

# **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:** Outstanding (1.33)

**Project Rating:**

<b>Project</b>	<b>Title</b>	<b>Average Score</b>
1085801	Examining Impact of Individualized Positive Psychosocial Interventions in Nursing Homes	Outstanding (1.33)

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**Project Number:** 1085801  
**Project Title:** Examining Impact of Individualized Positive  
Psychosocial Interventions in Nursing Homes  
**Investigator:** Van Haitsma, Kimberly

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### *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:

Overall this project exceeded expectations and represents a wise investment of the \$17,589.60 over 18 months. The potential for improvement in the lives of some of our most vulnerable citizens in Pennsylvania and across the nation could be profound.

The project aims are particularly noteworthy, exploring the value of the intervention from three key stakeholder vantage points. The project team has adapted concepts from efficacy research to apply to a real-world setting in an effectiveness trial. The content extends the insights gained from self-determination theory (SDT)-based research to cognitively impaired individuals.

This reviewer had a number of design and analytic questions going into the review, and the project team has answered each one. The design and analysis used rigorous methodology to address the project aims, which should stand up to the rigors of the peer-reviewed publication that is planned. The exploration of outcomes stratified by Mini-Mental State Examination (MMSE) and activities of daily living (ADL) scores is a particular strength. The project provided further confirmation that not all social interactions are interpreted positively.

There are a few opportunities for improvement. The presentation of the approach and results would have been strengthened by inclusion of a recruitment diagram. Given that this project is purported to be an effectiveness trial, the reader needs a sense of the percent of residents who would be eligible and among those the percent who might participate. It would also have been of value to contrast the population of residents who could articulate their preferences versus those who had a family member proxy.

##### Reviewer 2:

The stated purpose of this project is “to examine the impact of an innovative intervention designed to enhance behavior and affective quality of life outcomes for frail, cognitively impaired elders residing in a nursing home.” Secondly, the project hopes to “examine the efficacy of teaching nursing assistants simple, time-limited, individualized interventions that enhance positive staff-resident interactions.” These are excellent, and the hypotheses are clearly described, logical and reasonable. The objective of this research is to conduct analyses on an

existing data set to test hypotheses related to impacts on directly observed nursing assistant interactions, directly observed resident behavioral and affective responses, and staff-reported resident outcomes.

The research design and methods are adequate in light of the project objectives. Please note that although this project is a secondary data analysis, it does still involve the use of information from human subjects and the data should be treated confidentially as such. It is a minor weakness that the available study population is not broadly representative of the United States nursing facility population, being somewhat homogeneous in age, ethnicity and gender due to the nature of the facility. It is also likely that the original study resulted in some contamination in study behaviors between the intervention and non-intervention groups over time, if the study was successful in altering baseline behaviors of residents and perceptions of staff as hypothesized. There is no study methodology outlined to adjust for the probable unintentional crossover behaviors by the nursing assistants under study either in the original study or in the statistical methods used to analyze the data in this study. The number of subjects studied would have been sufficient to reach primary conclusions but may not have been adequate to compensate for crossover. However, it is a strength that the analysis does compensate for multiple paired comparisons.

No progress was reported during the first six-month reporting period of January to June 2011. A subsequent progress report for the July 1, 2011 – June 30, 2012 reporting period provides data tables which support the author's conclusions that residents in the customized personal intervention group displayed more pleasure and alertness, as well as more positive verbal and nonverbal behavior (engagement in psychosocial tasks and positive touch, less restlessness), than those receiving usual care. While residents in the attention-provided control group experienced similar benefits, they exhibited more anger and uncooperative behavior. Anxiety was unaffected by type of intervention.

It is of note that there was an unusually low incidence of aggression and high incidence of null behaviors for typical nursing facility residents, leading one to question whether this population is actually representative of a "typical" nursing facility population. The slightly increased incidence of some negative emotions and behaviors, however, is reassuring and validates the traditionally cited truism that "some attention is better than no attention." The interventions interestingly did not seem to trigger an unacceptable incidence of observed agitation in the residents, which can happen in persons with dementia whether the stimulus is positive or negative. Unfortunately, the results may also be confounded by whether or not the less responsive residents were on psychoactive medications which may have altered behaviors. This is not described at all in the descriptive data of the original study provided by the author.

Major weakness: The issue of how many residents in which treatment groups were on differing types of psychoactive medications at baseline, had such medications added during the study, or became treated as a result of study observations is highly significant. This could obviously have had a major impact on the potential causality of the behaviors observed in the study.

Reviewer 3:

The project met its stated objectives. The analysis proposed has been carried out, and the report is thorough and complete.

***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:

Given that the potential impact for this project on the lives of vulnerable nursing home residents with dementia is significant, the project team is encouraged to plan for success beyond the next rigorous design. They might consider exploring how this intervention would fit into the daily workflow. They might consider controlling for concurrent use of psychoactive medications. Further the project team might begin to construct the business case for the intervention. With three arms to the trial they could look at a sensitivity analysis for the different gradations of contact with the resident. They might also be more explicit for just how much support is needed from the project team and also look at the variation of uptake across certified nursing assistants (CNAs) and the range of attitudinal response. They could also explore whether a reduction in negative behavior ultimately reduces/saves CNA time and whether the intervention has the potential to reduce use of psychoactive medications. Looking even further ahead, the project team might explore how the intervention, once implemented, would be viewed and evaluated by state surveyors.

#### Reviewer 2:

The author correctly notes that there is great potential for improving health outcomes for a very large population of cognitively impaired nursing facility residents with high rates of neuropsychiatric behaviors (NPB) and depression adversely affecting quality of life and health. It is also universally agreed upon by expert consensus and professional organizations that it is critically important to develop nonpharmacologic interventions for these symptoms, since the medications used are frequently off-label and actually harmful in some instances. Certified nursing assistants certainly have the most contact time with facility residents and currently have the least professional training to implement these types of interventions.

The ability to devise interventions requiring this group of caregivers to receive appropriate amounts of training time which can be effective will be essential for the success of any intervention for this resident population. Improving quality of life for this vulnerable population and their stressed caregivers is very difficult, and any incremental improvement is quite valuable. Presumably, a decrease in adverse behaviors and perceptions by residents and staff could also improve job satisfaction and time management, and perhaps reduce staffing turnover, reducing health care costs. The data does not appear to have been available from the original study for this relatively short time period to document these levels of potential benefits.

According to the authors, the future plans for this research project are:

- 1) Results will be incorporated into a paper that will be submitted to a peer-reviewed journal;
- 2) Results will be incorporated into a grant application designed to test a preference-based care intervention.

No information is provided as to whether the interventions have been continued in the original study facility.

Reviewer 3:

The project generated results that will be useful to persons throughout Pennsylvania and the nation who are responsible for developing activity programs or otherwise providing psychosocial care for persons with Alzheimer's disease and related dementia. Particularly novel and useful is the finding that any type of stimulation appears to raise agitation and occasionally will result in negative behaviors, but that the overall effect of appropriate stimulation is much more positive in terms of affect. (The ratio is nearly 10 to 1 in terms of frequency of observation.) Also, the study provides scientific evidence of the positive impact of individualizing activity choices – something that is inherently believed by many experts in the field but for which, until now, had little objective support due to the lack of research.

***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:

We are not given adequate detail to understand why the initial trial supported by the Alzheimer's Association was not completed and the data set went unused for 10+ years. Suffice it to say that this is a great investment for this funding mechanism, though the same cannot be said for the Alzheimer's Association investment. Regardless, some acknowledgment for the initial Alzheimer's Association investment should be made. The project team indicates it will pursue NIH funding.

Reviewer 2:

No leveraging of additional funds was expected or occurred. No grant application had yet been submitted at the time of this report, although the intent to do so has been stated as above.

Reviewer 3:

This project analyzed data from a study that cost many times the cost of the analysis.

***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 project team has expressed intent to publish this work. There was a passing statement that an upcoming article might make reference to the experience of the intervention from the CNA perspective, but this was not mentioned in the final report as a planned product.

Reviewer 2:

No evidence of products as listed above was provided. No publication manuscript had yet been submitted at the time of this report, although the intent to do so has been stated as above.

Reviewer 3:

A paper is planned, but at the time of the final report it had not yet been submitted for publication. However, the final report would constitute a good first draft of a manuscript for publication.

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

***STRENGTHS AND WEAKNESSES***

Reviewer 1:

The project team did not include any enhancement to the quality or capacity for research.

Reviewer 2:

None was described.

Reviewer 3:

The project supported established investigators at the institution, but this is appropriate considering the modest amount of funding provided.

***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:

The project team did not include any collaborative opportunities.

Reviewer 2:

None was described.

Reviewer 3:

There is no evidence that new collaborations resulted from this project; however, it did extend a collaboration that already existed between the grantee institution and another outside institution.

## ***Section B. Recommendations***

### **SPECIFIC WEAKNESSES AND RECOMMENDATIONS**

#### Reviewer 1:

None

#### Reviewer 2:

1. There are methodological issues which limit the generalizability of the study results. First, the consistency of staff assignments needed to reach the same target residents described in the original study methodology is not typical of the vast majority of nursing facility operations in the United States. A methodology which evaluates the feasibility of training multiple different nursing assistants to work with the same resident on implementing the positive interventions would be far more realistic. Second, this is an atypical study population which is quite homogeneous, and the interventions chosen cannot be generalized as being of benefit to other populations who are dramatically different, for example, a Veterans Administration long-term care facility. It would be much more widely applicable if these strategies could be demonstrated to have beneficial outcomes in a more commonly representative facility, such as a community long-term care facility. If the author carries out her stated intent to use the results of this study to support continued research, her study methodology should be modified to address these issues.
2. The issue of how many residents, in which treatment groups, were on what types of psychoactive medications at baseline, or had them added during the study, or became treated as a result of study observations is a major confounding factor. This could obviously have had a major impact on the potential causality of the behaviors observed in the study. It is of note that there was an unusually low incidence of aggression and high incidence of null behaviors for typical nursing facility residents, leading one to question again whether this population is actually representative of a “typical” nursing facility population or may be overmedicated. It is essential that the author include this data demographically at baseline, track it during the study period, and as much as possible control for psychoactive medication use and baseline psychiatric diagnoses during the randomization process.
3. There is no quantitative data available from the original study for this relatively short time period to document the economic impact of the study interventions. Since the training and utilization of one-to-one interventions represents a facility cost in personnel time, it is essential to demonstrate a concrete benefit in health care costs which justifies this investment. Potentially, a decrease in adverse behaviors and perceptions by residents and staff could improve job satisfaction and time management, and perhaps reduce staffing turnover, reducing health care costs. This type of data should be gathered during the next study.
4. It is likely, despite the efforts described in the final report regarding the original study, that the original study resulted in some contamination in study behaviors between the intervention and non-intervention groups over time, particularly since the study appears to have been successful in altering behaviors of residents and perceptions of staff as hypothesized. There

is no study methodology outlined to adjust for the probable unintentional crossover behaviors by the nursing assistants under study either in the original study or in the statistical methods used to analyze the data in this study. There were no restrictions described about imitating use of the study interventions for usual care residents, for additional episodes, or by theoretically untrained staff. The number of subjects studied would have been sufficient to reach primary conclusions but may not have been adequate to compensate for crossover. Consideration must be given when designing the next study to limiting the use of the study methodology outside of the study in the comparison population and to perhaps increasing the size of the study population to allow for statistical adjustment for effect size.

Reviewer 3:

This reviewer has a couple of comments for the authors to consider in developing an article for submission to a scientific journal. These represent areas that are unclear in the description of the study methods, the reporting of analytical results, or the discussion:

1. Under methods, the authors state that three covariates were employed “to control or remove shared influences from the observational variables.” More text is needed to explain why this is scientifically justified and how the variables were chosen. In particular, it is unclear a) how ADL capacity would have an impact on emotional responses independent of MMSE, and b) how and why withdrawal (which is quite similar to some of the outcome variables) was used as a control variable. Was it to control for baseline differences in responses? If so, that should have been unnecessary, since the study was randomized, unless (see #2 below) there were clear baseline differences between groups.
2. There should be a table (new table 1) that compares the characteristics of the treatment groups for variables such as age, sex, race, MMSE, years in the nursing home, comorbidities, and functional status. This is a notable omission.
3. Table 3 is not adequately labeled. It is not at all clear as presented that it is making pairwise comparisons between treatment groups. This made it confusing because the reviewer (as would be the case with many readers) looked at the table first before consulting the text. Better labeling would solve this issue. The “individualization” reported in the methods was indeed quite standardized. This was useful for the purposes of research; however, theoretically it could be argued that even more individualization and flexibility might be considered. On the other hand, more flexibility might not work as well with nursing assistants as the limited menu provided in the study. The authors are therefore encouraged to continue this important line of research.