

Pennsylvania Department of Health Final Performance Summary Report Formula Grants

Overview of the Health Research Project Performance Review Process and Criteria

An applicant that receives a health research grant under Tobacco Settlement Act / Act 77 of 2001, Chapter 9, is subject to a performance review by the Department of Health upon completion of the research project. The performance review is based on requirements specified by Act 77 and criteria developed by the Department in consultation with the Health Research Advisory Committee.

As part of the performance review process, each research project contained in a grant is reviewed by at least three experts who are physicians, scientists or researchers. Reviewers are from the same or similar discipline as the research grant/project under review and are not from Pennsylvania. Reviewers use the applicant's proposed research plan (strategic plan), the annual progress report and final progress reports to conduct the review. A grant that receives an unfavorable performance review by the Department may be subject to a reduction in funding or become ineligible for health research funding in the future. The overall grant evaluation rating is based on the ratings for the individual research projects contained in the grant.

This performance review report contains the outcome of the review for the grant as a whole (outstanding, favorable, or unfavorable), strengths and weaknesses of each research project, as well as recommendations for future improvement.

The following criteria were applied to information submitted by research grant recipients:

- **Criterion 1 - How well did the project meet its stated objectives? If objectives were not completely met, was reasonable progress made?**
 - Did the project meet the stated objectives?
 - Were the research design and methods adequate in light of the project objectives?
 - Consider these questions about data and empirical results: Were the data developed sufficiently to answer the research questions posed? Were the data developed in line with the original research protocol?
 - If changes were made to the research protocol, was an explanation given, and, if so, is it reasonable?
 - Consider (only for clinical research projects) the extent of laboratory and clinical activities initiated and completed and the number of subjects relative to the target goal.
 - Were sufficient data and information provided to indicate or support the fact that the project met its objectives or made acceptable progress?
 - Were the data and information provided applicable to the project objectives listed in the strategic research plan?

- **Criterion 2 - What is the likely beneficial impact of this project? If the likely beneficial impact is small, is it judged reasonable in light of the dollars budgeted?**
 - What is the significance of this project for improving health?
 - Consider the value of the research completed towards eventual improvement in health outcomes.
 - Consider any changes in risk factors, services provided, incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of impact and effectiveness of the research being conducted.
 - Consider any major discoveries, new drugs and new approaches for prevention, diagnosis and treatment, which are attributable to the completed research project.
 - What are the future plans for this research project?

- **Criterion 3 - Did the project leverage additional funds or were any additional grant applications submitted as a result of this project?**
 - If leveraging of funds were expected, did these materialize?
 - Are the researchers planning to apply for additional funding in the future to continue or expand the research?

- **Criterion 4 - Did the project result in any peer-reviewed publications, licenses, patents, or commercial development opportunities? Were any of these submitted/filed?**
 - If any of the above listed were expected, did these materialize?
 - Are the researchers planning to submit articles to peer-reviewed publications, file for any licenses, or patents or begin any commercial development opportunities in the future?
 - Consider the number/quality of each.

- **Criterion 5 - Did the project enhance the quality and capacity for research at the grantee's institution?**
 - Were there improvements made to infrastructure?
 - Were any new investigators added or were any researchers brought into the institution to help carry out this research?
 - Were funds used to pay for research performed by pre- or post-doctoral students?

- **Criterion 6 - Did the project lead to collaboration with research partners outside the institution, or new involvement with the community?**
 - Are the researchers planning to begin any collaborations as a result of the research?
 - For clinical research only: consider the number of hospitals and health care professionals involved and the extent of penetration of the studies throughout the region or the Commonwealth.

Overall Evaluation Rating

An overall evaluation rating is assigned to each research project. The rating reflects the overall progress the project attained in meeting the stated goals and objectives. The rating is based on a scale of 1–3, with 1 being the highest. An average rating is obtained from all the reviews (minimum of 3) of each project and is the basis for the determination of the final overall rating for each project as follows:

1.00 – 1.33 = *Outstanding*

1.34 – 2.66 = *Favorable*

2.67 – 3.00 = *Unfavorable*

The grant level rating is an average rating from all projects as above. The numerical rating appears in parentheses for the grant and each project in the ***Overall Grant Performance Review Rating*** section of the report.

Overall Grant Performance Review Rating

Grant Rating: Favorable (2.33)

Project Rating:

Project	Title	Average Score
0864401	The SEA Preparatory Intervention for Women with Metastatic Breast Cancer	Favorable (2.33)

Project Number: 0864401
Project Title: The SEA Preparatory Intervention for Women with
Metastatic Breast Cancer
Investigator: Rosenzweig, Margaret

Section A. Project Evaluation Criteria

Criterion 1 - How well did the project meet its stated objectives? If objectives were not completely met, was reasonable progress made?

STRENGTHS AND WEAKNESSES

Reviewer 1:

The primary strength of this project is the use of pre-existing research that informed the need for the SEA intervention. As such, the PI and research staff were familiar with the population and the needs of these women. Subsequently, the investigators did develop and pilot test their intervention and identified implementation issues. One major finding of the pilot test is that participants generally indicated that intervention was useful. In addition, the test provides some context for the future delivery of support interventions.

Despite these strengths, there are some noteworthy weaknesses. This study encountered difficulties in study recruitment. The sample size was not recruited. Given the length of the study, it seemed that there was ample amount of time that could have been used to recruit participants and change recruitment protocols.

Although investigators propose a theory of why women failed to participate, the anecdotal evidence provides limited support. Investigators should have conducted more in-depth process data activities to better understand how to deliver the intervention. For the intervention to be useful and have significant impact, better understanding of barriers to participation is needed, rather than just noting barriers. Future researchers need to understand how support interventions can be delivered for women with metastatic breast cancer (MBC).

The target population was not enrolled as proposed. The sample was primarily one race. However, it is not clear if investigators hypothesized that there would be racial differences. Additionally, sample size might not have allowed for sufficient data analysis to answer any sub-analyses.

Reviewer 2:

Strengths: The project addressed an unmet need for newly diagnosed MBC patients. The proposed sample size and stratification were appropriate. The outcome measures for feasibility and efficacy were appropriate.

Weaknesses:

- The investigators were able to recruit only 32 women (67% of their proposed target).
- The investigators only recruited six black women, and most of the women had income > \$30,000; therefore, they were unable to stratify the randomization.
- The eligibility criteria of entry within two weeks of MBC diagnosis was not met for most of the women. Most were recruited and enrolled several months after diagnosis.
- A minor weakness is that while four time points for data collection were specified in the strategic plan (baseline, one month, three months, six months) only three times points were collected. The investigators do not state the times corresponding to time points two and three.
- These concerns suggest that the investigators did not have full collaboration from their clinical colleagues and/or did not have adequate promise of coordination of study activities with clinical care.

Reviewer 3:

The project did not meet its stated objectives:

- They recruited only 32 out of 48 proposed subjects, and that was a modest sample size to begin with. Recruiting diminished to 3 in year three, due to lack of potential subject interest and increased restrictions by referring oncologists. This may reflect an adverse response to the intervention or decreasing interest or effort from the investigative team. Clearly there were recruitment problems. There should have been an adequate supply of potential research subjects.
- There were concerns raised about the intervention itself. It is useful that the investigators obtained feedback from participants. They seemed to like the educational DVD, but some were disturbed by expression of emotion by others with the illness in the materials presented. There is nothing wrong *per se* with discussion of anger, fear and sadness; but providing adequate means of processing such inevitable feelings is important, and the intervention did not seem to provide this.
- There were no differences on any of the quality-of-life and mood measures between intervention and control group. The study was underpowered to show any difference, but the numbers were virtually identical at baseline and both follow-ups. So the study seems to indicate that the intervention did not produce any positive effects.
- There were no publications produced, and no grants were obtained as a result.
- The idea of providing electronic information about coping and preparation for possible later palliative care is a good one, although right after a diagnosis of metastasis most patients will be focused on treatment decisions and are not likely to be willing or able to consider palliation until later. The intervention may not have been intensive or structured enough to help subjects deal with the major existential, medical, family, and emotional concerns that arise with a diagnosis of metastatic disease. The prognosis becomes more guarded, treatments more intense, and needs for support greater.

Criterion 2 - What is the likely beneficial impact of this project? If the likely beneficial impact is small, is it judged reasonable in light of the dollars budgeted?

STRENGTHS AND WEAKNESSES

Reviewer 1:

The investigators acknowledged that the intervention was found not to be efficacious. There were no significant differences found for primary outcomes between study groups. Investigators should examine intervention materials to ensure that they are designed to reach the complex psycho-social variables that are attempted to be changed with the intervention. Given that no differences were found between study groups, the actual content and dose of intervention needs to be examined further to ensure that it had the strength to really change outcomes in participants. Ensuring that the intervention materials are developed so that they are capable of changing knowledge, attitudes, and behavior is the first step in developing effective interventions. Using an intervention development strategy (i.e., Intervention Mapping) increases the likelihood of developing effective programs.

The main benefit derived from this study was determining why women did not want to participate. Given the overall scope of the project, this has a small beneficial impact to cancer care. Nonetheless, given the total investment spent on supporting this study, the findings seem reasonable and do help guide the field. Had further research been conducted to learn how better to deliver a support intervention to newly diagnosed women, a greater clinical benefit would have been achieved.

Reviewer 2:

Weaknesses: The role of the SEA intervention (renamed Sensory and Coping Intervention) in future studies is unclear, since there is no suggestion of a difference between patients who received it and usual care patients. The only justification provided for its future use is that the patients found the information helpful.

Reviewer 3:

No conclusions can be drawn, given the small number of subjects and lack of difference between treatment and control subjects over time. The implication would seem to be that the intervention was insufficient to provide meaningful emotional, cognitive, and social support. The investigators plan some further non-government grants. They should probably redesign the intervention and think carefully about recruitment in the future.

Criterion 3 - Did the project leverage additional funds or were any additional grant applications submitted as a result of this project?

STRENGTHS AND WEAKNESSES

Reviewer 1:

No additional funding or resources were received during the funding period. Investigators note the submission of three proposals during the funding period. The first two proposals were submitted approximately one year after funding began. A third proposal was submitted to

Patient-Centered Outcomes Research Institute (PCORI) and appears to use data directly related to the funded project.

Reviewer 2:

Strengths: The authors leveraged the data from this project to inform a proposal, "Creation and Evaluation of a Clinic for Women with Metastatic Breast Cancer," that was submitted to PCORI. This is a reasonable benefit given the relatively small amount of funding provided.

Weaknesses: It is unclear how the SEA intervention (renamed Sensory and Coping Intervention) was used in the PCORI proposal. If the PCORI proposal is not funded, no future plans are provided.

Reviewer 3:

No new funds materialized.

Criterion 4 - Did the project result in any peer-reviewed publications, licenses, patents, or commercial development opportunities? Were any of these submitted / filed?

STRENGTHS AND WEAKNESSES

Reviewer 1:

The investigators have not submitted any publications. Publishing lessons-learned from recruitment would be useful to the field and a potential strength. However, this might be hindered by the limited process data collected.

Reviewer 2:

The investigators have not submitted any peer-reviewed publications to date. They plan to submit the quantitative results informed by the qualitative data.

Reviewer 3:

The project did not result in any peer-reviewed publications, licenses, patents, or commercial development opportunities.

Criterion 5 - Did the project enhance the quality and capacity for research at the grantee's institution?

STRENGTHS AND WEAKNESSES

Reviewer 1:

There appears to be no significant enhancement to the quality and capacity of research at the institution. Given the aims of the study, this is reasonable. However, given the difficulty in recruiting study participants, it would be useful to identify how the institution could be used to increase the capacity to support clinical research in participant recruitment.

Reviewer 2:

No improvements were made to the quality and capacity for research at the grantee's institution. No pre- or post-doctoral students were included.

Reviewer 3:

The project did not enhance the quality and capacity for research at the grantee's institution.

Criterion 6 - Did the project lead to collaboration with research partners outside of the institution or new involvement with the community?

STRENGTHS AND WEAKNESSES

Reviewer 1:

Investigators note that this research led to collaboration with partners outside of the institution. This collaboration resulted in the submission of a proposal to PCORI aimed at providing patients the option to meet with experts in breast cancer and clinical trials, in addition to their oncologist, as part of ongoing care for women with metastatic breast cancer.

The PCORI application included a community-level collaboration of patients, care providers and community advocates. If funded, this proposal will facilitate involvement of the community in funded activities.

A strength of this application is that the investigators pursued other proposals and research opportunities using a community infrastructure. When examining the current project, their collaboration was lacking. The investigators could have collaborated with area partner and community organizations. The lesson learned from conducting clinical trial research, especially with minority participants, is the importance of community agencies to help recruit study participants.

Reviewer 2:

The PCORI grant application required interaction with patients, care providers and community advocates. This is an indirect benefit from the completed research.

Reviewer 3:

The project did not lead to collaboration with research partners outside of the institution or new involvement with the community.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

1. Although the investigators did not achieve noteworthy research outcomes, investigators did gain some insight into the delivery of the intervention. However, the information gained was anecdotal at best. Given that this was a feasibility study, more emphasis on process data was warranted. It is not clear if investigators learned how better to implement support interventions of this type to this population.
2. Since the intervention was found not to be efficacious, more emphasis needs to be placed on intervention development. Developing specific interventions that address changeable targets is the first step. Although not clear from the documents provided, it is essential to show that a need exists and the intervention is addressing this need. Similar changes in both experimental and control group suggest that the support resources may be available elsewhere and no specific need of a program of this type is warranted.
3. The investigators proposed a pilot study. The goal of pilot testing is to test the waters so that larger trials are more effective. When investigators realized the difficulties in recruiting study participants, this provided opportunities to modify recruitment procedures without threatening the internal validity of the study. Given the importance of recruitment to any study, more emphasis should have focused on attempting different recruitment strategies to learn the best way to recruit study participants. Identifying the best strategy would greatly benefit all future research with this patient population.

Reviewer 2:

The project appears to have suffered from either a lack of collaboration from the clinicians involved in treating the MBC patients or a limited understanding of the barriers to the coordination of study activities with clinical care. Future projects should include letters of support from the appropriate clinical faculty.

Reviewer 3:

- The intervention was too limited. It needs improvement to help subjects manage emotions that inevitably occur with diagnosis of metastatic disease. Some elements seemed good, e.g., the DVD; but the one coping framework they employed to design the intervention would seem to have been shown to be insufficient.
- Recruitment was insufficient; they recruited only 32 out of 48 proposed. Perhaps earlier interaction between researchers and referring oncologists could have improved the intervention and recruitment.
- There was no indication of benefit on outcome measures. This is ok, but it further indicates a need to redesign an intervention of this type.
- Some publications should result probably based on the reflections of participants about what was helpful and what was not. Feedback from referring oncologist would also be helpful.
- No other grant funding was obtained.

Recommendations for Oncology Nursing Society

Reviewer 1:

Overall, the investment in this project was reasonable, and falls within the guidelines of the CURE program. The investigators derived some secondary benefit from conducting this research, but benefits were anecdotal and have limited impact at this juncture. However, to maximize gains from research investment, ensuring that funded projects have secondary aims that contribute to the field is essential. These secondary aims should be developed sufficiently well so that more than just anecdotal qualitative findings are derived from population-based research.