

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
0990601	Novel Biofuel Cell Based on High Surface Area Enzymatic Microelectrodes	Unfavorable (2.67)

Project Number: 0990601
Project Title: Novel Biofuel Cell Based on High Surface Area Enzymatic Microelectrodes
Investigator: Koepsel, Richard

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 project had ambitious objectives that were partially met. The amount of work proposed was clearly beyond what could be supported by the small amount of funds (\$12,224 provided), and the project only makes sense as part of a larger funded project.

The first specific aim was to make a working fuel cell with increased theoretical power density using fructose dehydrogenase. From the reports, it does not appear that a working fuel cell was made.

The second specific aim was to increase enzyme concentration on electrodes using high surface area microfiber gold electrodes. Gold electrodes were formed with enzymes attached and characterized.

Performance was stated to include publication of papers and patents, but no papers were submitted or published and no patents were filed.

There are published results for enzymatic fuel cells similar to those proposed in this project that did function and produce power. The results of this project did not go beyond or even reach the performance of the previously published work. The major results of the project seem to be associated with the formation and characterization of gold fiber electrodes that could in the future possibly have utility in fuel cells, but no publications or patents resulted from this work.

I do not think that one should expect major results from a \$12K one-year project. There was apparently credible work done on electrode/enzyme techniques, but this group has a long way to go to catch up to other ongoing efforts in biofuel cell research. It will take a significant amount of work to get this to the stage where it would be practical power for implanted medical devices.

Reviewer 2:

This project started with preliminary data on fructose dehydrogenase bioanodes and proposed in the first six months to develop a laccase biocathode and characterize it for oxygen reduction followed by a study of the biofuel cell fabricated from combining the bioanode and biocathode. The team continued their bioanode work and examined additional methods for making high

surface area electrodes and expanded from fructose fuel to glucose fuel. But they did not make a biocathode or test a full biofuel cell; so, they did not make reasonable progress toward their stated objectives. The bioanodes and materials development are interesting from a biosensor perspective, but it is unclear what their impact would be on biofuel cells, because they were never tested in a biofuel cell.

Reviewer 3:

The project did not meet the specific aim, “To fabricate a biofuel cell that will use fructose as the fuel source and will have high power output.”

The biocatalysed oxidation of fructose was demonstrated and the microelectrode, which was planned to be used as the anode, behaved as a fructose sensor. That is the only pertinent part in relation to a biofuel cell. No work was done on the cathode; therefore, the fuel cell has not been constructed.

The problem might be related to the design of the work. They assume that the formal potential of the enzyme fructose dehydrogenase is about -0.35 V, but their results showed a 0.2 V potential for the oxidation of fructose. This is too high for an anode. It is difficult to find a cathode providing a potential higher than this value so that the two electrodes can work together as a fuel cell.

Also, the project failed to demonstrate the mediatorless operation.

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 results of this work are limited to the formation and testing of gold fiber electrodes and their coating with enzymes. It is not clear if this was done with the small amount of project funding provided or with the other Armed Forces Institute funding of the work. Overall, there were some results from this work, but they were less than promised in the strategic plan.

The new Ph.D. recruits to the institution were listed, and expertise in biofuel cell techniques was noted.

The likely beneficial impact is modest, but consistent with the small amount of funding.

Reviewer 2:

The overall, long-term significance of this project is to develop biodegradable and biocompatible implantable batteries that are recharged by *in vivo* fuels. This would be high impact and would allow for the user not to have to recharge batteries that were implanted in patients. However, implantable batteries require stability, and the authors did not study stability. More importantly, they require the immobilization and stabilization of the mediator, which was

not addressed in this work or the discussion of future plans.

Reviewer 3:

The principal investigator talked about implantable power sources using fructose as the fuel source. Would they be implantable in plants? And, which plants need a fuel cell inserted in them? The principal investigator should explain.

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:

An NSF grant for leveraged funding was submitted early in the grant period. The Final Report indicates that it was funded.

Reviewer 2:

The project did leverage additional funds from Armed Forces Institute for Regenerative Medicine matching funds and an NSF grant. These funds allowed for more research to be completed for the low cost (\$12K) of this project. The NSF funding also will allow the researchers to continue the project after the grant period.

Reviewer 3:

No strengths or weaknesses noted.

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:

There were no patents filed. There were no publications published or submitted.

Reviewer 2:

The project stated that the researchers would be publishing and presenting the work, but no publications or listed presentations materialized. This was likely due to the researchers being unable to complete the proposed work. No intellectual property was derived from this project.

Reviewer 3:

No patents or publications resulted from this work.

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

STRENGTHS AND WEAKNESSES

Reviewer 1:

The new Ph.D. recruits to the institution were listed, and expertise in biofuel cell techniques was noted. The capacity and skills added by the two recruits were not noted.

Reviewer 2:

The researchers gained considerable experience in bioelectrochemistry and expanded their bioanode work. This was successful enough for them to get follow-on funding from the National Science Foundation. This provided for the training of an undergraduate student and a post-doctoral researcher, as well as bringing new talent to the institution by recruiting Dr. Marx and Dr. Jose.

Reviewer 3:

No, the project did not enhance research capacity at the 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:

There was no external collaboration or business involvement.

Reviewer 2:

The researchers are planning to expand this project from fundamental science to the development of implantable self-powered medical devices. The plan to transition from a bioanode to a self-powered medical device is unclear, but they do wish to do this and have received funding from NSF to continue this project. It is unclear if this will lead to research partners outside of the institution, and it is unlikely to result in new involvement in the community.

Reviewer 3:

No new collaborations resulted from the project.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

No publications, patents or significant collaborations resulted from the work. Goals were only partially met.

This grant was too small to expect much. It should have been reviewed in the beginning not just at the end of the work. The results were small, but so was the funding.

A functioning and improved fuel cell was not made.

There were no publications or patents. This would be the most significant indicator of progress.

The impact of Ph.D. recruits was not indicated. This should have been noted.

There were no collaborations.

Reviewer 2:

The project proposed to take their preliminary/previous work on fructose bioanodes and develop a laccase biocathode in the first six months; and in the second six months, they proposed to marry the bioanode with biocathode and test a full functioning biofuel cell. They did continue their bioanode work, but they did not develop a biocathode or test a full functioning biofuel cell. Also, their bioanode was tested as a sensor but was not evaluated as a fuel cell electrode. In addition, this project is not particularly novel; the enzymes used are commercially available and common in the field. The team utilized a gold electrode that was interesting, but the data did not show any particular advancement in the field.

The team should develop a biocathode and test both electrodes via polarization in half cell mode before testing a complete biofuel cell. Biofuel cell testing should be done galvanostatically instead of with external resistors and a multimeter.

Mediators are a clear issue for implantable power sources. The team should address how they will eliminate mediators or protect from leaching mediators from the biofuel cell.

The team should build both intellectual property and peer-reviewed publications in the field.

Bioanode and biocathode stability should be addressed if they are considering implantable applications.

Reviewer 3:

The general design of the research is flawed. A basic understanding of the principles of fuel cells is needed. More convincing preliminary results are needed. The potential applications and impacts of the work need to be studied carefully.

Generic Recommendations

Reviewer 2:

My recommendation is not to continue this project. They did not meet their two main goals for 2010, so they are not making sufficient progress or addressing the issues for making progress in this project. The project is also low on novelty, and there are several issues above that need to be addressed.