

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: Unfavorable (2.67)

Project Rating:

Project	Title	Average Score
1085701	Plasma Protein Biomarkers of Chronic Obstructive Pulmonary Disease in African Americans	Unfavorable (2.67)

Project Number: 1085701
Project Title: Plasma Protein Biomarkers of
Chronic Obstructive Pulmonary Disease in African Americans
Investigator: Swinton, Derrick J.

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:

Strengths:

1. The research goal and specific aims are adequate.
2. The project has a collaboration with the Temple-Fox Chase Cancer Center to access Caucasian COPD plasma samples.
3. The PI (Dr. Swinton) has the capability to analyze serum and urine samples from African Americans smokers to ascertain quantitative information on nicotine and its major metabolites, cotinine, and 3-hydroxycotinine.

Weaknesses:

1. There is no information on whether there was sufficient data collected to perform analyses.
2. There are no detailed statistical data analysis methods.

Reviewer 2:

The investigator had originally listed four performance measures, including:

1. Presentation of data at scientific conferences;
2. Preparation and publication of a manuscript;
3. The number of African Americans participating in the COPD study; and,
4. Leveraging of project with additional funding.

There has been no success with numbers one, two, and four and partial success with number three.

It appears that as many as 64 subjects were estimated to be recruited, and to date there have been 10 subjects. It is not clear that ten subjects are sufficient to address the study aims.

There is no evidence that Aim 1 has been completed. There is no evidence that Aim 2 has been completed.

There are no study findings reported, so it is not clear whether or not the project met its objectives.

Reviewer 3:

The overall goal is to determine plasma protein biomarkers of COPD in African Americans, with the hypothesis that there were two listed specific aims:

- SA1. Testing of ten males patients from sample repository
- SA2. Validation of previously identified biomarkers in Caucasians and African Americans.

No data is presented to demonstrate that the project met its objectives or made any progress. There are major weaknesses in the description of the research plan and methods. There are significant clinical confounders that may make interpretation of the data difficult. How are they defining COPD? Do they have pulmonary function tests on subjects? How will they control for differences in smoking rates? This is a particularly relevant question, since differences in smoking may account for enhanced susceptibility and progression.

The aim states ten pre-existing samples will be studied but then states samples will be pooled. Given the heterogeneity of the population and limited number of samples to be analyzed, the investigators will lose a significant amount of information by pooling samples. It is unclear how comparisons will be made and how they will interpret data. Justification for iTRAQ (versus other proteomic methodologies) should be provided. Information on analysis of data, including pathway analysis and clustering methodologies, should be provided, including a strategy to deal with multiple comparisons and false discovery rates.

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:

Strengths:

1. The major goal of this project is to identify plasma protein biomarkers of COPD. Identifying biomarkers would provide the significance of this project for improvement in health outcomes. The identified biomarkers would predict risk of progression, allowing early intervention studies and treatment decisions to be individualized.
2. The PI is planning to continue the research and submit a research proposal to NIH.

Weaknesses:

1. The research work cannot be completed to achieve outcomes as expected for the project period.
2. There are no detailed statistical data analysis methods. The study was designed to compare by multidimensional quantitative iTRAQ multiplexed mass spectrometry the plasma proteomes of African COPD patients versus non-COPD smoker controls. Statistical data analysis procedures of study group versus controls are needed.

Reviewer 2:

There are no concrete findings that can be translated into improving health or other outcomes. There are no reported findings that can be used to judge the potential impact of the research.

Future plans include completing the proposed research and seeking additional funding.

Reviewer 3:

Understanding differences underlying development of COPD in African-American and Caucasian subjects is a clinically relevant question and has the potential to facilitate tailored treatment among the different ethnic groups. Given the lack of new data, there is no progression to improvement in any measure of health outcomes. If completed, the project would provide proof of principle of methodology for sample analysis and would require significant expansion to be able to achieve their overall objectives.

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:

Strengths:

1. An additional year of work for 2012 is being funded by a successive CURE program formula grant.
2. The PI is planning to apply for funds through partnership work with the Fox Chase Cancer Center and Lincoln University.

Reviewer 2:

There was no leveraging of additional funds. The investigators indicate a plan to submit a future application to NIH, but no application has been submitted to date.

Reviewer 3:

No additional funds were obtained or submitted. The PI states that he is planning to apply for additional funds in the future.

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:

Strength: A report based on preliminary data will be submitted for publication in the Journal of Biotechniques and will be presented at the Annual Biomedical Conference for Minority Students.

Weakness: There is no peer-reviewed publication.

Reviewer 2:

There are no publications. The investigator plans to submit findings to a journal and to a conference.

Reviewer 3:

No publications have been submitted, accepted or published. The PI states preliminary data has been obtained for future publication. However, given the absence of data presented, any publication is likely to be in the distant future.

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

STRENGTHS AND WEAKNESSES

Reviewer 1:

Strengths:

1. Six undergraduate students participated in the project.
2. The PI was partnering with Fox Chase Cancer Center, allowing the institution access to experienced researchers and resources not available at Lincoln University.
3. The PI and his collaborators plan to apply for funding to continue and expand the research project.

Weaknesses:

1. There is no post-doctoral student working on the project.
2. There is no statistician working on the project who can analyze the data collected.

Reviewer 2:

There were six undergraduate students who were involved in the research, and funds were allocated to pay them. It is unclear if there were infrastructure changes based on the award. The investigator indicates that the award allowed them to establish a partnership with Fox Chase Cancer Center, allowing access to otherwise unavailable researchers and other resources.

Reviewer 3:

Funds from the project were used to support in part the salaries of the PI and seven technicians. However, given the lack of progress, it is difficult to assess the value of the experience to trainees.

The project should be enhancing the interactions of Lincoln University with Fox Chase, but again, the lack of significant progress makes it difficult to determine the efficacy of the interactions.

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:

Strengths:

1. In addition to Fox Chase Cancer Center, the PI has established partnerships with local shelters/agencies/hospitals/clinics to collect specimens from willing participants.
2. The PI provided educational information to the candidates regarding smoking cessation and COPD.

Reviewer 2:

Strengths included developing a relationship with a research institution (Fox Chase Cancer Center) and partnerships with local sites for subject recruitment. The sites include shelters, agencies, hospitals and clinics. These new relationships should enhance the feasibility of conducting future research.

Reviewer 3:

The PI states new partnerships were established in the community to obtain additional specimens. However, the proposed project did not include any plans for recruitment of additional subjects (proposed analyzing banked samples), and there is no information provided on how many new subjects were enrolled, what sites were included, etc.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

1. Weakness: The PI did not have any peer-reviewed publication based on data collected in the research project.
Recommendation: The PI needs to submit several articles for publication to the Journal of Biotechniques or *COPD: The Journal of Chronic Obstructive Pulmonary Disease*.
2. Weakness: Although data analysis will be performed in collaboration with Fox Chase Cancer Center, no detailed statistical data analysis methods were described.
Recommendation: A health statistician could be hired or consulted as a research team member for statistical design and data analysis. Detailed statistical data analysis procedures would be described.

Reviewer 2:

1. Weakness: Incomplete recruitment based on initial goals.
Recommendation: Continue recruitment to meet stated goals.

2. Weakness: Lack of presentation of results and publication of results.
Recommendation: Complete the study, including analysis of data when available. Prepare results for presentation at a national meeting and for submission of a manuscript to a peer-reviewed journal.
3. Weakness: Lack of follow-on funding.
Recommendation: Complete the study and prepare an application for external funding.

Reviewer 3:

1. There is no evidence of any progress on the project. Preliminary data should be obtained and presented, along with any difficulties encountered in achieving the specific aims.
2. The description of the research plans and methods is unacceptable. The plan needs to be significantly revised and strengthened.