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TITLE: Increasing Pain Related Communication Skills to Improve Pain Management in Metastatic Breast Cancer Patients

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CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*
The goal of the study is to improve the management of pain related to metastatic breast cancer (MBC) through a psycho-social intervention. Although clinical guidelines for the treatment of pain have been issued, under-treatment of pain in MBC patients remains a problem. This study builds upon prior research which has identified poor patient-provider communication as a key barrier to adequate cancer pain management. MBC patients are randomly assigned to either a pain communication skills (PCS) intervention or a nutrition education control condition. The impact of the PCS intervention will be evaluated by comparing the misconceptions about pain and pain treatment, level of pain, psychological adjustment, and quality of life of MBC patients who receive the PCS intervention to those who receive the nutrition education. Patients undergo four interviews using standardized measures before and after receiving the PCS intervention or nutrition education. To date, twenty-seven patients have been recruited. Preliminary results indicate that study participants have moderate to severe pain and have many misconceptions about pain and pain treatment. These misconceptions are most prevalent among Latinas. The study results will indicate the impact of a PCS intervention on MBC patients' misconceptions, level of pain, psychological distress, and quality of life.

14. SUBJECT TERMS
breast cancer, pain management, metastatic, psychosocial intervention, communication skills, psychological distress, psychological adjustment

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INTRODUCTION

The goal of the proposed study is to improve the management of pain related to metastatic breast cancer (MBC) through psycho-social intervention. Pain is a common and highly debilitating symptom for persons with MBC and has been shown to diminish their quality of life in many ways. Indeed, 60% to 90% of MBC patients report pain that interferes with their mood (makes them depressed, nervous), as well as their ability to sleep, work, and function sexually. Although clinical guidelines for the treatment of MBC pain exist, under-treatment of pain remains a pervasive problem.

Poor communication between patients and their health providers has been identified as a key barrier to adequate pain management. The proposed study seeks to address this issue of patient failure to communicate about pain to their health care provider by testing the impact of a pain communication skills intervention on MBC patients' misconceptions about pain management, level of pain and quality of life. The pain communication skills intervention combines a 30-minute one-on-one session with an interventionist and instruction on the use of a pain diary. The one-on-one session addresses: (1) participants' misconceptions about pain and pain management; (2) how to describe pain in terms of the 5 "L's": Length (or duration), Location (on the body), Like (i.e., what the pain feels like), Loss (i.e., the ways in which the pain has affected their sleeping patterns or ability to carry out daily activities), and Level of pain (i.e., pain intensity); (3) effective participant communication about pain via the use of role-play; and (4) how patients can question their health care provider about their pain management.

This longitudinal, randomized clinical trial has two arms. One arm is the pain communication skills (PCS) intervention ("experimental condition") and the other arm is a nutrition education session ("control condition"). An ethnically diverse sample of patients are being randomly assigned (i.e., have a 50/50 chance of being assigned) to either the PCS intervention or the control condition. The impact of the PCS intervention will be assessed by comparing participants who receive the PCS intervention to those participants in the control condition on misconceptions about pain management, level of pain, psychological adjustment (i.e., mood), and quality of life (e.g., ability to work, have relationships with others).

Patients are assessed using standardized measures of pain, psychological adjustment and quality of life before and after receiving the PCS intervention or nutrition education. If the intervention is found to impact study outcomes –such as reduce participants' pain management misconceptions and level of pain- and improves their quality of life, it may be incorporated into existing approaches to pain management in MBC patients. The dissemination of information from this study will facilitate the implementation of such an intervention for breast cancer patients in other cancer centers and general medical settings.

BODY

The overall goal of this study is to improve pain management for MBC patients by addressing patients' misconceptions about pain management by teaching them how to talk in more descriptive and specific terms about their pain symptoms to their main health care provider. This study examines the impact of a pain communication skills intervention on the pain, psychological adjustment (i.e., mood), and quality of life (e.g., ability to work, have relationships with others) of MBC patients. The primary study hypotheses are that for women with MBC, a pain communications skills intervention will lead to:(1) increased pain management and thus reduced pain; (2) reduced psychological distress; and (3) increased quality of life.

Procedure: Study sites include: Mt. Sinai's Oncology Outpatient Clinic, two Mt. Sinai-affiliated private practices, and Elmhurst's Oncology Outpatient Clinic. Participants are interviewed four times on three separate days. The first interview (Interview #1) occurs immediately prior to the participant's regularly scheduled appointment with their oncologist or physician/health care provider who is the main individual responsible for their cancer-related medical care. Participants are assessed on a variety of measures including pain, pain treatment, pain treatment misconceptions, mood, quality of life, and well-being. Following the interview, the interventionist randomly assigns the participant to one of the two study arms. The participants then do the following: (1) receive either the 35 minute control condition (nutrition session) or the experimental condition (PCS intervention); (2) upon completion of the session, return to the waiting room area; and (3) see their physician/health care provider for their scheduled appointment. Participants' health care provider is not informed as to which study arm the participant has been assigned. If the patient and the health care provider consent, the medical visit with the healthcare provider is audio-taped.

The second interview occurs after the medical visit (medical visit #1) on the same day as interview #1. During this interview, participants complete standard measures of pain communication skills, questionnaire items on socio-demographics, and medical treatment and history. They also provide information about their main physician/health care provider (e.g., length of time been his/her patient, and gender of provider).

The third interview occurs after the participant's next medical visit (medical visit #2) and is conducted in person or over the telephone (approximately three to four weeks post-time 1 interview). Participants are assessed on a variety of measures including pain, pain treatment, pain treatment misconceptions, mood, quality of life, and well-being. The fourth interview occurs approximately 12 weeks post-interview # 1, after medical visit #3.

After medical visits #1, #2, and #3, the participant's main cancer physician/health care provider completes a brief (approximately two minute) questionnaire concerning the participant's: current prescribed pain medications; whether the pain medication regimen has been changed during this visit and if so, in what ways (e.g., same medication but change in dosage level; whether participant reported having any symptoms (and if so, what types and how many); whether the participant mentioned pain as a symptom, and if so, how the participant described the pain; the number of questions the participant asked and on what topics. (However, as noted in last year's annual report, the information from the physician/health care provider is not obtained if a follow-up interview is conducted over the telephone). Intervention sessions are being audio-taped for quality assurance checks. A randomly selected sample (20%) of these tapes are being reviewed by Dr. DuHamel to ensure uniform delivery of treatment arms.

Training Accomplishments To Date: Within the past year, two bilingual research staff have been trained in the study assessments, intervention protocol, and implementation of the control condition. Staff supervision is provided on an ongoing basis by Dr. DuHamel. Supervision includes a periodic review of a sample of the audio-taped participant-interventionist interaction. Consultation with senior investigators (e.g., Dr. Smith and Dr. Winkel) is ongoing.

Research Accomplishments To Date: We are currently in month 37 of the study. Tasks noted in the Statement of Work in months 7 to 36 are ongoing. Due to slower than anticipated participant recruitment, we are still in data collection mode of the study. The following tasks noted in the Statement of Work from months 7 to 32 are being performed: recruiting patients at all the sites, conducting study assessments, implementing the two treatment arms (pain and nutrition), data entry –including storing, coding, and entering data, and preliminary data analysis. Staff meetings are held to review tape-recordings of interviews for quality assurance purposes. Tasks included in Months 32 through 36 are also ongoing. For example, preliminary data has been presented by Dr. DuHamel in four forums (See Reportable Outcomes).

To date we have recruited 27 participants (see preliminary results below). Participant accrual has taken longer than expected, a situation that has been exacerbated by staff turnover within the past year. To address the issue of slow participant accrual, we are adding Saint Vincent's Catholic Medical Center as a study site. Saint Vincent's serves a large number of breast cancer patients in Lower-Manhattan and we anticipate this will be our largest recruitment site (See attached approval form from Saint Vincent's IRB dated 3/18/02. Saint Vincent's consent forms will follow this report).

Preliminary results: Of the 27 women recruited to date, the majority are in mid-life (M = 53.26 years SD = 7.56), not married (33% have never been married, 4% are separated, 26% divorced, 15% widowed), low income (65% $20,000 or less), and educated beyond high-school(63% reported post-high school education). In terms of self-reported ethnicity, 48% are Latina. Of the Latina participants, 92% preferred that the intervention and interviews to be conducted in Spanish.

Preliminary analysis indicates that on a scale of 0 ("no pain") to 10 (" pain as bad as you can imagine") participants' worst and average pain in the past two weeks were 7.15 and 5.70, respectively, indicating severe to moderate pain. Fifty-six percent of the participants "sometimes," "rarely," or "never" talk about their pain symptoms to their health care provider. Forty-one percent reported that "most of the time" or "all the time" it is up to them to bring up the topic of pain during their medical appointment. Participants reported many misperceptions about pain and pain management. These misperceptions include: "Drowsiness from pain medication is really a bother" (89% endorsed) and "When you use pain medicine your body becomes used to its effects and pretty soon it won't work any more" (93% endorsed). On average, participants reported 18 misconceptions out of a possible 30. Participants' misconceptions varied by their ethnicity, such that participants who identified themselves as Latina were more likely to agree with such beliefs than other ethnic groups ($t = 2.12$, $p < .05$).

These preliminary results suggest that: (1) Many MBC patients are experiencing moderate to severe pain, and (2) that many believe it is up to them (the patients) to bring up the topic with their provider. In addition, these participants have multiple misconceptions about pain and pain management. These misconceptions are more pronounced in Latinas. A manuscript will be prepared on this descriptive data. A manuscript on the impact of the pain communication skills intervention which addresses these misconceptions and facilitates patient-provider communication will be prepared once data collection has been completed.

Recent Literature: Recent literature has added to our knowledge on the topic of patients' barriers to adequate pain management and the importance of patient-health care provider communication (e.g., Harris and Templeton, 2001; Anderson et al., 2002; Von Roenn, 2001). Recent studies also indicate that cancer-related pain is under-managed, despite guidelines for pain management (Von Roenn, 2001). Research continues to indicate that under-mangement of cancer-related pain is a particularly prevalent problem in minority populations. One example illustrating this problem is a recent study conducted by Anderson and colleagues (2002) with 31 African-American and Hispanic cancer patients who had recurrent or metastatic disease and pain. The results included that many patients (57% of the African-American patients and 38% of Hispanic patients) did not ask their health care provider about pain. Furthermore, patients reported that they would wait until their pain was severe before they would call their health care provider. Additional barriers to pain medication included fear of medication and the belief that one should be strong and not lean on pain medications (i.e., stoicism). Interestingly, when they were asked what information should be included in educational materials on cancer pain, both ethnic groups suggestions including information about working with health care providers to manage pain. Thus, recent research supports our efforts to include minority patients in our intervention, to reduce breast cancer patients' barriers to adequate pain management, and to improve patient-provider communication about pain. This recent research also underscores the importance of the current study by indicating the need of interventions of this type, particularly for patients of minority populations.

KEY RESEARCH ACCOMPLISHMENTS

- This study is being conducted as proposed at 2 hospitals.
- A third hospital, Saint Vincent's Catholic Medical Center is being added as a study site.
- A significant percentage of minority patients has been recruited.
- Presentations are being conducted at study sites and nationally.
- Preliminary data analysis indicates that many breast cancer patients report barriers to adequate pain management.
- Preliminary data analysis indicates that barriers to pain management are higher in Latina women.

REPORTABLE OUTCOMES

Within the past year, a description of the study and preliminary data has been presented by Dr. DuHamel in four forums: (1) Invited Speaker on Cancer Diagnosis and Treatment: Psychosocial Problems at the Medical Disorders: Neuropsychological and Psychiatric Aspects: Interdisciplinary Approaches for Effective Patient Care Conference, Mount Sinai School of Medicine, May 11, 2002; (2) Invited Speaker on Current Issues in Pain Psychology at Ferkauf Today: Learning from Each Other, Ferkauf Graduate School of Psychology, Yeshiva University, May 19, 2002; (3) Lecture series at Mount Sinai School of Medicine; (4) Symposium delivered at the American Pain Society 2002 Annual Scientific Meeting, March 14, 2002 (noted as submitted in last year's report). In addition, an abstract entitled "Increasing Pain Related Communication Skills to Improve Pain Management" has been submitted by DuHamel, K., Smith, M., Egert, J., Kreitzer, J., McEvoy, M., Mezzich, J., Raptis, G., Chio, L., Benisovich, V., Capponi, A., & Portenoy, R. to the Era of Hope 2002 Department of Defense Breast Cancer Research Program Meeting.

CONCLUSIONS

The study staff has been hired and trained, and the study recruitment for this randomized clinical trial is ongoing. To date, preliminary analyses have been conducted. Consistent with prior research, our preliminary data indicates that many women have barriers to adequate pain management. Also consistent with prior research, our data suggests that these barriers are more prevalent among Latina cancer patients. As the number of subjects accrued is increased and the results analyzed, we will continue to investigate the impact of a pain communication skills intervention in reducing pain, psychological distress, and increasing quality of life in MBC patients. Information obtained from the proposed research may be used more generally to develop treatment strategies to reduce the pain and suffering of breast cancer patients. For example, if the intervention is found to impact study outcomes such as reduce participants' pain management misconceptions and level of pain, and improves their quality of life, it may be incorporated into existing approaches to pain management

in MBC patients. The dissemination of information from this study will facilitate the implementation of such an intervention for breast cancer patients in other cancer centers and general medical settings. The proposed study will also extend the existing general knowledge base about patients' participation in the management of pain.

REFERENCES:

K.O. Anderson, S.P. Richman, J. Hurley, G. Palos, V. Valero, T. Mendoza, I. Gning, C. Cleeland, "Cancer Pain Management among Undersaved Minority Outpatients. Perceived Needs and Barriers to Optimal Control." *Cancer* **94**, 2295 (2002).

S.R. Harris, E. Templeton, "Who's listening? Experiences of Women with Breast Cancer in Communicating with Physicians." *The Breast Journal* **7**, 444 (2002).

R. Serlin et al., "When is cancer pain mild, moderate or severe? Grading pain severity by its interference with function." *Pain* **61**, 277(1995).

J.H. Von Roenn, "Are We the Barrier?" *Journal of Clinical Oncology* **19**, 4273 (2001)

APPENDICES

1.) DuHamel, K.N. et al. (2002) A communication skills intervention to address breast cancer patients' barriers to pain management. In: K. Syrjala (Chair), Enhancing Doctor-Patient Communication to Improve Pain Management for Minority Patients with Chronic Pain. Paper presented at the annual meeting of the American Pain Society, Baltimore, MD (noted as submitted in last years report).

Enhancing Doctor-Patient Communication to Improve Pain Management for Minority Patients with Chronic Pain

Meredith Smith Ph.D., Katherine DuHamel, Ph.D., Karen O. Anderson, Ph.D., Karen Syrjala, Ph.D.

Pain is a common and highly debilitating symptom for many chronically ill patients, especially those with HIV/AIDS or late stage cancer . Despite this, chronic pain, particularly in minority patients, is often inadequately treated. Barriers to adequate pain management are numerous, and include both health care provider and patient-related factors. For example, health care providers may not know how to appropriately use opiates. Patients, on the other hand, may be reluctant to take pain medication for fear of addiction, of developing tolerance, or of being perceived as a "complainer." The proposed symposia will present data on barriers to pain management among minority cancer patients and preliminary data illustrating the beneficial impact of interventions designed to improve patient-doctor communication about pain, reduce patient's pain and distress, and enhance their quality of life. Four investigators will be featured in this symposium: three will present study findings, and the fourth will serve as a discussant. Dr. Smith will present data from a recently completed randomized clinical trial of minority persons living with HIV/AIDS (PWHAs) in New York City. The presentation will examine patient misconceptions about pain medication and how these misconceptions relate to perceived patterns of doctor-patient communication. Dr. DuHamel will present data from an ongoing randomized clinical trial investigating the impact of a pain communication skills intervention on minority breast cancer patients' pain beliefs, pain symptoms, quality of life and patient-provider communication. Dr. Anderson will report on the efficacy of a pain education intervention being tested in a third, ongoing randomized clinical trial with African-American and Hispanic cancer patients. She will report on preliminary findings regarding the efficacy of the pain management intervention. As the discussant, Dr. Syrjala will synthesize findings from the three studies, highlight the commonalities and differences in pain management barriers among the different ethnic/racial groups, and comment on implications for future research.

STUDY APPROVAL
FOR MOUNT SINAI SCHOOL OF MEDICINE

1) IRB APPROVAL
2) Patient Consent Forms (English & Spanish)
3) Physician Consent Form

MOUNT SINAI
SCHOOL OF
MEDICINE

Institutional Review Board

One Gustave L. Levy Place
Box 1075
New York, NY 10029-6574

Phone: 212.659.8980
Facsimile: 212.876.6789

Date: June 10, 2002

GCO Project # 98-538 0001 04 CA *
Principal Investigator
Katherine DuHamel, PhD

Army

Dear Sir/Madam,

The project entitled **IMPROVING PATIENT COMMUNICATION ABOUT BREAST CANCER RELATED PAIN** includes activities involving human subjects. This project was reviewed at a convened meeting of the Institutional Review Board of the Mount Sinai School of Medicine on **6/4/02** in accordance with our assurance to the Department of Health and Human Services **M-1155.** This project is approved for continuation for the period **7/1/02** through **6/30/03**.

Sincerely yours,

Joseph S. Eisenman, Ph.D.
Vice-Chairperson
Institutional Review Board

Mount Sinai
Institutional Review Board Posting

From: Elan Czeisler, Administrative Director
Institutional Review Board
1425 Madison Avenue
East Building 4-78 Box 1075
Extension 88980

Date: June 25, 2002

98-885 (0001) 03 CA *
IMPROVING PATIENT COMMUNICATION ABOUT BREAST CANCER RELATED PAIN
Katherine DuHamel, Ph.D.
Note: Approved for medical record review
Approved for both Mount Sinai Medical Center and Elmhurst Hospital Center
This project was reviewed at a convened meeting of the IRB on **6/4/02** and was approved for continuation for the period **7/1/02** through **6/30/03.**

Enclosed is a copy of the IRB approved and stamped consent form. This is the only form that is approved for the conduct of this research. Destroy all previous versions. Make sure to retain a copy of the approved, stamped consent document, as it must be submitted to the IRB at the time of submission of your annual renewal. The enclosed IRB stamped form must be used when consent is obtained from research subjects. One signed copy of the stamped form must be given to the subject, one must be placed in the subject's chart, and the principal investigator must keep one.

No changes may be made to the protocol or to the consent form without IRB approval. Submit any proposed changes promptly in order to avoid delays. Please indicate the GCO project number on all pages. *When presenting revisions, please submit a memo explaining the changes as well as two copies of the consent form: one copy with all revisions highlighted and a clean copy to be stamped when granted final approval.*

Please Note: Any notices or advertisements recruiting subjects for this study or asking other physicians' cooperation in identifying potential subjects must be approved by the Institutional Review Board prior to distribution. All advertisements must include the GCO number and expiration date. If you have any questions, please call the IRB administrator at the number listed above.

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Mount Sinai
Institutional Review Board Posting

From: Elan Czeisler, Administrative Director
Institutional Review Board
1425 Madison Avenue
East Building 4-78 Box 1075
Extension 88980

Date: June 10, 2002

98-538 (0001) 04 CA *
IMPROVING PATIENT COMMUNICATION ABOUT BREAST CANCER RELATED PAIN
Katherine DuHamel, PhD
Note: Approved for medical record review
(Participants for this study are enrolled under GCO# 98-885)
This project was reviewed at a convened meeting of the IRB on **6/4/02** and was approved for continuation for the period **7/1/02** through **6/30/03**.

No changes may be made to the protocol or to the consent form without IRB approval. Submit any proposed changes promptly in order to avoid delays. Please indicate the GCO project number on all pages. *When presenting revisions, please submit a memo explaining the changes as well as two copies of the consent form: one copy with all revisions highlighted and a clean copy to be stamped when granted final approval.*

Please Note: Any notices or advertisements recruiting subjects for this study or asking other physicians' cooperation in identifying potential subjects must be approved by the Institutional Review Board prior to distribution. All advertisements must include the GCO number and expiration date. If you have any questions, please call the IRB administrator at the number listed above.

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GCO # 98-885

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT: Improving Patient Communication About Breast Cancer Related Pain

A. PURPOSE OF THE STUDY:

You are being asked to participate in a research study. The purpose of this study is to examine the effectiveness of a program aimed at the control of symptoms in advanced breast cancer patients. Research has shown that this kind of program may increase patient's active participation in treatment, and improve their quality of life. You qualify for this study because you: (1) are 18 years of age or older; (2) speak English or Spanish; (3) are a breast cancer patient with advanced disease; (4) report a moderate or greater level of pain within the past two weeks (as measured on our checklist); (5) don't have concentration problems that would interfere with ability to participate in this study; and (6) are currently receiving care from a physician at Mount Sinai or a Mount Sinai affiliated hospital.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with breast cancer that has spread beyond the breast. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition. If you are eligible for participation and if you agree to participate, a research assistant will ask you a series of questions about your pain and pain treatment, how you are feeling, and your satisfaction with your care. This interview, which we call the baseline interview, will take about 35-45 minutes to complete.

Next, you will be randomly assigned (like flipping a coin) to receive either the control of symptoms or nutrition program. Random assignment means that you have a 50-50 chance of being in either condition. Depending on how you are assigned, you will then participate in either the control of symptoms or the nutrition program. The session will take about 30 minutes to complete and will be carried out by a member of the study staff. It will be tape-recorded. As part of the program you will be taught how to fill out a diary recording your pain symptoms or your nutritional habits. You will be asked to fill

Subject/Surrogate Initials _____

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From: 7/1/02 To: 6/30/03

out one page of the diary every day for two weeks, and then once a week for about two weeks after that. Diary completion will take about five minutes of your time.

After completing the program session, you will meet with your health care provider for your regularly scheduled appointment. When you meet with your health care provider, we may ask to tape record the session to provide us with additional research data. All tapes will be kept confidential (each tape will be identified by a code number only). Tapes will be kept in a locked file cabinet in accordance with IRB procedure for research data. At the end of this consent form, we will ask whether or not you will agree to have your session's tape-recorded. When your appointment is over you will be interviewed again for about 15 minutes. You will be asked some questions about your medical visit, your health care provider and your background (for example, what your age is, what your medical history is). Your health care provider will also complete a brief information form about the medical visit and your health status.

Approximately 3 to 4 weeks later you will be interviewed by a research assistant for the third time for about 35 minutes. We call this a follow-up interview. Whenever possible, this interview will occur at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. The research assistant will ask you many of the same questions he/she asked of you at the first interview (for example, how you are feeling, what your pain has been like, how satisfied you are with your health care). The research assistant may also ask about whether any family members or friends have been helping you monitor your symptoms. Your health care provider will again complete a brief information form about the medical visit and your health status.

Approximately 8 weeks later you will be interviewed for the final time by a research assistant for about 35 minutes. Again, whenever possible, this interview will occur at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. This interview will ask you many of the same questions asked at the baseline and the two follow-up interviews (for example, what your health has been like, whether you have been having any pain, how satisfied you are with your health care).

In addition to these interviews, we will obtain some information about your health status and medical history from your medical chart.

We recognize that this research study requires intensive participation and we greatly appreciate your contribution. Your collaboration will enable us to further understand the adjustment of advanced breast cancer patients and possibly improve their care. The results of this research study will inform us of the benefits of our program with advanced breast cancer patients.

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From: 7/1/02 To: 6/30/03

GCO # 98-885

To find out your wishes about being audiotaped while meeting with your health care provider, please let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participation in this study will involve no costs to you. In consideration of your participation, you will receive $15 each day of the three days that you are interviewed for your time and expenses. This will be disbursed to you by either cash or check.

D. POTENTIAL RISKS AND DISCOMFORTS:

There is no known physical risk to those who participate in this study. You may experience some emotional discomfort as a result of speaking about your experience of breast cancer. If you do experience emotional discomfort, the research assistant is trained to assess, and if appropriate to refer you to a professional therapist or a counselor for a therapeutic session at no cost to you.

E. POTENTIAL BENEFITS:

Although we can not assure you that you will benefit from participating in this study, you may benefit directly by gaining skills that enable you to become involved in your control of symptom or your nutrition. In addition, you may benefit from the knowledge that your involvement may help other patients with breast cancer.

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MOUNT SINAI SCHOOL OF MEDICINE
CONSENT FOR RESEARCH

F. ALTERNATIVES TO PARTICIPATION:

While you are in this study, you also may take part in other support programs available through this hospital or in your community. You are in no way excluded from other support programs or research studies.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by law. However, your medical record may be reviewed by government agencies or the agency sponsoring this research, if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

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From: 7/1/02 To: 6/30/03

MOUNT SINAI SCHOOL OF MEDICINE
CONSENT FOR RESEARCH

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Katherine DuHamel, at telephone number (212) 659-5556. If you still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number (212) 659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None.

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From: 7/1/02 To: 6/30/03

GCO # _____

AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Participant's Name (printed):_____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Katherine DuHamel and his/her associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Katherine DuHamel has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

Subject/Surrogate Initials _____

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From: 7/1/02 To: 6/30/03

GCO # _____

AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the above-mentioned research program, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such procedures and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____
Print Name of person who obtained consent Title

Date: _____ Time: _____

Subject/Surrogate Initials _____

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From: 7/1/02 To: 6/30/03

GCO # 98-885

PART I: Hoja Informativa Para Los Participantes en la Investigación

Título Del Proyecto: Mejoramiento de la Communicación con las Pacientes Acerca de los Dolores Relacionado con el Cáncer de los Senos

A. Propósito Del Estudio:

Se le está solicitando participar en una investigación. El propósito de la misma es determinar la efectividad de un programa cuyo propósito es el de controlar los síntomas sufridos por las pacientes de cáncer avanzado en los senos. La investigación ha demostrado que este tipo de programa puede aumentar la participación activa de las pacientes en su tratamiento, mejorando incluso su calidad de vida. Usted califica para este estudio porque: 1) es mayor de 18 años; 2) habla inglés o español; 3) sufre de cáncer en los senos en su etapa más avanzada; 4) ha sufrido un grado de moderado a serio de dolor, durante las últimas dos semanas (tal y como figura en nuestra lista de comprobación); 5) no sufre de problemas de concentración que podrían impedirle participar en este estudio; y 6) está actualmente bajo la atención de un médico del Mt. Sinai o de un hospital afiliado al Mt. Sinai.

B. Descripción Del Estudio:

Este estudio investigará la efectividad de un programa concebido especialmente para las mujeres con cáncer de los senos, que se haya proliferado más allá del tórax. La meta del programa es la de mejorar el control de los síntomas y la calidad general de vida de las pacientes. El programa tiene como objetivo suministrar a las mujeres información acerca del tratamiento de sus síntomas y enseñarles cómo mejor describirlos a su médico. Compararemos los resultados de este programa centrado en el control de los síntomas con otro centrado en la nutrición.

Si califica para participar, y está de acuerdo en hacerlo, un asistente de investigación le hará una serie de preguntas relacionadas con sus dolores y tratamiento de los mismos, su estado de ánimo y opinión acerca de la atención médica que recibe. Esta entrevista, que llamamos básica (baseline interview), le tomará alrededor de 35-45 de su tiempo.

Seguidamente, será escogida al azar (como cuando se lanza una moneda para que salga cara o cruz) para recibir el programa de control de síntomas o el de la nutrición. Su asignación al azar significa que tendrá un 50 por ciento de probabilidades de ser asignada a cualquiera de los dos programas. Dependiendo de su suerte, participará

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entonces en el programa de control de los síntomas o en el centrado en la nutrición. La sesión durará unos 30 minutos y será impartida por un miembro del personal a cargo del estudio. Esta sesión será grabada. Como parte del programa, se le enseñará a llenar un diario para registrar y describir sus síntomas o sus hábitos alimenticios. Se le solicitará llenar una página del diario cada día, durante dos semanas, y después de eso sólo una vez por semana durante dos semanas. Cumplir con esta tarea le tomará unos cinco minutos diarios de su tiempo.

Luego de completar la sesión del programa, irá a su consulta programada habitual con su médico. Cuando se encuentre con él, podríamos solicitarle que nos permita grabar la consulta, a fin de recabar datos adicionales para nuestra investigación. Las cintas grabadas serán mantenidas en confidencia (siendo identificadas sólo con un número). Las mismas serán también mantenidas bajo llave de acuerdo con los procedimientos IRB para la conservación de datos de investigación. Al finalizar este formulario de consentimiento, le preguntaremos si está o no de acuerdo en permitirnos grabar sus sesiones. Cuando su cita haya terminado, será entrevistada de nuevo por alrededor de 15 minutos. Se le harán preguntas acerca de su consulta médica, de su médico y de sus antecedentes (por ejemplo, su edad, e historial médico). Su médico deberá también llenar un breve formulario informativo acerca de su visita y de su estado de salud.

Aproximadamente 3 a 4 semanas después usted será entrevistada por un asistente de investigación por tercera vez alrededor de 35 minutos. A esto lo llamamos entrevista de seguimiento. Cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita está cancelada o pospuesta, la entrevista de la continuación se puede completar a una hora más conveniente por teléfono. El asistente le preguntará muchas de las preguntas formuladas en su primera entrevista (por ejemplo, cómo se siente, cómo están sus dolores, y su estado de satisfacción con la atención médica recibida). Querrá también averiguar si sus parientes y amigos la han estado ayudando a vigilar sus síntomas. Su médico completará de nuevo un breve formulario informativo acerca de su visita y su estado de salud.

Aproximadamente 8 semanas después usted será entrevistada por última vez por un asistente de investigación alrededor de unos 35 minutos. Otra vez, cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita está cancelada o pospuesta, la entrevista de la continuación se puede completar a una hora más conveniente por teléfono. En esta entrevista se le harán muchas de las preguntas formuladas en la entrevista básica y en las dos entrevistas de seguimiento (por ejemplo, cómo se siente, cómo están sus dolores, y su estado de satisfacción con la atención médica recibida.

Además de estas entrevistas, recabaremos alguna información acerca de su estado de salud e historial médico, de su expediente.

Reconocemos que esta investigación supone una participación intensa y agradecemos sobremanera su contribución. Su colaboración nos permitirá

Subject/Surrogate Initials _____

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entender mejor los medios de ajuste y adaptación de las pacientes de cáncer avanzado de los senos, así como los que posiblemente puedan mejorar su tratamiento. Los resultados de este estudio investigativo nos suministrarán información acerca de los beneficios de nuestro programa para beneficio de las pacientes de cáncer avanzado de los senos.

A fin de determinar sus deseos en cuanto al uso de audio grabadoras durante sus encuentros o consultas con su médico, favor de marcar a continuación:

_____ Consiento a que se graben mis conversaciones

_____ No consiento a que se graben mis conversaciones

C. Costos/Rembolso De Costos:

Su participación en este estudio no conllevará gastos para usted. Considerando su participación, recibirá $15 por cada uno de los días en que será entrevistada, a fin de contribuir a que cubra su tiempo y costos. Esta suma se le pagará mediante efectivo o cheque.

D. Riesgos E Incomodidades Potenciales:

El tomar parte en este estudio no conlleva riesgos físicos de ninguna índole. Podrá experimentar algún desasosiego emocional al hablar acerca de sus experiencias como paciente de cáncer de los senos. Si este es el caso, el asistente de investigación está debidamente entrenado para evaluar su situación y referirla a un terapeuta profesional o a un consejero para una sesión de terapia sin costo alguno para usted.

E. Beneficios Potenciales:

A pesar de que no le podemos garantizar que su participación en este estudio redundará en beneficios directos para usted, podrá beneficiarse directamente adquiriendo conocimientos que le permitirán controlar mejor sus síntomas o su nutrición. Se beneficiará además al considerar que su intervención podría ayudar a otras pacientes de cáncer de los senos.

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F. Alternativas A La Participación:

Mientras se encuentre sometida a estudio, podrá también tomar parte de otros programas de apoyo disponibles a través de este hospital o en su comunidad. De ningún modo será excluida de otros programas de asistencia o investigación.

G. Confidencialidad:

Su identidad como participante en este estudio será mantenida como confidencial para fines de publicación de los resultados de este estudio. Su hoja médica relacionada con este estudio será mantenida como confidencial, hasta donde lo permitan las leyes. Sin embargo,la misma podrá ser revisada por las agencias del gobierno o la agencia patrocinadora de este estudio, si así lo requirieran las leyes o reglamentos vigentes.

H. Tratamiento Compensatorio:

Fuera de la atención médica que pueda recibir o de cualquier pago específicamente acordado en el formulario de consentimiento, no habrá otra compensación por su participación en esta investigación. Si cree haber sufrido una lesión con relación a esta investigación, deberá dirigirse a la Dra. Catherine DuHamel, al teléfono (212) 659-5556.

I. Participación Voluntaria:

Su participación en este estudio es puramente voluntaria. En caso de decidir no participar, su decisión no comprometerá su capacidad de recibir atención médica en el Mt. Sinai o de recibir otros beneficios a los que pudiera tener derecho.

Cualquier otra información que surja de este estudio, y que pudiera afectar su decisión de participar, le será suministrada inmediatamente.

Una copia firmada de este formulario de consentimiento le será entregada.

Subject/Surrogate Initials _____

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J. Fin De La Participación:

La decisión de participar o no en este estudio será enteramente suya. Podrá interrumpir su participación en el mismo, o rehusar responder preguntas determinadas en cualquier momento y sin penalidades o pérdidas de beneficios a los que pudiera tener derecho.

K. Personal De Contacto:

Si tiene alguna pregunta, en cualquier momento, acerca de este estudio, favor de hacer contacto con la Dra. Catherine DuHamel, al teléfono (212) 659-5556. Si después de esto tuviera aún alguna otra pregunta, podrá tratarla con un miembro del Institutional Review Board (el comité encargado de las investigaciones en la Mt. Sinai School of Medicine), número de teléfono (212) 659-8980.

L. La Revelación De Intereses Financieros:

Ningunos.

Subject/Surrogate Initials _____

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Autorización Para Participar en Investigación

Este formulario deberá estar firmado por una participante/representante y el investigador/delegado.

Participante (nombre en letra de molde):_____

1. Por este medio me ofrezco como voluntaria para participar en un programa de investigación bajo la supervisión de las Dras. DuHamel, y sus asociados de la Mt. Sinai School of Medicine.

2. Declaro haber leído, o haberme sido explicado en un idioma que puedo entender, el documento de consentimiento anexo, y que la Dra. Catherine DuHamel me explicaron la naturaleza y propósito de estos estudios. Esta explicación incluyó una descripción de las partes del estudio que son experimentales, las posibles molestias, síntomas, efectos secundarios y riesgos que podría razonablemente esperarme, así como las posibles complicaciones, de haberlas, que pudiera razonablemente experimentar por causas tanto conocidas como desconocidas, como resultado de mi participación en estos estudios. Tuve la oportunidad de hacer las preguntas que tenía acerca de este estudio, y todas fueron respondidas a mi plena satisfacción.

3. Entiendo que estoy libre de retirar esta autorización y de descontinuar mi participación en estos estudios, en cualquier momento. Las consecuencias y riesgos, si alguno, de retirarme de la investigación mientras se halle en curso, me fueron explicados. Entiendo que dicho retiro o interrupción no comprometerá mi capacidad de recibir la atención médica a la que pudiera, en todo caso, tener derecho.

4. Confirmo haber leído, o que me fue leída, esta autorización integralmente, y que los espacios en blanco o declaraciones que requieren ser llenados, fueron debidamente llenados antes de yo firmarla.

Sujeto de la Investigación/: _____
Representante Firma

Nombre:_____
Escriba en letra de molde

Relación: _____
Si es firmado por sustituto

Fecha:_____ Hora: _____

Subject/Surrogate Initials _____

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GCO # 98-885

Autorización Para Participar en Investigación (continuación)

Para aquellos que no estén en condiciones de leer por sí mismos este documento de consentimiento, lo siguiente deberá ser llenado:

Confirmo haber traducido y/o leído la información al interesado:

Nombre: _____
Firma

Nombre: _____
Escriba en letra de molde

Dirección: _____
Número y Calle Ciudad Estado Código Postal

Fecha: _____ Hora: _____

Confirmo que el documento de consentimiento fue traducido y/o leído al participante:

Nombre del testigo : _____
Firma

Nombre del testigo: _____
Escriba en letra de molde

Fecha: _____ Hora: _____

He explicado debidamente al anteriormente indicado voluntario/ pariente/ representante la naturaleza y propósito del programa de investigación de referencia (incluyendo hasta el grado en que estos estudios son experimentales), las posibles complicaciones que pudieran surgir de causas conocidas como desconocidas como resultado de la misma, así como las consecuencias o riesgos, si alguno, en caso de que el sujeto decida interrumpir su participación. Entiendo que él/ella entiende la naturaleza, propósitos y riesgos de estos estudios. Asimismo, me ofrecí también para responder cualquier pregunta relacionada con estos estudios, y respondí integralmente dichas preguntas.

_____
Firma del Director de la Investigación/Delegado

_____
Nombre en letra de molde Título

Fecha: _____ Hora: _____

Subject/Surrogate Initials _____

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From: 7/1/02 To: 6/30/03

GCO # 98-885

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT: Improving Patient Communication about Breast Cancer-Related Pain

A. PURPOSE OF THE STUDY:

Physician Consent Form

You are being asked to participate in a research study. The purpose of this study is to test an intervention to improve communication between patients with cancer and their physicians during the medical visit.

You qualify for participation in this study because you provide outpatient care to women with metastatic breast cancer.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with advanced breast cancer. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition.

After the medical visit, you as the patient's physician will be asked to complete a two minute open-ended questionnaire about the patient's status.

Audio-tape recording: The medical visit will be audiotaped. The purpose of the audiotaping is to permit analysis of patient-physician communication patterns. All participants (both physicians and patients) will receive unique identification numbers. Data will be analyzed using a coding system that characterizes the content, process, linguistic and behavioral components of the interaction. With the physician's permission, a study research assistant will enter the exam room at the beginning of the medical appointment to start the tape recorder and again at the end to stop it. All audiotaped data will remain strictly confidential. Once the study is finished, the Principal

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Investigator, Dr. Katherine DuHamel will erase all the tapes. Until then, the tapes will be kept in a locked file cabinet in Dr. DuHamel's office. Only the researchers here at Mt. Sinai will have access to those tapes.

To find out your wishes about being audiotaped while meeting with your patient, please let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participating patients will receive $15 for each of the three days interviewed.

Physicians will incur no costs and will receive no financial reimbursements for their participation in this investigation.

D. POTENTIAL RISKS AND DISCOMFORTS:

Taking part in this study involves no physical risk to either patient or physician.

E. POTENTIAL BENEFITS:

The purpose of the study is to test an approach to improving communication between patients with cancer and their doctors. Since this is a new approach, however, the researchers do not know yet if it will help. You may not get any direct benefit from taking part in it. By being in this study, though, you will help researchers plan programs to improve medical care delivery for persons with cancer. In this way, you may help other persons with cancer and their physicians.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate.

Subject/Surrogate Initials _____

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G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Representatives of the U.S. Army Medical Research and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

Subject/Surrogate Initials _____

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K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Katherine DuHamel (212) 659-5556. If you still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number (212) 659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None.

Subject/Surrogate Initials _____

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AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Research Subject's Name (printed):_____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Katherine DuHamel and his/her associates at Mount Sinai School of Medicine and/or its affiliated institution.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Katherine DuHamel has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

Subject/Surrogate Initials _____

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AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the foregoing drugs, devices or procedures, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such drugs, devices or procedures and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____
Print Name of person who obtained consent Title

Date: _____ Time: _____

Subject/Surrogate Initials _____

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STUDY APPROVAL
FOR ELMHURST HOSPITAL

1.IRB APPROVAL
2.Patient Consent Forms (English & Spanish)
3.Physician Consent Form

Elmhurst
HOSPITAL CENTER

New York City
Health and Hospitals Corporation
Affiliated with
Mt. Sinai School of Medicine

Date: July 8, 2002

To: V. Benisovich, MD
Oncology

From: Andy Veeraraj, PhD
Research Administrator

Title: "Increasing Pain Related Communication Skills to Improve Pain Management" EHC 01-286 [IQ]

Control #s: Elmhurst #: EHC-01-286
HHC #: 99-176
GCO/IRB #: 98-885

HHC/EHC Authorization/Approval Period: **7/8/02—7/7/03**

Compliance Category: **Renewal, Amendments & Revise Consent**

This letter authorizes recruitment or research activities to begin on the above-captioned protocol for the authorization period specified. A copy of the approved application with stamp consent form is enclosed.

Continued authorization is contingent upon maintaining continued compliance with all NYC Health and Hospital Corporation/EHC Research Committee and MSSM IRB Guidelines. Should these conditions not be met, the Research Administrator (ext. 44903) must be notified immediately and all experimental/research activities on this protocol are subject to termination (while providing for the safety and well-being of the patient/subjects).

AUTHORIZATION FOR RENEWAL

Research protocols which call for activity extending beyond the one year HHC/EHC authorization period must be renewed. This HHC process is a separate process from that of the IRB review. In order to comply and meet deadlines for renewal you must contact the Research Administrator before **6/7/03**. No protocol may continue unless EHC, HHC, and MSSM IRB authorizations are all current. Should these conditions not be met, the Research Administrator must be notified immediately and all experimental/research activities on this protocol are subject to termination (while providing for the safety and well being of the patient/subjects). Submit the required application forms and documents outlined in Elmhurst Research Policies and Procedures, Section III.

79-01 Broadway
Elmhurst, New York 11373
Tel: 718 334-4000

Cont...2

STATUS CHANGE
Investigators must notify the Research Administrator promptly, in writing, when a protocol has been amended or concluded or withdrawn. Submit the necessary application forms outlined in Elmhurst Research Policies and Procedures, Section III, IV & V.

SUBJECT LISTS -- FOR MONITORING AND BILLING
EHC/HHC requires that PIs submit to the Research Administrator with lists of subjects enrolled in protocols. The lists include: Name of PI, Name of Protocol, EHC #, HHC #, GCO #, Date submitted, Authorized Project period, and each subject's initials, date of enrollment and medical record number. Lists of subjects enrolled must be submitted to the Research Administrator and the Patient Accounts Department. Investigators must ensure that all costs for research related tests/procedures are kept separate and charged to the grants and not to the patients' account. For questions regarding billing issues, contact the Patients' Accounts Department, ext. 44700.

FUNDING AND OTHER CHANGES
All significant changes in funding must be reported to the Research Administrator (ext. 44903) promptly, in writing. Any adverse events that significantly alter the protocol must be reported to the Research Administrator.

CONSENT FORMS
A copy of the written, signed and dated consent form must always be maintained in the patient's current medical chart while on protocol and must be maintained as a part of the patient's permanent medical record. This is in addition to any other records kept by the PI.

ATTRIBUTION OF COOPERATION
Research reports and articles, whether published or not, must acknowledge cooperation of the Elmhurst Hospital and the NYC Health and Hospitals Corporation.

If you have questions or need clarification on any HHC/EHC research-related issues, please contact me, ext. 44903. While contacting, always refer to the
EHC Control # 01-286.

cc: M. Neff, MD
B. Stahura

GCO # 98-885 (EHC-286)

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT: Improving Patient Communication About Breast Cancer Related Pain

A. PURPOSE OF THE STUDY:

You are being asked to participate in a research study. The purpose of this study is to examine the effectiveness of a program aimed at the control of symptoms in advanced breast cancer patients. Research has shown that this kind of program may increase patient's active participation in treatment, and improve their quality of life. You qualify for this study because you: (1) are 18 years of age or older; (2) speak English or Spanish; (3) are a breast cancer patient with advanced disease; (4) report a moderate or greater level of pain within the past two weeks (as measured on our checklist); (5) don't have concentration problems that would interfere with ability to participate in this study; and (6) are currently receiving care from a physician at Mount Sinai or a Mount Sinai affiliated hospital.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with breast cancer that has spread beyond the breast. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition. If you are eligible for participation and if you agree to participate, a research assistant will ask you a series of questions about your pain and pain treatment, how you are feeling, and your satisfaction with your care. This interview, which we call the baseline interview, will take about 35-45 minutes to complete.

Next, you will be randomly assigned (like flipping a coin) to receive either the control of symptoms or nutrition program. Random assignment means that you have a 50-50 chance of being in either condition. Depending on how you are assigned, you will then participate in either the control of symptoms or the nutrition program. The session will take about 30 minutes to complete and will be carried out by a member of the study staff. It will be tape-recorded. As part of the program you will be taught how to fill out a

Subject/Surrogate Initials _____

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diary recording your pain symptoms or your nutritional habits. You will be asked to fill out one page of the diary every day for two weeks, and then once a week for about two weeks after that. Diary completion will take about five minutes of your time.

After completing the program session, you will meet with your health care provider for your regularly scheduled appointment. When you meet with your health care provider, we may ask to

tape record the session to provide us with additional research data. All tapes will be kept confidential (each tape will be identified by a code number only). Tapes will be kept in a locked file cabinet in accordance with IRB procedure for research data. At the end of this consent form, we will ask whether or not you will agree to have your session's tape-recorded. When your appointment is over you will be interviewed again for about 15 minutes. You will be asked some questions about your medical visit, your health care provider and your background (for example, what your age is, what your medical history is). Your health care provider will also complete a brief information form about the medical visit and your health status.

Approximately 3 to 4 weeks later you will be interviewed by a research assistant for the third time for about 35 minutes. We call this a follow-up interview. Whenever possible, this interview will occur at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. The research assistant will ask you many of the same questions he/she asked of you at the first interview (for example, how you are feeling, what your pain has been like, how satisfied you are with your health care). The research assistant may also ask about whether any family members or friends have been helping you monitor your symptoms. Your health care provider will again complete a brief information form about the medical visit and your health status.

Approximately 8 weeks later you will be interviewed for the final time by a research assistant for about 35 minutes. Again, whenever possible, this interview will occur at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. This interview will ask you many of the same questions asked at the baseline and the two follow-up interviews (for example, what your health has been like, whether you have been having any pain, how satisfied you are with your health care).

In addition to these interviews, we will obtain some information about your health status and medical history from your medical chart.

We recognize that this research study requires intensive participation and we greatly appreciate your contribution. Your collaboration will enable us to further understand the adjustment of advanced breast cancer patients and possibly improve their care. The results of this research study will inform us of the benefits of our program with advanced breast cancer patients.

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To find out your wishes about being audio-taped while meeting with your health care provider, please let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participation in this study will involve no costs to you. In consideration of your participation, you will receive $15 each day of the three days that you are interviewed for your time and expenses. This will be disbursed to you by either cash or check.

D. POTENTIAL RISKS AND DISCOMFORTS:

There is no known physical risk to those who participate in this study. You may experience some emotional discomfort as a result of speaking about your experience of breast cancer. If you do experience emotional discomfort, the research assistant is trained to assess, and if appropriate to refer you to a professional therapist or a counselor for a therapeutic session at no cost to you.

E. POTENTIAL BENEFITS:

Although we can not assure you that you will benefit from participating in this study, you may benefit directly by gaining skills that enable you to become involved in your control of symptom or your nutrition. In addition, you may benefit from the knowledge that your involvement may help other patients with breast cancer.

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F. ALTERNATIVES TO PARTICIPATION:

While you are in this study, you also may take part in other support programs available through this hospital or in your community. You are in no way excluded from other support programs or research studies.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Vladimir Benisovich here at Elmhurst Hospital at telephone number (718) 334-3723. You may also wish to contact the Mount Sinai Researcher, Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at Elmhurst Hospital or to receive any benefits to which you are otherwise entitled.

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Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Vladimir Benisovich here at Elmhurst Hospital at (718) 334-3723. You may also wish to contact the Mount Sinai Researcher, Dr. Katherine DuHamel, at telephone number (212) 659-5556. If you still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number (212) 659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None.

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AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Participant's Name (printed):_____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Vladimir Benisovich here at Elmhurst Hospital and Dr. Katherine DuHamel and her associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Vladimir Benisovich and Dr. Katherine DuHamel have explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

Subject/Surrogate Initials _____

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ELMHURST HOSPITAL CENTER
CONSENT FOR RESEARCH

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AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the above-mentioned research program, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such procedures and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____Print
Name of person who obtained consent Title

Date: _____ Time: _____

Subject/Surrogate Initials _____

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PART I: Hoja Informativa Para Los Participantes en la Investigación

Título Del Proyecto: Mejoramiento de la Communicación con las Pacientes Acerca de los Dolores Relacionado con el Cáncer de los Senos

A. Propósito Del Estudio:

Se le está solicitando participar en una investigación. El propósito de la misma es determinar la efectividad de un programa cuyo propósito es el de controlar los síntomas sufridos por las pacientes de cáncer avanzado en los senos. La investigación ha demostrado que este tipo de programa puede aumentar la participación activa de las pacientes en su tratamiento, mejorando incluso su calidad de vida. Usted califica para este estudio porque: 1) es mayor de 18 años; 2) habla inglés o español; 3) sufre de cáncer en los senos en su etapa más avanzada; 4) ha sufrido un grado de moderado a serio de dolor, durante las últimas dos semanas (tal y como figura en nuestra lista de comprobación); 5) no sufre de problemas de concentración que podrían impedirle participar en este estudio; y 6) está actualmente bajo la atención de un médico del Mt. Sinai o de un hospital afiliado al Mt. Sinai.

B. Descripción Del Estudio:

Este estudio investigará la efectividad de un programa concebido especialmente para las mujeres con cáncer de los senos, que se haya proliferado más allá del tórax. La meta del programa es la de mejorar el control de los síntomas y la calidad general de vida de las pacientes. El programa tiene como objetivo suministrar a las mujeres información acerca del tratamiento de sus síntomas y enseñarles cómo mejor describirlos a su médico. Compararemos los resultados de este programa centrado en el control de los síntomas con otro centrado en la nutrición.

Si califica para participar, y está de acuerdo en hacerlo, un asistente de investigación le hará una serie de preguntas relacionadas con sus dolores y tratamiento de los mismos, su estado de ánimo y opinión acerca de la atención médica que recibe. Esta entrevista, que llamamos básica (baseline interview), le tomará alrededor de 35-45 de su tiempo.

Seguidamente, será escogida al azar (como cuando se lanza una moneda para que salga cara o cruz) para recibir el programa de control de síntomas o el de la nutrición. Su asignación al azar significa que tendrá un 50 por ciento de probabilidades de ser

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asignada a cualquiera de los dos programas. Dependiendo de su suerte, participará entonces en el programa de control de los síntomas o en el centrado en la nutrición. La sesión durará unos 30 minutos y será impartida por un miembro del personal a cargo del estudio. Esta sesión será grabada. Como parte del programa, se le enseñará a llenar un diario para registrar y describir sus síntomas o sus hábitos alimenticios. Se le solicitará llenar una página del diario cada día, durante dos semanas, y después de eso sólo una vez por semana durante dos semanas. Cumplir con esta tarea le tomará unos cinco minutos diarios de su tiempo.

Luego de completar la sesión del programa, irá a su consulta programada habitual con su médico. Cuando se encuentre con él, podríamos solicitarle que nos permita grabar la consulta, a fin de recabar datos adicionales para nuestra investigación. Las cintas grabadas serán mantenidas en confidencia (siendo identificadas sólo con un número). Las mismas serán también mantenidas bajo llave de acuerdo con los procedimientos IRB para la conservación de datos de investigación. Al finalizar este formulario de consentimiento, le preguntaremos si está o no de acuerdo en permitirnos grabar sus sesiones. Cuando su cita haya terminado, será entrevistada de nuevo por alrededor de 15 minutos. Se le harán preguntas acerca de su consulta médica, de su médico y de sus antecedentes (por ejemplo, su edad, e historial médico). Su médico deberá también llenar un breve formulario informativo acerca de su visita y de su estado de salud.

Aproximadamente 3 a 4 semanas después usted será entrevistada por un asistente de investigación por tercera vez alrededor de 35 minutos. A esto lo llamamos entrevista de seguimiento. Cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita está cancelada o pospuesta, la entrevista de la continuación se puede completar a una hora más conveniente por teléfono. El asistente le preguntará muchas de las preguntas formuladas en su primera entrevista (por ejemplo, cómo se siente, cómo están sus dolores, y su estado de satisfacción con la atención médica recibida). Querrá también averiguar si sus parientes y amigos la han estado ayudando a vigilar sus síntomas. Su médico completará de nuevo un breve formulario informativo acerca de su visita y su estado de salud.

Aproximadamente 8 semanas después usted será entrevistada por última vez por un asistente de investigación alrededor de unos 35 minutos. Otra vez, cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita está cancelada o pospuesta, la entrevista de la continuación se puede completar a una hora más conveniente por teléfono. En esta entrevista se le harán muchas de las preguntas formuladas en la entrevista básica y en las dos entrevistas de seguimiento (por ejemplo, cómo se siente, cómo están sus dolores, y su estado de satisfacción con la atención médica recibida.

Además de estas entrevistas, recabaremos alguna información acerca de su estado de salud e historial médico, de su expediente.

Reconocemos que esta investigación supone una participación intensa y agradecemos sobremanera su contribución. Su colaboración nos permitirá

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entender mejor los medios de ajuste y adaptación de las pacientes de cáncer avanzado de los senos, así como los que posiblemente puedan mejorar su tratamiento. Los resultados de este estudio investigativo nos suministrarán información acerca de los beneficios de nuestro programa para beneficio de las pacientes de cáncer avanzado de los senos.

A fin de determinar sus deseos en cuanto al uso de audio grabadoras durante sus encuentros o consultas con su médico, favor de marcar a continuación:

_____ Consiento a que se graben mis conversaciones

_____ No consiento a que se graben mis conversaciones

C. Costos/Rembolso De Costos:

Su participación en este estudio no conllevará gastos para usted. Considerando su participación, recibirá $15 por cada uno de los días en que será entrevistada, a fin de contribuir a que cubra su tiempo y costos. Esta suma se le pagará mediante efectivo o cheque.

D. Riesgos E Incomodidades Potenciales:

El tomar parte en este estudio no conlleva riesgos físicos de ninguna índole. Podrá experimentar algún desasosiego emocional al hablar acerca de sus experiencias como paciente de cáncer de los senos. Si este es el caso, el asistente de investigación está debidamente entrenado para evaluar su situación y referirla a un terapeuta profesional o a un consejero para una sesión de terapia sin costo alguno para usted.

E. Beneficios Potenciales:

A pesar de que no le podemos garantizar que su participación en este estudio redundará en beneficios directos para usted, podrá beneficiarse directamente adquiriendo conocimientos que le permitirán controlar mejor sus síntomas o su nutrición. Se beneficiará además al considerar que su intervención podría ayudar a otras pacientes de cáncer de los senos.

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F. Alternativas A La Participación:

Mientras se encuentre sometida a estudio, podrá también tomar parte de otros programas de apoyo disponibles a través de este hospital o en su comunidad. De ningún modo será excluida de otros programas de asistencia o investigación.

G. Confidencialidad:

Su identidad como participante en este estudio será mantenida como confidencial para fines de publicación de los resultados de este estudio. La información obtenida durante esta investigación (Registro de Investigación) sera mantendio como confidencial al grado que lo permite la ley. Sin embargo, este Registro de Investigación y su Registro Médico personal podrán ser revisados por agencias gubernamentales (tal como la Administación de Alimentos y Drogas o el Departamento de Salud y Servicios Humanos), la agencia que patrocina esta investigación, o el IRB (el comité que revisa todas las investigaciones con humanos en Mount Sinai), si así lo requirieran las leyes o reglamentos vigentes.

H. Tratamiento Compensatorio:

Fuera de la atención médica que pueda recibir o de cualquier pago específicamente acordado en el formulario de consentimiento, no habrá otra compensación por su participación en esta investigación. Si cree haber sufrido una lesión con relación a esta investigación, deberá dirigirse a la Dra. Catherine DuHamel, al teléfono (212) 659-5556.

I. Participación Voluntaria:

Su participación en este estudio es puramente voluntaria. En caso de decidir no participar, su decisión no comprometerá su capacidad de recibir atención médica en el Mt. Sinai o de recibir otros beneficios a los que pudiera tener derecho.

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Cualquier otra información que surja de este estudio, y que pudiera afectar su decisión de participar, le será suministrada inmediatamente.

Una copia firmada de este formulario de consentimiento le será entregada.

J. Fin De La Participación:

La decisión de participar o no en este estudio será enteramente suya. Podrá interrumpir su participación en el mismo, o rehusar responder preguntas determinadas en cualquier momento y sin penalidades o pérdidas de beneficios a los que pudiera tener derecho.

K. Personal De Contacto:

Si tiene alguna pregunta, en cualquier momento, acerca de este estudio, favor de hacer contacto con la Dra. Catherine DuHamel, al teléfono (212) 659-5556. Si después de esto tuviera aún alguna otra pregunta, podrá tratarla con un miembro del Institutional Review Board (el comité encargado de las investigaciones en la Mt. Sinai School of Medicine), número de teléfono (212) 659-8980.

L. La Revelación De Intereses Financieros:

Ningunos.

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Autorización Para Participar en Investigación

Este formulario deberá estar firmado por una participante/representante y el investigador/delegado.

Participante (nombre en letra de molde):_____

1. Por este medio me ofrezco como voluntaria para participar en un programa de investigación bajo la supervisión de las Dras. DuHamel, y sus asociados de la Mt. Sinai School of Medicine.

2. Declaro haber leído, o haberme sido explicado en un idioma que puedo entender, el documento de consentimiento anexo, y que la Dra. Catherine DuHamel me explicaron la naturaleza y propósito de estos estudios. Esta explicación incluyó una descripción de las partes del estudio que son experimentales, las posibles molestias, síntomas, efectos secundarios y riesgos que podría razonablemente esperarme, así como las posibles complicaciones, de haberlas, que pudiera razonablemente experimentar por causas tanto conocidas como desconocidas, como resultado de mi participación en estos estudios. Tuve la oportunidad de hacer las preguntas que tenía acerca de este estudio, y todas fueron respondidas a mi plena satisfacción.

3. Entiendo que estoy libre de retirar esta autorización y de descontinuar mi participación en estos estudios, en cualquier momento. Las consecuencias y riesgos, si alguno, de retirarme de la investigación mientras se halle en curso, me fueron explicados. Entiendo que dicho retiro o interrupción no comprometerá mi capacidad de recibir la atención médica a la que pudiera, en todo caso, tener derecho.

4. Confirmo haber leído, o que me fue leída, esta autorización integralmente, y que los espacios en blanco o declaraciones que requieren ser llenados, fueron debidamente llenados antes de yo firmarla.

Sujeto de la Investigación/Representante: _____
Firma

Nombre:_____
Escriba en letra de molde

Relación: _____
Si es firmado por sustituto

Fecha:_____ Hora: _____

Subject/Surrogate Initials _____

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Autorización Para Participar en Investigación (continuación)

Para aquellos que no estén en condiciones de leer por sí mismos este documento de consentimiento, lo siguiente deberá ser llenado:

Confirmo haber traducido y/o leído la información al interesado:

Nombre: _____
Firma

Nombre: _____
Escriba en letra de molde

Dirección: _____
Número y Calle Ciudad Estado Código Postal

Fecha: _____ Hora: _____

Confirmo que el documento de consentimiento fue traducido y/o leído al participante:

Nombre del testigo : _____
Firma

Nombre del testigo: _____
Escriba en letra de molde

Fecha: _____ Hora: _____

He explicado debidamente al anteriormente indicado voluntario/ pariente/ representante la naturaleza y propósito del programa de investigación de referencia (incluyendo hasta el grado en que estos estudios son experimentales), las posibles complicaciones que pudieran surgir de causas conocidas como desconocidas como resultado de la misma, así como las consecuencias o riesgos, si alguno, en caso de que el sujeto decida interrumpir su participación. Entiendo que él/ella entiende la naturaleza, propósitos y riesgos de estos estudios. Asimismo, me ofrecí también para responder cualquier pregunta relacionada con estos estudios, y respondí integralmente dichas preguntas.

_____
Firma del Director de la Investigación/Delegado

_____Nombre en letra de molde Título

Fecha: _____ Hora: _____

Subject/Surrogate Initials _____

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GCO # 98-885 (ECH-286)

PART I: RESEARCH PARTICIPANT INFORMATION SHEET

TITLE OF PROJECT: Improving Patient Communication about Breast Cancer-Related Pain

A. PURPOSE OF THE STUDY:

Physician Consent Form

You are being asked to participate in a research study. The purpose of this study is to test an intervention to improve communication between patients with cancer and their physicians during the medical visit.

You qualify for participation in this study because you provide outpatient care to women with metastatic breast cancer.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with advanced breast cancer. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition.

After the medical visit, you as the patient's physician will be asked to complete a two minute open-ended questionnaire about the patient's status.

Audio-tape recording: The medical visit will be audiotaped. The purpose of the audiotaping is to permit analysis of patient-physician communication patterns. All participants (both physicians and patients) will receive unique identification numbers. Data will be analyzed using a coding system that characterizes the content, process, linguistic and behavioral components of the interaction. With the physician's permission, a study research assistant will enter the exam room at the beginning of the medical appointment to start the tape recorder and again at the end to stop it. All audiotaped data will remain strictly confidential. Once the study is finished, the Principal Investigator, Dr. Katherine DuHamel will erase all the tapes. Until then, the tapes will be kept in a locked file cabinet in Dr. DuHamel's office. Only the researchers here at Mt. Sinai will have access to those tapes.

Subject/Surrogate Initials _____

For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)

From: 7/18/02 To: 6/30/03

GCO # 98-885 (ECH-286)

To find out your wishes about being audiotaped while meeting with your patient, please let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participating patients will receive $15 for each of the three days interviewed.

Physicians will incur no costs and will receive no financial reimbursements for their participation in this investigation.

D. POTENTIAL RISKS AND DISCOMFORTS:

Taking part in this study involves no physical risk to either patient or physician.

E. POTENTIAL BENEFITS:

The purpose of the study is to test an approach to improving communication between patients with cancer and their doctors. Since this is a new approach, however, the researchers do not know yet if it will help. You may not get any direct benefit from taking part in it. By being in this study, though, you will help researchers plan programs to improve medical care delivery for persons with cancer. In this way, you may help other persons with cancer and their physicians.

F. ALTERNATIVES TO PARTICIPATION:

The alternative is not to participate.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your

Subject/Surrogate Initials _____

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GCO # 98-885 (ECH-286)

personal Medical Record (if any and if relevant to the study) may be reviewed by govemment agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION :

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

Subject/Surrogate Initials _____

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From: 7/18/02 To: 6/30/03

GCO # 98-885 (EHC-286)

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Katherine DuHamel (212) 659-5556. If you still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number (212) 659-8980.

L. DISCLOSURE OF FINANCIAL INTERESTS:

None.

Subject/Surrogate Initials _____

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This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)
From: 7/18/02 To: 6/30/03

ELMHURST HOSPITAL CENTER
CONSENT FOR RESEARCH

GCO # 98-885 (EHC-286)

AUTHORIZATION TO PARTICIPATE IN RESEARCH

The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.

Research Subject's Name (printed):_____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Katherine DuHamel and his/her associates at Mount Sinai School of Medicine and/or its affiliated institution.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Katherine DuHamel has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: _____
Signature

Name: _____
Print Name

Relationship: _____
If signed by surrogate

Date: _____ Time: _____

Subject/Surrogate Initials _____

For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)
From: 7/18/02 To: 6/30/03

GCO # 98-885 (EHC-286)

AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Name: _____
Signature

Name: _____
Print Name

Address: _____
Number and Street City State Zip Code

Date: _____ Time: _____

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: _____
Signature

Name of Witness: _____
Print Name

Date: _____ Time: _____

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the foregoing drugs, devices or procedures, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such drugs, devices or procedures and have fully and completely answered all such questions.

_____
Signature of Principal Investigator/Delegate (person who obtained consent)

_____ Print
Name of person who obtained consent Title

Date: _____ Time: _____

Subject/Surrogate Initials _____

For IRB Official Use Only

This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)
From: 7/18/02 To: 6/30/03

STUDY APPROVAL
FOR SAINT VINCENT'S HOSPITAL

1. IRB APPROVAL

SAINT VINCENTS CATHOLIC MEDICAL CENTERS
SAINT VINCENTS – NEW YORK
RESEARCH COMMITTEE AND INSTITUTIONAL REVIEW BOARD (IRB)

Martin Payne Building - Suite 2G
153 WEST 11 STREET
NEW YORK, N.Y. 10011

Mark Astiz, M.D. ,Chairman
IRB #00002116

TEL: (212) 604-2665
FAX: (212) 604-3272

NOTICE OF IRB ACTION

__X__ INITIAL REVIEW ____ RE-REVIEW ____ AMENDMENT No. ____ REVISED CONSENT ____ EXPEDITED REVIEW

To: **Paula Klein, M.D.**

Re: **#02-02**

Protocol Title: *99-258 "Improving Patient Communication About Breast Cancer Related Pain"*

At the I.R.B. meeting held on 03/18/02 the following action was voted on the research project cited above.

__X__ The study protocol and the informed consent process were approved for 1 year.

____ The consent form submitted was deficient as noted below. Please resubmit.

____ The protocol and/or consent form was disapproved for reasons noted below.

____ The IRB is in receipt of the information and it has been reviewed.

____ The IRB is in receipt of the investigator brochure and it has been reviewed.

____ The Revised Informed Consent Form has been approved.

All changes were made to the consent form.

Mark Astiz
Chairman or Vice Chairman

3/18/02
Date

NOTE:
1. Any change in the protocol that alters the risk to participants must be approved by the IRB prior to implementation.
2. Experimental drugs MUST be dispensed to in-patients by the Hospital's pharmacy. The P.I. must supply the pharmacy one complete copy of the study protocol.
3. Each enrolled subject must receive a copy of the signed informed consent.4. Study-related adverse reactions must be reported in writing to the IRB.
4. Study-related adverse reactions must be reported in writing to the IRB.
4. Study-related adverse reactions must be reported in writing to the IRB.

IRB # 01-02
Initial IRB APPROVAL: 01-28-02
IRB MODIFICATIONS APPROVED: 03-18-02
Amendment-1 approval: 07-15-02

TITLE OF PROJECT: 98-885 ***Improving Patient Communication about Breast Cancer-Related Pain***

PART I - RESEARCH PARTICIPANT INFORMATION SHEET:
A. PURPOSE OF THE STUDY

You are being asked to participate in a research study. The purpose of this research is to examine the effectiveness of a program aimed at the control of symptoms in advanced breast cancer patients. Research has shown that this kind of program may increase patient's active participation in treatment, and improve their quality of life. You qualify for this study because you: (1) are 18 years of age or older; (2) speak English or Spanish; (3) are a breast cancer patient with advanced disease; (4) report a moderate or greater level of pain within the past two weeks (as measured on our checklist); (5) don't have concentration problems that would interfere with ability to participate in this study; and (6) are currently receiving care from a physician at St. Vincent Catholic Medical Centers of New York or Mount Sinai.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with breast cancer that has spread beyond the breast. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition.

If you are eligible for participation and if you agree to participate, a research assistant will ask you a series of questions about your pain and pain treatment, how you are feeling, and your satisfaction with your care. This interview, which we call the baseline interview, will take about 35-45 minutes to complete.

Next, you will be randomly assigned (like flipping a coin) to receive either the control of symptoms or nutrition program. Random assignment means that you have a 50-50 chance of being in either condition. Depending on how you are assigned, you will then participate in either the control of symptoms or the nutrition program. The session will take about 30 minutes to complete and will be carried out by a member of the study staff. It will be tape-recorded. As part of the program you will

Init: Date:

be taught how to fill out a diary recording your pain symptoms or your nutritional habits. You will be asked to fill out one page of the diary every day for two weeks, and then once a week for about two weeks after that. Diary completion will take about five minutes of your time.

After completing the program session, you will meet with your health care provider for your regularly scheduled appointment. When you meet with your health care provider, we may ask to tape record the session to provide us with additional research data. All tapes will be kept confidential (each tape will be identified by a code number only). Tapes will be kept in a locked file cabinet in accordance with IRB procedure for research data. At the end of this consent form, we will ask whether or not you will agree to have your sessions tape-recorded. When your appointment is over you will be interviewed again for about 15 minutes. You will be asked some questions about your medical visit, your health care provider and your background (for example, what your age is, what your medical history is). Your health care provider will also complete a brief information form about the medical visit and your health status.

Approximately 3 to 4 weeks later you will be interviewed by a research assistant for the third time for about 35 minutes. We call this a follow-up interview. Whenever possible, this interview will be at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. The research assistant will ask you many of the same questions he/she asked of you at the first interview (for example, how you are feeling, what your pain has been like, how satisfied you are with your health care). The research assistant may also ask about whether any family members or friends have been helping you monitor your symptoms. Your health care provider will again complete a brief information form about the medical visit and your health status.

Approximately 8 weeks later you will be interviewed for the final time by a research assistant for about 35 minutes. Again, whenever possible, this interview will be at the time of your next scheduled medical visit and *after* you have seen your health care provider. If your scheduled appointment is cancelled or postponed, the follow-up interview can be conducted at a mutually convenient time over the telephone. This interview will ask you many of the same questions asked at the baseline and the two follow-up interviews (for example, what your health has been like, whether you have been having any pain, how satisfied you are with your health care).

In addition to these interviews, we will obtain some information about your health status and medical history from your medical chart.

We recognize that this research study requires intensive participation and we greatly appreciate your contribution. Your collaboration will enable us to further understand the adjustment of advanced breast cancer patients and possibly improve their care. The results of this research study will inform us of the benefits of our program with advanced breast cancer patients.

Init: **Date:**

To find out your wishes about being audiotaped while meeting with your health care provider, please to let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participation in this study will involve no costs to you. In consideration of your participation, you will receive $15 each day of the three days that you are interviewed for your time and expenses. This will be disbursed to you by either cash or check.

D. POTENTIAL RISKS AND DISCOMFORTS:

There is no known physical risk to those who participate in this study. You may experience some emotional discomfort as a result of speaking about your experience of breast cancer. If you do experience emotional discomfort, the research assistant is trained to assess, and if appropriate to refer you to a professional therapist or a counselor for a therapeutic session at no cost to you.

E. POTENTIAL BENEFITS:

Although we cannot assure you that you will benefit from participating in this study, you may benefit directly by gaining skills that enable you to become involved in your control of symptom or your nutrition. In addition, you may benefit from the knowledge that your involvement may help other patients with breast cancer.

Init: **Date:**

F. ALTERNATIVES TO PARTICIPATION (where applicable)

While you are in this study, you also may take part in other support programs available through this hospital or in your community. You are in no way excluded from other support programs or research studies.

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by law. However, your medical record may be reviewed by government agencies or the agency sponsoring this research, if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Paula Klein at telephone number (212) 604-6021 or Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in this study is voluntary. Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION:

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

Init: **Date:**

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Paula Klein at telephone number (212) 604-6021 or Dr. Katherine DuHamel, at telephone number (212) 659-5556. If you still have questions you may discuss them with Dr. Mark Asiz of the Institutional Review Board (the committee which oversees research at St. Vincent's) at telephone number (212) 604-6025.

Authorization to Participate in Research

This form must be signed by the participant and the investigator/delegate:

Participant _____
(Print Name) (Unit #)

1. I hereby volunteer to participate in a research program under the supervision of Dr. Paula Klein and her associates at St. Vincent Catholic Medical Centers of New York or Dr. DuHamel, and his/her associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Paula Klein or Dr. Katherine DuHamel or their delegate has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies at any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were, in fact, properly completed before I signed this authorization

Research Subject: _____ Date: _____
(Signature)

Name: _____ Time: _____
(Print)

Permanent Address: _____

Witnes _____
(Signature) (Print) (Date)

Init: **Date:**

Authorization to Participate in Research (continued)

For subjects who are not able to read this consent document themselves, the following must be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Witness: _____
(SIGNATURE)

Name: _____
(PRINT NAME)

Address: _____
NUMBER AND STREET CITY STATE ZIPCODE

ATTESTATION OF PRINCIPAL INVESTIGATOR/DELEGATE:

I have fully explained to the above volunteer the nature and purpose of the above-mentioned research program (including the extent to which the studies are experimental), the possible complications which may arise from both known and unknown causes as a result thereof and the consequences and risks, if any, if the subject decides to discontinue participation. I believe that he /she understands the nature, purposes, and risks of these studies. I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions

_____
(Signature of Principal Investigator/Delegate) (Date)

_____
(Print Name) (Title)

Init: **Date:**

TÍTULO DEL PROYECTO: 98-885 Mejoramiento de la Comunicación con las Pacientes acerca de los Dolores Relacionados con el Cáncer de los Senos

PART I: HOJA INFORMATIVA PARA LOS PARTICIPANTES EN LA INVESTIGACIÓN:

A. PROPÓSITO DEL ESTUDIO

Se le está solicitando participar en una investigación. El propósito de la misma es determinar la efectividad de un programa cuyo propósito es el de controlar los síntomas sufridos por las pacientes de cáncer avanzado en los senos. La investigación ha demostrado que este tipo de programa puede aumentar la participación activa de las pacientes en su tratamiento, mejorando incluso su calidad de vida. Usted califica para este estudio porque: 1) es mayor de 18 años; 2) habla inglés o español; 3) sufre de cáncer en los senos en su etapa más avanzada; 4) ha sufrido un grado de moderado a serio de dolor, durante las últimas dos semanas (tal y como figura en nuestra lista de comprobación); 5) no sufre de problemas de concentración que podrían impedirle participar en este estudio; y 6) está actualmente bajo la atención de un médico del St. Vincent Catholic Medical Centers of New York o Mt. Sinai

B. DESCRIPCIÓN DEL ESTUDIO:

Este estudio investigará la efectividad de un programa concebido especialmente para las mujeres con cáncer de los senos, que se haya proliferado más allá del tórax. La meta del programa es la de mejorar el control de los síntomas y la calidad general de vida de las pacientes. El programa tiene como objetivo suministrar a las mujeres información acerca del tratamiento de sus síntomas y enseñarles cómo mejor describirlos a su médico. Compararemos los resultados de este programa centrado en el control de los síntomas con otro centrado en la nutrición.

Si califica para participar, y está de acuerdo en hacerlo, un asistente de investigación le hará una serie de preguntas relacionadas con sus dolores y tratamiento de los mismos, su estado de ánimo y opinión acerca de la atención médica que recibe. Esta entrevista, que llamamos básica (baseline interview), le tomará alrededor de 35-45 minutos de su tiempo.

Seguidamente, será escogida al azar (como cuando se lanza una moneda para que salga cara o cruz) para recibir el programa de control de síntomas o el de la nutrición. Su asignación al azar significa que tendrá un 50 por ciento de probabilidades de ser asignada a cualquiera de los dos programas. Dependiendo de su suerte, participará entonces en el programa de control de los síntomas o en el centrado en la nutrición. La sesión durará unos 30 minutos y será impartida por un miembro del personal a cargo del estudio. Esta sesión será grabada. Como parte del programa, se le enseñará a llenar un diario para registrar y describir sus síntomas o sus hábitos

Init: **Date:**

alimenticios. Se le solicitará llenar una página del diario cada día, durante dos semanas, y después de eso sólo una vez por semana durante dos semanas. Cumplir con esta tarea le tomará unos cinco minutos diarios de su tiempo.

Luego de completar la sesión del programa, irá a su consulta programada habitual con su médico. Cuando se encuentre con él, podríamos solicitarle que nos permita grabar la consulta, a fin de recabar datos adicionales para nuestra investigación. Las cintas grabadas serán mantenidas en confidencia (siendo identificadas sólo con un número). Las mismas serán también mantenidas bajo llave de acuerdo con los procedimientos IRB para la conservación de datos de investigación. Al finalizar este formulario de consentimiento, le preguntaremos si está o no de acuerdo en permitirnos grabar sus sesiones. Cuando su cita haya terminado, será entrevistada de nuevo por alrededor de 15 minutos. Se le harán preguntas acerca de su consulta médica, de su médico y de sus antecedentes (por ejemplo, su edad, e historial médico). Su médico deberá también llenar un breve formulario informativo acerca de su visita y de su estado de salud.

Aproximadamente 3 a 4 semanas después usted será entrevistada por un asistente de investigación por tercera vez alrededor de 35 minutos. A esto lo llamamos entrevista de seguimiento. Cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita programada se cancela o pospone, la entrevista de seguimiento podra realizarse por telefono a una hora mutuamente conveniente. El asistente le preguntará muchas de las preguntas formuladas en su primera entrevista (por ejemplo, cómo se siente, cómo ha sido su dolor, y su estado de satisfacción con la atención médica recibida). El asistente de investigación querrá también averiguar si sus parientes y amigos la han estado ayudando a vigilar sus síntomas. Su médico completará de nuevo un breve formulario informativo acerca de su visita y su estado de salud.

Aproximadamente 8 semanas después usted será entrevistada por última vez por un asistente de investigación alrededor de unos 35 minutos. Otra vez, cada vez que sea posible, esta entrevista será al mismo tiempo que usted tenga su cita médica y *después* que usted haya visto a su doctor. Si su cita programada se cancela o pospone, la entrevista de seguimiento podra realizarse por telefono a una hora mutuamente conveniente. En esta entrevista se le harán muchas de las preguntas formuladas en la entrevista básica y en las dos entrevistas de seguimiento (por ejemplo, cómo se siente, si ha estado sintiendo algún dolor, y su estado de satisfacción con la atención médica recibida).

Además de estas entrevistas, recabaremos alguna información acerca de su estado de salud e historial médico, de su expediente.

Reconocemos que esta investigación supone una participación intensa y agradecemos sobremanera su contribución. Su colaboración nos permitirá entender mejor los medios de ajuste y adaptación de las pacientes de cáncer avanzado de los senos, así como los que posiblemente puedan mejorar su tratamiento. Los resultados de este estudio investigativo nos suministrarán

información acerca de los beneficios de nuestro programa para beneficio de las pacientes de cáncer avanzado de los senos.

A fin de determinar sus deseos en cuanto al uso de audio grabadoras durante sus encuentros o consultas con su médico, favor de marcar a continuación:

_____ Consiento a que se graben mis conversaciones

_____ No consiento a que se graben mis conversaciones

C. COSTOS /-REMBOLSO DE COSTOS:

Su participación en este estudio no conllevará gastos para usted. Considerando su participación, recibirá $15 por cada uno de los días en que será entrevistada, a fin de contribuir a que cubra su tiempo y costos. Esta suma se le pagará mediante efectivo o cheque.

D. RIESGOS E INCOMODIDADES POTENCIALES:

El tomar parte en este estudio no conlleva riesgos físicos de ninguna índole. Podrá experimentar algún desasosiego emocional al hablar acerca de sus experiencias como paciente de cáncer de los senos. Si este es el caso, el asistente de investigación está debidamente entrenado para evaluar su situación y referirla a un terapeuta profesional o a un consejero para una sesión de terapia sin costo alguno para usted.

E. BENEFICIOS POTENCIALES:

A pesar de que no le podemos garantizar que su participación en esté estudio redundará en beneficios directos para usted, podrá beneficiarse directamente adquiriendo conocimientos que le permitirán controlar mejor sus síntomas o su nutrición. Se beneficiará además al considerar que su intervención podría ayudar a otras pacientes de cáncer de los senos.

F. ALTERNATIVAS A LA PARTICIPACIÓN (cuando corresponda):

Mientras se encuentre sometida a estudio, podrá también tomar parte de otros programas de apoyo disponibles a través de este hospital o en su comunidad. De ningún modo será excluida de otros programas de asistencia o investigación.

G. CONFIDENCIALIDAD:

Su identidad como participante en este estudio se mantendra como confidencial para fines de publicación de los resultados de este estudio. Su hoja médica relacionada con este estudio será mantenida como confidencial, hasta donde lo permitan las leyes. Sin embargo, la misma podrá ser revisada por las agencias del gobierno o la agencia patrocinadora de este estudio, si así lo requirieran las leyes o reglamentos vigentes.

H. TRATAMIENTO COMPENSATORIO:

Fuera de la atención médica que pueda recibir o de cualquier pago específicamente acordado en el formulario de consentimiento, no habrá otra compensación por su participación en esta investigación. Si cree haber sufrido una lesión con relación a esta investigación, deberá dirigirse a la Dra Paula Klein, al telefono (212) 604-6021 o Dra.Katherine DuHamel, al teléfono (212) 659-5556.

I. PARTICIPACIÓN VOLUNTARIA:

Su participación en este estudio es puramente voluntaria. Cualquier otra información que surja de este estudio, y que pudiera afectar su decisión de participar, le será suministrada inmediatamente.

Una copia firmada de este formulario de consentimiento le será entregada.

J. FIN DE LA PARTICIPACIÓN:

La decisión de participar o no en este estudio será enteramente suya. Podrá interrumpir su participación en el mismo, o rehusar responder preguntas determinadas en cualquier momento y sin penalidades o pérdidas de beneficios a los que pudiera tener derecho.

K. PERSONAL DE CONTACTO:

Init: **Date:**

IRB # 01-02
Initial IRB APPROVAL: 01-28-02
IRB MODIFICATIONS APPROVED: 03-18-02
Amendment-1 approval: 07-15-02

Si tiene alguna pregunta, en cualquier momento, acerca de este estudio, favor de hacer contacto con la Dra. Paula Klein, al telefono (212) 604-6021 o Dra. Katherine DuHamel, al teléfono (212) 659-5556. Si después de esto tuviera aún alguna otra pregunta, podrá tratarla con Dr. Mark Astiz, Presidente del Institutional Review Board (el comité encargado de las investigaciones en la St. Vincents Catholic Medical Center of New York), número de teléfono (212) 604-2065.

Init:

Date:

PROYECTO GCO # 98-885

Autorización para Participar en Investigación

Este formulario deberá estar firmado por una participante y el investigador/delegado.

Participante_____ _____
[Nombre en letra de molde] [Unidad N°]

1. Por este medio me ofrezco como voluntaria para participar en un programa de investigación bajo la supervisión de las Dra. Paula Klein y sus asociados de la St. Vincents Catholic Medical Centers of New York o Katherine DuHamel y sus asociados de la Mt. Sinai School of Medicine.

2. Declaro haber leído, o haberme sido explicado en un idioma que puedo entender, el documento de consentimiento anexo, y que la Dra. Paula Klein, Dra. Katherine DuHamel o su delegado me explicó la naturaleza y propósito de estos estudios. Esta explicación incluyó una descripción de las partes del estudio que son experimentales, las posibles molestias, síntomas, efectos secundarios y riesgos que podría razonablemente esperarme, así como las posibles complicaciones, de haberlas, que pudiera razonablemente experimentar por causas tanto conocidas como desconocidas, como resultado de mi participación en estos estudios. Tuve la oportunidad de hacer las preguntas que tenía acerca de este estudio, y todas fueron respondidas a mi plena satisfacción.

3. Entiendo que estoy libre de retirar esta autorización y de descontinuar mi participación en estos estudios, en cualquier momento. Las consecuencias y riesgos, si alguno, de retirarme de la investigación mientras se halle en curso, me fueron explicados. Entiendo que dicho retiro o interrupción no comprometerá mi capacidad de recibir la atención médica a la que pudiera, en todo caso, tener derecho.

4. Confirmo haber leído, o que me fue leída, esta autorización integralmente, y que los espacios en blanco o declaraciones que requieren ser llenados, fueron debidamente llenados antes de yo firmarla.

_____ Firma: _____
Sujeto de la Investigación

Nombre: _____ Hora: _____
[Escriba en letra de molde]

Dirección Permanente:_____

Testigo: _____ _____ _____
(Firma) (Escriba en letra de molde) (Fecha)

Autorización para Participar en Investigación (continuación)

Para aquellos que no estén en condiciones de leer por sí mismos este documento de consentimiento, lo siguiente deberá ser llenado:

Confirmo haber traducido y/o leído la información al interesado:

Testigo: _____
[Firma]

Nombre: _____
[Escriba en letra de molde]

Dirección: _____
[Número y Calle] [Ciudad, Estado y Código Postal]

CERTIFICACIÓN DEL DIRECTOR DE LA INVESTIGACIÓN/DELEGADO

He explicado debidamente al anteriormente indicado voluntario la naturaleza y propósito del programa de investigación de referencia (incluyendo hasta el grado en que estos estudios son experimentales), las posibles complicaciones que pudieran surgir de causas conocidas como desconocidas como resultado de la misma, así como las consecuencias o riesgos, si alguno, en caso de que el sujeto decida interrumpir su participación. Entiendo que él/ella entiende la naturaleza, propósitos y riesgos de estos estudios. Asimismo, me ofrecí también para responder cualquier pregunta relacionada con estos estudios, y respondí integralmente dichas preguntas.

_____
[Firma del Director de la Investigación/Delegado] [Fecha]

_____
[Nombre en letra de molde] [Título]

TITLE OF PROJECT: 98-885 *Improving Patient Communication about Breast Cancer-Related Pain*

PART I - RESEARCH PARTICIPANT INFORMATION SHEET:
A. PURPOSE OF THE STUDY:

Physician Consent Form

You are being asked to participate in a research study. The purpose of this study is to test an intervention to improve communication between patients with cancer and their physicians during the medical visit.

You qualify for participation in this study because you provide outpatient care to women with metastatic breast cancer.

B. DESCRIPTION OF THE RESEARCH:

This study will investigate the effectiveness of a program designed specifically for women with advanced breast cancer. The goal of the program is to improve the control of symptoms and quality of life. The program is designed to provide women with information about symptom treatment and skills to describe symptoms to their health care provider. We will compare the effectiveness of a program focusing on the control of symptoms with a program focusing on nutrition.

After the medical visit, you as the patient's physician will be asked to complete a two minute open-ended questionnaire about the patient's status.

Audio-tape recording: The medical visit will be audiotaped. The purpose of the audiotaping is to permit analysis of patient-physician communication patterns. All participants (both physicians and patients) will receive unique identification numbers. Data will be analyzed using a coding system that characterizes the content, process, linguistic and behavioral components of the interaction. With the physician's permission, a study research assistant will enter the exam room at the beginning of the medical appointment to start the tape recorder and again at the end to stop it. All audiotaped data will remain strictly confidential. Once the study is finished, the Principal Investigators, Dr. Paula Klein and Dr. Katherine DuHamel will erase all the tapes. Until then, the tapes will be kept in a locked file cabinet in doctor Duhamel's office. Only the researchers at Mt. Sinai will have access to those tapes.

Init: **Date:**

To find out your wishes about being audiotaped while meeting with your patient, please let us know by marking below:

_____ I CONSENT TO BEING AUDIOTAPED

_____ I DO NOT CONSENT TO BEING AUDIOTAPED

C. COSTS/REIMBURSEMENTS:

Participating patients will receive $15 for each of the three days interviewed.
Physicians will incur no costs and will receive no financial reimbursements for their participation in this investigation.

D. POTENTIAL RISKS AND DISCOMFORTS:

Taking part in this study involves no physical risk to either patient or physician.

E. POTENTIAL BENEFITS:

The purpose of the study is to test an approach to improving communication between patients with cancer and their doctors. Since this is a new approach, however, the researchers do not know yet if it will help. You may not get any direct benefit from taking part in it. By being in this study, though, you will help researchers plan programs to improve medical care delivery for persons with cancer. In this way, you may help other persons with cancer and their physicians.

F. ALTERNATIVES TO PARTICIPATION (where applicable):

The alternative is not to participate.

Init: **Date:**

G. CONFIDENTIALITY:

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Representatives of the U.S. Army Medical Research and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

H. COMPENSATION/TREATMENT:

Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Paula Klein at telephone number (212) 604-6021 or Dr. Katherine DuHamel at telephone number (212) 659-5556.

I. VOLUNTARY PARTICIPATION:

Participation in the study is voluntary. Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J. TERMINATION OF PARTICIPATION:

The choice to enter, or not to enter, this study is yours. You may discontinue participation in the study, or refuse to answer any specific questions at any time without penalty or loss of benefits to which you are otherwise entitled.

K. CONTACT PERSON(S):

If you have any questions, at any time, about this research, please contact Dr. Paula Klein at

Init: **Date:**

(212) 604-6021 or Klein Dr. Katherine DuHamel at (212) 659-5556. If you still have questions you may discuss them with Dr. Mark Astiz, Chairman, Institutional Review Board, the committee which oversees research at St Vincents Catholic Medical Centers of New York, at telephone number (212) 604-2065.

Authorization to Participate in Research

This form must be signed by the participant and the investigator/delegate:

Participant _____
(Print Name) (Unit #)

1. I hereby volunteer to participate in a research program under the supervision of Dr. Klein, and her associates at St. Vincents Catholic Medical Centers of New York, or Dr. DuHamel and her associates at Mount Sinai School of Medicine.

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that Dr. Klein and/or Dr. Katherine DuHamel or their delegate has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies at any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were, in fact, properly completed before I signed this authorization.

Research Subject: _____ Date: _____
(Signature)

Name: _____ Time: _____
(Print)

Permanent Address: _____

Init: **Date:**

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Initial IRB APPROVAL: 01-28-02
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Witness: _____
(Signature) (Print) (Date)

Init: Date: