

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 (1.67)

Project Rating:

Project	Title	Average Score
0864801	Novel Biofuel Cell Based on High Surface Area Enzymatic Microelectrodes	Favorable (1.67)

Project Number: 0864801
Project Title: Novel Biofuel Cell Based on High Surface Area Enzymatic Microelectrodes
Investigator: Marx, Sharon

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 goal of this project was to fabricate a mediator-less biofuel cell based on the use of high surface area micro-gold electrodes that can result in high power output.

Most of the goals were demonstrated, although the efficiency is lower than expected. The research design is adequate. An adequate amount of data was provided.

Reviewer 2:

The ultimate goal of this project was to develop a biofuel cell that employs the glucose as a fuel and could be implanted for utilization by pumps or sensors for active health condition monitoring or delivery of drugs.

Strength: The PI was able to fabricate microfiber electrodes, immobilize redox enzyme on the electrodes and characterize the cell's function.

Weakness: Some of the cross linkers utilized for the immobilization are toxic and may hinder the ultimate goal.

Reviewer 3:

This project met each of the stated objectives. The only weakness, as identified by the PI, was that they did not meet the desired maximum output of 100 microWatts/square cm (rather they achieved 20 microWatts/square cm). Although they did not meet their goal, they have a clear path to achieve this with the results obtained from this study. Specifically, they will increase the amount of enzyme on the electrode, use a gold-carbon composite material, and increase the available surface area of the fibers by using hollow fibers. It appears that they will achieve their desired output with these approaches.

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:

There is no benefit in improving health and no new drugs will be discovered. This is bioenergy research, but it may play a role in medical diagnostics.

Reviewer 2:

The biofuel cell, if fully demonstrated, has great potential for all therapies that require implantable devices for continuous monitoring or drug delivery.

Reviewer 3:

The impact of this project could be large; however, it is currently unknown. What is missing from this proposal and project report is the biological assessment of the novel biofuel cell. It is highly recommended to the PI to quickly begin biological assessments since the intention aims to use these biofuel cells for insulin delivery or pacemakers (as stated in the proposal), the degree of cell interactions will be influential towards its output. That is, if the materials used to create the biofuel cell will generate scar tissue, this will limit its function and, thus, limit the significance of this project. The health-related use of this biofuel cell was not the focus of this project. Considering the low cost of this project, significant data were generated.

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:

They tried once for an NSF grant, but it was not funded. No other plans for outside funding were included.

Reviewer 2:

There is no evidence to suggest leveraging of additional funding; however, the amount of data generated during the year is sufficient to apply for federal funding.

Reviewer 3:

This project did not use any other funding. One proposal was submitted but was not funded. The PI is encouraged to submit more proposals for this idea.

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:

No publication or patent was included.

Reviewer 2:

There is no evidence that suggests any publications.

Reviewer 3:

No papers or presentations are listed. The PI is encouraged to present and publish the results from this study.

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

STRENGTHS AND WEAKNESSES

Reviewer 1:

One post-doctoral student was partially supported.

Reviewer 2:

The project requested a small amount (\$15K); therefore, it is hard to assume an increase in capacity besides the potential of the data generated.

Reviewer 3:

It is stated that this project introduced electrochemical techniques and CV to the institute, bringing in an external PI.

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:

No collaboration was reported.

Reviewer 2:

No new collaboration was sited.

Reviewer 3:

There is no mention of collaborations for the research.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

1. The team has successfully fabricated gold microelectrodes through electrospinning; however, no comparison was made with other nano gold electrodes to highlight the benefits in electrical properties (if any). It is also unclear how this microelectrode structure is more beneficial for enzyme immobilization when compared to a bundle of nano scale electrodes.

2. Enzyme immobilization was successfully demonstrated using well-known cross-link chemistry such as glutaraldehyde. Although the immobilized enzymes were shown to be active, no assessment was made to investigate the level of deactivation due to the cross linking. Clearly, the K_m values of the enzymes are significantly affected. In addition, no information was provided to test the effect of enzyme loading on biofuel performance. An indirect experiment on the effect of fiber weight was reported.
3. They have successfully demonstrated the generation of electricity using the proposed biofuel format. Again, some comparison here with other setups will be very helpful. The current power density of $20 \mu\text{W}/\text{cm}^2$ is lower than the desired goal ($100\mu\text{W}/\text{cm}^2$). They propose to address this by increasing the enzyme density. How much can they increase without seeing any diffusional limitation? Some quantitative assessment must be provided.

Reviewer 2:

1. The power generated did not meet the desired level.

Recommendation: This project is worthy of additional investment. Extension with a larger budget will yield better return.

2. Some of the immobilization agents or their component are considered toxic.

Recommendation: Evaluate the toxicity of all components in the system should the system be considered for in vivo application.

Reviewer 3:

1. The PI is encouraged to submit proposals centered on the biological response of the novel biofuel cell since a detrimental biological response could severely inhibit its function leading to redesigning.
2. The PI is encouraged to present and publish the results of this study.

Generic Recommendations for Pittsburgh Tissue Engineering Initiative

Reviewer 1:

It is unclear if this project is within the scope of the program.

ADDITIONAL COMMENTS

Reviewer 2:

Great potential was shown through the first year's progress. The PI is capable of carrying the full development for an implantable biofuel cell forward.