_____

_____

_____

_____

_____

Lymphedema Knowledge Scale

Lymphedema is a build up of fluid that causes swelling in an arm or the chest wall after breast cancer surgery that includes removal of lymph nodes and/or radiation therapy to the underarm area. Before or after your breast surgery, you were given information about recommended "arm and hand" precautions that you can take to reduce the risk of developing lymphedema.

The following statements represent beliefs that women may have regarding lymphedema and lymphedema "arm and hand" precautions. Please indicate whether you believe that the statement is true (Yes) or false (No).

	Yes	No
1. Breast cancer treatment increases your chances of developing lymphedema.		
2. Women who have axillary node surgery followed by radiation therapy have a higher risk of developing lymphedema.		
3. Lymphedema can only occur within the first month following surgery for breast cancer.		
4. Lymphedema can occur at any time following breast cancer surgery.		
5. It is advisable to avoid blood pressure readings and injections on the affected arm.		
6. Consult with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall.		
7. When manicuring your nails, it is recommended that you always cut the cuticles.		
8. It is recommended that you keep your affected arm very clean and well moisturized.		
9. It is recommended that you avoid traveling by air.		
10. It is advisable that you always wear gloves when doing housework or gardening.		
11. It is recommended that you regularly expose your affected arm to the sun.		
12. It is recommended that you avoid heavy lifting and carrying handbags with over-the-shoulder straps.		

13. It is acceptable to wear tight jewelry around the affected fingers or arm.		
14. Try to avoid extreme temperature changes when bathing, washing dishes, etc.		
15. An inflammation or infection in the affected arm is not a sign of lymphedema.		
16. Try to avoid any trauma in the affected arm (bruising, cuts, sunburn or other burns, sports injuries, insect bites, cat scratches).		
17. It is advisable that you wear a well-fitted bra with wire support.		
18. It is recommended that you only use an electric razor to remove hair from under your arm.		
19. If you cut or puncture your affected arm, wash the area immediately and cover with a gauze dressing.		

Uptake of, and Adherence to, Lymphedema-related Arm and Hand Precautions

⇒ Below is a list of recommended "arm and hand" precautions for reducing lymphedema risk. Please indicate whether you are currently practicing the precaution (Yes) or you are not practicing the precaution (No).

*If you **are currently practicing a precaution**, please indicate how likely it is that you will be able to continue practicing this precaution for the rest of your life.

*If you are **NOT currently practicing the precaution**, please indicate how likely it is that you will establish this practice within the next 6 months.

1. Are you currently avoiding blood pressure readings and injections on the affected arm?

_____ **Yes** _____ **No**

If YES,

What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

2. Are you consulting with the doctor immediately if you have any slight increase of swelling in the affected arm, hand, fingers, or your chest wall?

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

3. **When manicuring your nails, do you avoid cutting your cuticles?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

4. **Are you keeping your affected arm very clean and well moisturized?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

5. **Are you always wearing gloves when doing housework or gardening?**

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

6. **Are you avoiding exposing your affected arm to the sun?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

7. **Are you avoiding heavy lifting and carrying handbags with over-the-shoulder straps?**

_____**Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

8. **Are you avoiding wearing tight jewelry around the affected fingers or arm?**

_____ **Yes** _____ **No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

9. Are you avoiding extreme temperature changes when bathing, washing dishes, etc.?

_____Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

10. Are you avoiding any trauma in the affected arm (bruising, cuts, burns, sports injuries, insect bites, cat scratches)?

_____ Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

11. Are you wearing loose dresses or shirt/blouse sleeves?

_____ Yes _____ No

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

12. **Are you only using an electric razor to remove hair from under your arm?**

_____ Yes **_____ No**

If YES,
What is the likelihood that you will continue this practice for the rest of your life?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

If NO,
What is the likelihood that you will establish this practice within the next 6 months?

1	2	3	4	5
Not at all likely	Somewhat	Moderately	Quite	Very likely

Lymphedema Symptom Measurement Scale

SECTION A:

Please answer the following background questions.

1. Are you right-handed, left-handed, or do you use both hands to the same extent?

(Please choose one)

_____Right-Handed

_____Left-Handed

_____Use both hands to the same extent

2. What is your date of birth? _____(month/day/year)

3. In what month and year was your breast cancer diagnosed?
_____(month/year)

4. Which breast was affected? (Please choose one)

_____Left _____Right _____Both

If both breasts were affected, please answer the following:

a. Was the breast cancer in both breasts diagnosed at the same time or at different times?

_____Same _____Different

b. Which side was diagnosed first?

_____Left Side _____Right Side

c. When was the *first* breast cancer diagnosed?

_____(month) _____(year)

d. When was the *second* breast cancer diagnosed?

_____(month) _____(year)

5. Was there any time <u>before</u> the date of your (first) diagnosis when your right and left hands or arms looked different to you?

_____YES _____NO ⇨ Please go to SECTION B on the next page.

a. How did the hands or arms appear different?
(Please check <u>all</u> that apply)

_____Size _____Shape

_____Feel of skin _____Something else
Please specify: _____
_____

b. Which side appeared larger, your right side or your left side?

_____Right Side ____Left Side

<u>If you placed a check next to "size" in question 5a</u>, please continue with question 6 below.

<u>If you did not place a check next to "size" in question 5a</u>, please go to SECTION B on the next page.

6. Did this difference appear suddenly, gradually, or was it something that was always there?

___Suddenly ____Gradually ____Always there ⇨ Please go to **SECTION B** on the next page.

a. In what month and year did you first notice this?
_____(month) _____(year)

b. Did the difference in size involve the:

(1) Hand: _____YES _____NO
(2) Lower Arm: _____YES _____NO
(3) Upper Arm: _____YES _____NO

c. Did any of the following happen that made one side larger than the other?
(Please check <u>all</u> that apply)

_____Injury _____Infection _____Illness

_____Exercise _____Something else,
please specify: _____

SECTION B:

Please answer the following questions about your arms.

1. During the past three months, did your right and left **hands** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 2 on the next page.

a. Which **hand** appeared larger?
_____ right hand _____ left hand

b. In what month and year did you first notice this difference in size?
_____ (month) _____ (year)

c. Did this difference in hand size appear suddenly or gradually?
_____Suddenly _____Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **hands** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **hands** change from day to day, or was it pretty steady?
_____ Changes
_____ Steady

f. Is the one **hand** still larger than the other?
_____ Yes
_____ No

If no, in what month and year did your **hands** return to being the same size?

_____(month) _____(year)

2. During the past three months, did your right and left **lower arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to Question 3 on the next page.

a. Which **lower arm** appeared larger, your right lower arm or your left lower arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **lower arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **lower arms** was: (Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **lower arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **lower arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **lower arms** return to being the same size?

_____ (month) _____ (year)

3. During the past three months, did your right and left **upper arms** seem to you to be different sizes from each other?

_____ YES _____ NO ⇨ Please go to SECTION C on the next page

a. Which **upper arm** appeared larger, your right upper arm or your left upper arm?

_____ right _____ left

b. In what month and year did you first notice this difference in size?

_____ (month) _____ (year)

c. Did this difference in **upper arm** size appear suddenly or gradually?

_____ Suddenly _____ Gradually

d. During the past three months, would you say that, on average, the difference in the size of your **upper arms** was:
(Please choose one)

_____ Very slight; you are the only person who would notice this
_____ Noticeable to people who know you well, but not to strangers
_____ Very noticeable

e. During the past three months, did the amount of difference between your **upper arms** change from day to day, or was it pretty steady?

_____ Changes
_____ Steady

f. Is the one **upper arm** still larger than the other?

_____ Yes
_____ No

If no, in what month and year did your **lower arms** return to being the same size?

_____ (month) _____ (year)

SECTION C

The following are ways that people notice that their hands or arms are different from each other. From the choices given, please indicate the extent you noticed each in the past three months.

1. Your rings got too tight on one side.

_____YES _____NO ⇨ Go to Question 2 below.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

2. Your watch got too tight.

_____YES _____NO ⇨ Go to Question 3 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

3. Your bracelets got too tight on one side.

_____YES _____NO ⇨ Go to Question 4 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

4. Your clothing was too tight on one side.

_____YES _____NO ⇨ Go to Question 5 next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

5. One side was puffy compared to the other.

_____YES _____NO ⇨ Go to Question 6 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

6. You couldn't see the knuckles of the hand on one side.

_____YES _____NO ⇨ Go to Question 7 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

7. You couldn't see the veins in the hand on one side.

_____YES _____NO ⇨ Go to Question 8 below.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

8. Your skin felt different on one side; for example firmer or "leathery" or some other way.

_____YES _____NO ⇨ Go to Question 9 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

9. Your hand or arm felt tired, thick, or heavy on one side.

_____YES _____NO ⇨ Go to Question 10 below.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it <u>distress or bother</u> you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

10. You had pain in your hand or arm on one side.

_____YES _____NO ⇨ Go to Question 11 on the next page.

a. How <u>often</u> did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How <u>severe</u> was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

11. You noticed indentations in the skin of your hand or arm on one side when you leaned against something.

_____YES _____NO ⇨ Go to Question 12 below.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

12. After exercise, your hand or arm swelled on one side.

_____YES _____NO ⇨ Go to Question 13 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

13. You had difficulty writing.

_____YES _____NO ⇨ Go to Question 13 on the next page.

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

14. You noticed the difference in some other way.

_____YES _____NO ⇨ Go to **SECTION D** on the next page.

Please explain:

_____

_____

a. How often did this occur in the past 3 months?

Rarely	Occasionally	Frequently	Almost Constantly
1	2	3	4

b. How severe was it in the past 3 months?

Slight	Moderate	Severe	Very Severe
1	2	3	4

c. How much did it distress or bother you in the past 3 months?

Not At All	A Little Bit	Somewhat	Quite A Bit	Very Much
1	2	3	4	5

IF YOU ANSWERED YES TO AT LEAST ONE OF THE QUESTIONS IN SECTION C ABOVE, PLEASE GO TO SECTION D (BELOW).

IF YOU ANSWERED NO TO ALL QUESTIONS IN SECTION C ABOVE, YOU HAVE COMPLETED THE QUESTIONNAIRE.
We greatly appreciate the time and effort you gave in helping us with our study. You are now officially finished with this study! Best wishes for a continued healthy recovery!

SECTION D

Please indicate your answers from the choices given.

1. Did you ever talk to a doctor, nurse, physical therapist or other health professional about your **hands** being different sizes from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

a. What type or types of health professionals did you talk with? (Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:
_____

b. In what month and year did you first talk with a health professional about your **hands** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **hands** were different from each other?

_____YES _____NO ⇨ Go to Question 2 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have?
(Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

2. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **lower arms** being different sizes from each other?

_____YES _____NO ⇨ Go to Question 3 on the next page.

a. What type or types of health professionals did you talk with?
(Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **lower arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **lower arms** were different from each other?

_____YES _____NO ⇨ Go to Question 3 on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have? (Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

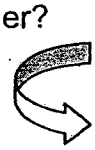
_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

3. Did you ever talk to a doctor, nurse, physical therapist, or other health Professional about your **upper arms** being different sizes from each other?



_____YES _____NO ⇨ Go to SECTION D on the next page.

a. What type or types of health professionals did you talk with? (Please check all that apply)

_____ Doctor _____ Physical Therapist

_____ Nurse _____ Other, please specify:

_____

b. In what month and year did you first talk with a health professional about your **upper arms** being different from each other?

_____(month) _____(year)

c. Did you ever receive treatment from a health professional because your **upper arms** were different from each other?

_____YES _____NO ⇨ Go to SECTION D on the next page.

(1) In what month and year did you begin treatment?

_____(month) _____(year)

(2) Which of the following treatments did you have? (Please check all that apply)

_____ Exercise _____Elevation

_____Wrap _____Medication

_____Sleeve _____Massage

_____Pump _____Other, please specify:

_____

(3) Are you still under treatment for this condition?

_____YES _____NO

YOU HAVE COMPLETED THE QUESTIONNAIRE.

We greatly appreciate the time and effort you gave in helping us with our study. You are now officially finished with this study! Best wishes for a continued healthy recovery!