

Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** Oncology Nursing Society
2. **Reporting Period (start and end date of grant award period):** 1/1/2009-6/30/2012
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Gail A. Mallory, PhD, RN, NEA-BC
4. **Grant Contact Person’s Telephone Number:** 412-859-6308
5. **Grant SAP Number:** 4100047644
6. **Project Number and Title of Research Project:** The SEA Preparatory Intervention for Women with Metastatic Breast Cancer
5. **Start and End Date of Research Project:** 1/1/2009-6/30/2012
7. **Name of Principal Investigator for the Research Project:** Margaret Rosenzweig, PhD, FNP-BC, AOCNP
8. **Research Project Expenses.**

9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

\$ 12,473

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project	Cost
Slavish	Research Assistant	5% YR1	2,773.92

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
Rosenzweig	Principal Investigator	10% YR1; 10% YR2; 10% YR3
Slavish	Research Assistant	95% YR1; 50% YR2; 50% YR3

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
None		

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes _____ No _____

If yes, please indicate the source and amount of other funds:

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes _____ No _____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If

you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
Sensory and Coping Information for Women with Newly Diagnosed Metastatic Breast Cancer	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:_____) <input type="checkbox"/> Nonfederal source (specify:_)	March 2010	\$416,625.00	\$ not funded
Enhancement of the Interventional Components of the Sensory and Coping Intervention	<input type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify:_____) <input checked="" type="checkbox"/> Nonfederal source (specify: _PA Breast Coalition Grant_)	October 2010	\$45,492.74	\$ not funded
Creation and Evaluation of a Clinic for Women with Metastatic Breast Cancer	<input type="checkbox"/> NIH <input checked="" type="checkbox"/> Other federal (specify: PCORI_) <input type="checkbox"/> Nonfederal source (specify:_)	July 2012	\$1,498,976.	Notice of funding has not been made

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes ___X___ No _____

If yes, please describe your plans:

We are currently submitting a grant: *Creation and Evaluation of a Clinic for Women with Metastatic Breast Cancer* (PCORI: submitted July 31, 2012) focused on patient centered outcomes that designs a plan for a clinic site focused only on women with metastatic breast cancer. We plan to use the educational materials developed through this project as the educational materials integrated into this program of care.

12. Future of Research Project. What are the future plans for this research project?

The data derived from this research project has helped inform a proposal; *Creation and Evaluation of a Clinic for Women with Metastatic Breast Cancer* (PCORI: submitted July 31, 2012) that specifically includes anticipatory guidance based on what is known to date about MBC prognosis and predicted response to therapy. This proposal attempts to measure the

outcomes from a program developed to ensure access to treatment resources and support services for women with MBC.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes _____ No X _____

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
White				
Black				
Asian				
Other				
Unknown				
Total				

14. Recruitment of Out-of-State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes _____ No X _____

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes _____ No X _____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes X No _____

If yes, please describe the collaborations:

The findings of this research have indicated the need for supportive and educational information among women with MBC but suggest the timing and presentation of information among this unique population is challenging. The patient with advanced illness is overwhelmed at time of diagnosis and while educational and supportive resources may help lessen the distress present, the patient is not always willing or comfortable speaking with a researcher about such a sensitive topic. The most recent PCORI proposal is unique in that it provides the patient with the option to meet with an expert physician in breast cancer and clinical trials, in addition to her own oncologist. A physician who is an expert in breast cancer and clinical trials from the University of Pittsburgh Cancer Institute (UPCI) leads this application and proposed study. Dr. Rosenzweig has collaborated with Dr. Shannon Puhalla and Dr. Adam Brufsky (UPCI) to serve as the nurse practitioner on this application. If funded, Dr. Rosenzweig will provide an assessment of supportive and palliative care needs of patients enrolled in the study.

16(B) Did the research project result in commercial development of any research products?

Yes _____ No X _____

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes X No _____

If yes, please describe involvement with community groups that resulted from the research project:

This project has led to the application *Creation and Evaluation of a Clinic for Women with Metastatic Breast Cancer* (PCORI: submitted July 31, 2012), The project demanded interaction with the community of patients, care providers and community advocates. We

sought and will seek community involvement with community stakeholders with metastatic breast cancer.

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant application's strategic plan). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (β) should not print as boxes (\square) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

The SEA Preparatory Intervention for Women with Metastatic Breast Cancer - The purpose of this pilot randomized controlled project is to provide information to women newly diagnosed with metastatic breast cancer (MBC) that they can use at diagnosis and across the illness continuum to maintain quality of life and reduce distress.

Aim 1: To determine the feasibility (recruitment, attrition, acceptability) of the use of an anticipatory guidance intervention, the SEA Intervention, in women newly diagnosed with MBC.

Recruitment

The SEA Intervention opened to recruitment in March 2010. During the reporting period, July 1, 2009-June 30, 2010, 16 subjects were enrolled. During the reporting period, July 1, 2010-June 30, 2011, an additional 13 subjects were enrolled. During the current reporting period, July 1, 2011-June 30, 2012, 3 subjects were enrolled. Therefore, at the time of this report, a total of 32 patients have been recruited, consented and enrolled in the study. Years 01 and 02 proved to be very successful for recruiting subjects into the study. However, Year 03 was not an ideal recruitment year. The research team experienced a decrease in recruitment attributed in part to lack of subject interest for participation in a research study as well as clinician restriction on patients deemed “eligible” for recruitment. Reasons for patients not consenting and enrolling in the study after contact and recruitment by a researcher included: 1) not interested in being part of a research study, 2) not wanting to be “bothered” and 3) fearful of learning information about disease. Reasons for clinician restriction on “eligible” patients included: 1) age of patient, 2) progression of disease and 3) mental status. While we were optimistic at the end of Year 02 that we would be able to meet our target recruitment goal by the end of reporting Year 03, we were not successful.

Recruiting from this unique population at a vulnerable time is challenging. Ideally, subjects would have been recruited on the day of MBC diagnosis. However, few subjects were recruited at the diagnosis of MBC and instead were recruited, enrolled and consented several months after diagnosis due to patient's reluctance to think about advanced disease or clinic staff not allowing recruitment.

This cohort represented regional demographics: white (n=26/32, 81%), married (20/32, 63%), completed high school education (32/32, 100%) and all (32/32, 100%) had health insurance. See Table 1.

Attrition

There has been no attrition due to failure to follow up with participants. There has been attrition due to death in three subjects (SEA=2 and UC=1). These three subjects completed baseline data but were deceased prior to completing time point 2 and time point 3 data. Reason for death for all three subjects included progression of disease.

Acceptability

Acceptability of the SEA Intervention materials has been measured for all subjects randomized to the intervention group. An acceptability questionnaire is administered at the final time point (time point 2, 6 months post enrollment) for all intervention group patients. The 13-item acceptability questionnaire consists of four 5-point Likert Scale questions assessing the timing, clarity, need and applicability of the intervention. Additionally, 8 open-ended questions assess the strengths and weaknesses of the intervention materials as well as suggestions for improvement in the delivery and content of the intervention. All subjects who have completed the acceptability questionnaire (n=13) have rated the intervention as favorable: 12.7 ± 2.8 (scale=0-16) and as “needed” information.

Aim 2: To explore the efficacy of the SEA Intervention on quality of life, physical and emotional distress and symptom distress in women newly diagnosed with MBC over the first six months of

illness as compared to care as usual.

32 subjects have completed baseline data collection, 29 patients completed follow up data at time point 2 and 29 patients completed follow up data at time point 3. The mean scores and standard deviations for the three outcome measures of quality of life (FACT), physical and emotional distress (Distress Thermometer) and symptom distress (McCorkle Symptom Distress) are listed in Table 2.

Quality of Life

Quality of Life is measured using the Functional Assessment of Cancer Therapy (FACT), a validated 33-item general cancer quality-of-life measure for evaluating patients receiving cancer treatment. Scores range from 0-108, with a higher score indicating better quality of life. Table 2 illustrates mean and standard deviation FACT scores for both the Intervention Group and the Usual Care Group.

Baseline

At baseline, the FACT scores for the Intervention group and Usual Care group scores were relatively similar. The mean FACT score for the Intervention group (n=15) was 77.2 (SD=4.5) and the mean score for the Usual Care group (n=17) was 78.9 (SD=3.8).

Time point 2

At time point 2, both the Intervention group and the Usual Care group illustrated an increase in mean FACT scores. The Intervention group (n=13) had a mean score of 82.7 (SD=3.4) and the Usual Care group (n=16) had a mean score of 83.3 (SD=3.9)

Time point 3

At time point 2, both the Intervention group and the Usual Care group illustrated slightly higher scores from baseline, but no major change from time point 2 mean FACT scores. The Intervention group (n=13) had a mean score of 82.0 (SD=3.0) and the Usual Care group (n=16) had a mean score of 84.5 (SD=4.4).

Emotional and Physical Distress

Emotional and physical distress is measured using the Distress Thermometer. The Distress Thermometer is a screening tool widely used by health professionals to assess the level of distress that a patient is experiencing in a 0-10 scale. 0 indicates no distress while 10 indicates extreme distress. See Table 2.

Baseline

At baseline, the distress scores for the Intervention group and Usual Care group were relatively similar. The mean distress score for the Intervention group (n=15) was 4.2 (SD=0.8) and the mean score for the Usual Care group (n=17) was 3.5 (SD=0.6).

Time point 2

At time point 2, the distress scores for the Intervention group (n=13) decreased slightly from what was recorded at baseline to a mean score of 3.3 (SD=0.9). The mean score for the Usual Care group (n=16) was 3.3 (SD=0.9).

Time point 3

At time point 3, the distress scores for the Intervention group (n=13) decreased slightly from what was recorded at baseline and at time point 2 to a mean score of 3.2 (SD=0.8). The mean score for the Usual Care group (n=16) was 2.1 (SD=0.7).

Symptom Distress

The McCorkle Symptom Distress scale has been developed and validated as a cancer-specific tool for assessing symptoms. This 13-item scale measures degree of distress on a 1-5 Likert scale. A total summed score of 25 or above indicates moderate distress; scores of 33 or above indicate severe distress that requires immediate intervention. See Table 2.

Baseline

At baseline, the symptom distress scores for the Intervention group and Usual Care group were relatively similar. The mean symptom distress score for the Intervention group (n=15) was 25.4 (SD=1.8) and the mean score for the Usual Care group (n=17) was 24.2 (SD=1.6).

Time point 2

At time point 2, the symptom distress scores for both the Intervention group and the Usual Care group remained relatively unchanged from the recorded baseline scores. The mean score for the Intervention group (n=13) was 24.5 (SD=1.6) and the mean score for the Usual Care group (n=16) was 23.7 (SD=1.8).

Time point 3

At time point 3, the symptom distress scores for both the Intervention group and the Usual Care group decreased from baseline and time point 2. The Intervention group (n=13) had a mean score of 22.6 (SD=1.9) and the Usual Care group (n=16) had a mean score of 22.9 (SD=2.1).

Conclusion

The results at the completion of this project do not suggest that the SEA Intervention had a measurable impact on the quality of life scores, distress scores or symptom distress scores of the subjects randomized to the Intervention arm. Baseline, time point 2 and time point 3 mean FACT, mean Distress and mean Symptom Distress scores were relatively similar between the SEA Intervention and Usual Care groups.

Despite the inability of the SEA Intervention to have a meaningful impact on the quality of life, distress and symptom distress scores as hypothesized, the comments from an open ended survey and Likert-Scale survey assessing the impact of the SEA Intervention's components suggests that the information provided in the intervention is both important and necessary as women receive the news of diagnosis of metastatic breast cancer. See Tables 3 and 4. Providing all women with appropriate and reliable information regarding diagnosis and treatment trajectory is essential in helping women achieve the advocacy necessary as well as the information to influence informed health care decision making.

Table 1. Socio-demographic Characteristics of Study Participants

Characteristic	SEA Intervention (n=15)	Usual Care (n=17)
Race:		
White	11(73)	15 (88)
Black	4 (27)	2 (12)
Age (years)	47.7± 12.3	53.1± 8.6
Education (years)	15.1± 2.5	15.4± 2.7
Marital status:		
Currently married	9 (60)	11 (65)
Other	6 (40)	6 (35)
Annual household income:		
< \$30,000	4 (27)	2 (12)
≥ \$30,000	9 (60)	14 (82)
Refused	2 (13)	1 (6)
Employment Status:		
Working full time	4 (27)	5 (29)
Working part time	1 (7)	3 (18)
Disabled	3 (20)	3 (18)
Other	7 (47)	6 (35)
MBC diagnosis (median days)	89	139

Table 2: Quality of Life, Symptom Distress and Overall Cancer Distress

Characteristic	SEA Intervention Baseline (n=15)	Usual Care Baseline (n=17)	SEA Intervention Time point 2 (n=13)	Usual Care Time point 2 (n=16)	SEA Intervention Time point 3 (n=13)	Usual Care Time point 3 (n=16)
Quality of Life (FACT-G)						
<i>Higher score indicates greater quality of life</i>						
FACT-G total (0-108)	77.2± 4.5	78.0± 3.8	82.7± 3.4	83.3± 3.9	82.0± 3.0	84.5± 4.4
Subscales						
Physical (0-28)	19.8±1.7	20.9± 1.0	21.7± 1.4	22.8± 1.2	21.8± 1.0	22.1± 1.6
Social (0-28)	23.2± 1.8	22.2± 1.3	23.4± 0.9	23.3± 1.3	24.2± 0.8	23.9± 1.3
Emotional (0-24)	17.5± 1.5	17.4± 1.1	19.0± 1.1	19.6± 0.9	18.0± 1.2	19.9± 0.9
Functional (0-28)	16.6± 1.1	17.4± 1.2	18.6± 1.1	17.6± 1.3	18.1± 0.9	18.6± 1.3
Symptom Distress						
<i>Higher score indicates greater distress</i>						
Symptom Distress (5-65)	25.4± 1.8	24.2± 1.6	24.5± 1.6	23.7± 1.8	22.6± 1.9	22.9± 2.1
Overall Cancer Distress						
<i>Higher score indicates greater overall cancer distress</i>						
Cancer Distress (0-10)	4.2± 0.8	3.5± 0.6	3.3± 0.9	3.3± 0.7	3.2± 0.8	2.1± 0.7

Table 3: Acceptability of the SEA Intervention (Likert Evaluation)

Acceptability of the SEA Intervention: 5-point Likert Scale Assessment (1= Strongly Disagree – 5=Strongly Agree)	
The SEA Intervention was well timed.	3.6 0.3 (SD)
The SEA Intervention was clear.	4.3 0.2 (SD)
The SEA Intervention content is needed information.	4.7 0.2 (SD)
The SEA Intervention was designed for me.	4.0 0.2 (SD)

Table 4: Acceptability of the SEA Intervention (Open-Ended Evaluation)

Open Ended Responses

- 1.) In recalling what your needs were when you were first told that you had metastatic breast cancer, can you tell me if these materials would meet your needs for information at that time?
 - I don't remember.
 - It is helpful to answer a lot of questions.
 - I think that the materials did meet the needs at this time. The materials provided information that was helpful to me.
 - I was happy with the presentation.
 - The information met my needs.
 - The materials met my needs. However, earlier delivery would have been better.
 - This was the only material that I got for this breast cancer [stage IV] and we [me and my family] had some questions which the books helped with.

- 2.) Can we specifically look at the 6 modules and comment on the content of method and presentation?
 - I can't think of any one particular thing now, but it was a helpful presentation.
 - I liked the pamphlets. I liked having the easy access to something for questions. Everything was there, I didn't have to go online and google everything because you don't want to go online when you have advanced breast cancer.

- I think it was a good general presentation. Everyone's case is so individual. Each person would have to take that information and do more research on their case. Nonetheless, good overall presentation.
- I thought it was good to have the DVD first and then have the materials to take home and use as needed.
- I thought the DVD modules were pretty thorough and well addressed.
- Perfect, I was able to use the materials at my leisure and go back and read again. I also shared with my family.
- The DVD was my favorite. I have watched it more than once, I like to see the women in the video still doing day to day things and doing well.
- The video was nice. It was nice to have my own packet to keep and refer to things. Having reference material about holistic treatment was interesting and helpful.
- There was a lot in there that helped. For example, "how you feel" and "diet", it was put together well.

3.) What are some things you particularly liked about the materials?

- At the time it was knowing that there were women in my situation. Actually seeing them on the DVD and not just reading about them was helpful. Plus, seeing Dr [Brufsky] made it more relevant for me.
- Easy to understand. The website was concise and clear. I used the website 2-3 times.
- I liked the folder, organization and easy access to materials on as needed basis.
- I liked that I was sought out to get these materials. It was nice to have someone give me these materials and resources that I was able to share with my family.
- I liked the interviews in the DVD with "survivors" and hearing about how they cope. There was also a lot of written material that gave good resources.
- I liked the subject order and organization.
- I thought the materials gave a view of everything you needed. It presented what you were feeling at diagnosis and throughout illness.
- It was informational but I cannot think of anything specifically.
- The DVD went over things that I had previously gone over when talking to the doctor. The DVD made me feel like I could always go back and talk to the doctor about my concerns.

4.) Can you tell me your recommendations for improvement of the modules?

- For me, I would have liked to have gotten it the day the doctor told me how bad it was. Even though I was upset, it would have been helpful to receive it on that day to know that there was hope.
- I thought it would be nice to have a younger face in the DVD because I am only 28.
- I thought the written materials were good, it covered all of my needs.
- I used the written materials as a reference. I didn't read it all the time, but used it as a reference. Sometimes when something new happened (symptom/side effect), I would reference the written information.
- One thing that has helped me personally is following a nutritional program. More information on nutrition would be helpful.

- 5.) Do you think the materials were representative for you?
- Yes.
 - Yes and no. At the time I didn't think it was something that I needed to use. Thinking back on it, it was a comforting thing, it was something that was available to use. It is good to know that there are resources that you can use.
- 6.) Was the language clear enough? Should we "break down" the language any more so that it is more easily understood?
- Everything was easily understood and explained.
 - I thought the language was clear enough.
 - I understood everything.
 - I understood it, but I had already done a lot of research prior to getting the materials. But for someone who had not done their research, it was very clear and helpful.
 - Yes, I think the language was done very nicely. Nothing was over your head and it was easy to understand.
- 7.) Did we accurately discuss the concerns that you had when you first found out that you had advanced or metastatic breast cancer?
- Everything was addressed.
 - This covered my questions and concerns.
- 8.) Do you believe these materials are sensitive and appropriate for your race and economic status?
- **yes**

18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be "No."

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

If "Yes" to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both "No.")

18(C) How many hospital and health care professionals were involved in the research project?

 0 Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

 48 Number of subjects originally targeted to be included in the study
 32 Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

 Gender:

 Males
 32 Females
 Unknown

 Ethnicity:

 Latinos or Hispanics
 32 Not Latinos or Hispanics
 Unknown

 Race:

 American Indian or Alaska Native
 Asian
 6 Blacks or African American
 Native Hawaiian or Other Pacific Islander
 26 White
 Other, specify: _____
 Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

Allegheny

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

Yes
 No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

Yes
 No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the “Cognition and MRI in Older Adults” research project (Project 1), and two publications for PI Zhang for the “Lung Cancer” research project (Project 3), the filenames should be:

Project 1 – Smith – Publication 1 – Cognition and MRI

Project 1 – Smith – Publication 2 – Cognition and MRI

Project 3 – Zhang – Publication 1 – Lung Cancer

Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
None				<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes X No _____

If yes, please describe your plans:

Yes, we will submit the quantitative results countered with the qualitative data. It is clear that patients were reluctant to be recruited due to concerns of “talking” about metastatic breast cancer. If this educational program is part of a program of care, it will integrate this education into routine cancer care.

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

Although there were no significant differences for chosen outcomes, the qualitative comments indicate that this education is really necessary; but women do not want this at the time of diagnosis due to fear of the unknown. We are now integrating this education into a plan of care for women with metastatic breast cancer. We propose and have written a grant for a dedicated metastatic breast cancer clinic in which the education developed through this project will be utilized as standard education for all women in the metastatic breast cancer clinic.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes _____ No X

If “Yes” to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is “No.”)

- a. Title of Invention:
- b. Name of Inventor(s):
- c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):
- d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes _____ No _____

If yes, indicate date patent was filed:

- e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes _____ No _____
If yes, indicate number of patent, title and date issued:
Patent number:
Title of patent:
Date issued:

- f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes _____ No _____

If yes, how many licenses were granted? _____

- g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes ___ No ___

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes _____ No X

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Rosenzweig, Margaret	POSITION TITLE Associate Professor		
eRA COMMONS USER NAME (credential, e.g., agency login) pegmros			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Carlow College, Pittsburgh, PA	BSN	1981	Nursing
University of Pittsburgh, Pittsburgh, PA	MSN	1986	Family Nurse Practitioner
University of Pittsburgh, Pittsburgh, PA	PhD	2001	Oncology Nursing Program in Palliative
Harvard University, Cambridge, MA		2003	Care: Research and Practice
City of Hope, Pasadena, CA		2004	End of Life Nursing Education Consortium

A. Personal Statement

Margaret Rosenzweig, PhD, FNP-BC, AOCNP is an Associate Professor with the University of Pittsburgh School of Nursing. Dr. Rosenzweig’s program of research is directed toward providing education and support for women with breast cancer to empower them in obtaining optimal health care. She received a NCI K07 Award (K07 CA 100588, 2003-2009) to explore the metastatic breast cancer (MBC) experience according to race and income. She also received funding from the American Cancer Society (RSGT-09-150-01-CPHPS) to support the “ACTS Intervention to Reduce Breast Cancer Treatment Disparity” to evaluate the success of a supportive and educational intervention developed to promote adherence to breast cancer chemotherapy among African America women.

B. Positions and Honors

Academic

1992-1994	Adjunct Faculty, LaRoche College, Pittsburgh, PA
1994-1996	Clinical Instructor, University of Pittsburgh, Pittsburgh, PA
1996-2001	Teaching Fellow, University of Pittsburgh, Pittsburgh, PA
2001-2004	Assistant Professor, Clinical Track, University of Pittsburgh, Pittsburgh
2004-2011	Assistant Professor, Research/Tenure Track, University of Pittsburgh
2011 – Present	Tenured, Associate Professor
2009-	Ethics Consult Service, University of Pittsburgh Medical Center

Non-Academic

1981-1982	Registered Nurse, Shadyside Hospital, Pittsburgh, PA
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1982-1983 Volunteer Registered Nurse, Teche Action Clinic, Franklin, LA
 1983-1984 Registered Nurse, St. Francis Medical Center, Pittsburgh, PA
 1985-1987 Registered Nurse, Forbes Hospice, Pittsburgh, PA
 1987-1990 Nurse Practitioner, Montefiore Hospital, Pittsburgh, PA
 1990-1993 Nurse Practitioner, West Penn Hospital, Pittsburgh, PA
 1992-1993 Practice Clinical Manager, West Penn Hospital, Pittsburgh, PA
 1997- Nurse Practitioner, University of Pittsburgh Cancer Institute, Pittsburgh
 2009- Volunteer Nurse Practitioner, Catholic Charities Free Clinic, Pittsburgh

Honors

2005 University of Pittsburgh Innovation in Education Award
 “Communication Skills for Acute Care Nurse Practitioner (ACNP)
 2005 Sigma Theta Tau/Eta Chapter Leadership in Nursing Award- Research
 2006 Extra Effort Award—Cancer Working Group—Center for Minority
 Health. University of Pittsburgh Graduate School of Public Health
 2006 Cancer Control Program Award—Cancer Education and Outreach.
 American Cancer Society, Greater Pittsburgh Unit
 2008 First Place—Poster Competition—Clinical. National Cancer Institute
 Disparities Summit
 2010 Greater Pittsburgh Chapter—Oncology Nursing Society—Exemplar
 Award
 2010 Elected, Coordinator, Nurse Practitioner Special Interest Group, Oncology
 Nursing Society

Funded Research

Principal Investigator

American Cancer Society, RSGT-09-150-01-CPHPS

The ACTS Intervention to Reduce Breast Cancer Treatment Disparity

(2009 – 2014) 25% effort. Award: \$1,241,000

Co-Investigator: Bender, C., PI, University of Pittsburgh School of Nursing

National Cancer Institute

Long Term Trajectory of Cognitive Function Related to Anastrozole Use in Women

(2011 – 2015) 5% effort

Principal Investigator Pittsburgh Affiliate of Komen Race for the Cure

Targeted Educational Materials for African American Breast Cancer Survivors

(2012-2013), 10% effort. Award \$19,000

Principal Investigator. National Cancer Institute: R25 1R25CA148050-01A1

Cancer Education for Nurse Practitioners New to Cancer Care

(2012-2017), 30% effort. Award \$1,400,000