

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
0864901	The Association of Drug Use and Sexual Risk for HIV Infection Among Black Men Who Have Sex with Men	Favorable (1.67)

Project Number: 0864901
Project Title: The Association of Drug Use and Sexual Risk for HIV Infection Among
Black Men Who Have Sex with Men
Investigator: Bond, Lisa

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 overall objective of the project was to delineate the relations between substance use and sexual risk-taking behaviors among black men who have sex with men (MSM) as a means of determining why rates of HIV are elevated in this segment of the population. This secondary data analysis drew data in 2005-2006 from the project *Brothers y Hermanos*. The objectives of the program were realized to some extent, but not fully. Rather than fully examining the relations of multiple substances and of HIV status on sexual risk-taking behaviors, the analyses focused primarily on the illicit substance, crack cocaine, as an antecedent of risk. The principal investigator (PI) argues that this decision was made to modify the second and third study aims to her review of the literature; however, the HIV drug-use literature would not necessarily support that direction. The analyses failed to capture the complexity of poly-drug use in fully explaining patterns of risk and differentiating such patterns along demographic factors including but not limited to HIV serostatus. Moreover, even in its original conception, the study objectives lacked sophistication and a nuanced investigation.

Reviewer 2:

The project did meet all its objectives in the time line proposed, and results were clearly described in the Progress Reports. It is hoped that a publication will be completed, as anticipated.

The analyses were, in general, appropriate for the data. I have some concerns that the use of a mediator variable (what might also be called a confounder) is not appropriate for the objective at hand. It seems that in the context of examining drug use as a risk factor for risky sexual behavior, the trading of sex for money is not a confounder but in fact an alternate outcome. That is, unprotected sex and sex for money are not just correlated but they describe different contexts of the same behavior: sex. Therefore, it would seem that inclusion of a related outcome as a predictor muddles the analysis substantially. The researcher will of course have the opportunity to have this manuscript peer reviewed upon submission, thus will receive other input on this issue.

Reviewer 3:

Major strengths:

1. The project has not quite achieved its stated objectives, but it has made excellent progress towards them. Relatively little time and funding was budgeted for the project, and the progress to date is eminently satisfactory.
2. The data were developed sufficiently and appropriately.
3. Aim 1 was fully addressed.
4. The progress demonstrated in the Final Report is quite satisfactory.

Strengths:

1. Aim 3 was fully addressed, though not for subgroups of black MSM in following the omission of Aim 2.
2. Time and funding were somewhat under budgeted to allow fully addressing all three aims, thus omitting Aim 2 is reasonable.
3. The progress demonstrated in the Final Progress Report is satisfactory.

Weakness:

Aim 2 was not addressed, comparing subgroups (HIV+ and HIV-; gay-identified or not) of black MSM; however, this would have required additional time and funds.

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:

It is unclear whether the analyses that were undertaken and the findings that were generated will help to advance our knowledge of the link that exists between drug use and sexual risk taking in black MSM. Such analyses, which are based on correlational analyses and cross-sectional data, are not new to the field of HIV prevention, and the findings of the current analyses add limited innovation to the field. The behavioral research regarding sexual risk taking among MSM has moved beyond the understanding this secondary data analysis has to offer.

Reviewer 2:

Strengths include the stated paucity of research in this specific area of research: the association between crack cocaine use and sexual risk behaviors in black MSM. An additional strength is the focus in a population clearly at extremely high risk of HIV acquisition and engaging in risky behaviors including high drug use. A third strength is the researcher's position as a PI on a recently completed large study, having access to already accrued data and having experience analyzing such data.

The researcher, however, does not well defend the need for drug-specific studies, or list plausible reasons why the associations between drug use and sexual behavior might be different between different types of illicit drugs. Perhaps it would be better to focus on the paucity of research in this vulnerable population than on the need for researching crack use and its influence on sexual behavior.

Reviewer 3:

Major Strengths:

1. This project provides a greater understanding of the prevalence of and association between sexual behaviors and drug behaviors (primarily crack cocaine usage) in this lower income black MSM population.
2. The PI solidly justifies looking primarily at crack cocaine usage. The findings surrounding crack cocaine are interesting and may be important.
3. A modest funding level was used to leverage an interesting and useful further analysis of this interesting and important data set. This should happen more often. The investigator is to be commended.

Weaknesses:

1. To fully understand whether these interrelationships affect the HIV incidence rate, it is necessary to compare to populations that have lower (or higher if such existed) HIV incidence rates. Thus, to fully understand whether crack cocaine usage may be a significant driver of risk behaviors (or HIV incidence), we need to compare the black population to Hispanics (which were available in the originating data set). Suppose (purely hypothetically) that sexual risk behaviors had the same level in the Hispanic population as in the black population. What would our conclusion be? In contrast (still hypothetically), suppose that the Hispanic MSM population had the same level of drug usage but with a lower HIV incidence rate. Again, what would our conclusion be?
2. As part of the goals, it would be helpful to analyze who has HIV and who does not, though this would be an analysis of prevalence and not of incidence, which would take additional time and funds.
3. In Table 2 of the Final Progress Report of demographics (rows) by crack cocaine use (columns), I am interested in "row percents" (not "column percents" as given) and in the percentage of cocaine users for a given level of the demographic variable. In contrast, for sexual behaviors (also in rows), I am interested in "column percents" (as indeed were supplied in the tables) exhibiting the behavior for given crack cocaine use.

Possible Weakness:

A careful understanding of the data set is needed. Respondent-driven sampling (RDS) does not supply a usual cross-sectional data set; subjects are correlated with each other because of the recruiter-recruitee relationship. RDS also seems to produce unusually poor and un- or under-employed participants, and it over samples gregarious participants who are acquainted with many other (potential) participants.

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 other funds have been leveraged or plan to be leveraged.

Reviewer 2:

Additional funds were neither sought nor needed to complete this research.

Reviewer 3:

The project did not leverage additional funds, which is fine and not a problem.

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:

One peer-reviewed publication had been planned for submission to the journal *AIDS and Behavior* in fall 2010. Given the lack of sophistication of the analyses, this manuscript is likely to be rejected in this journal, which has a very high impact factor. It is also unclear if this manuscript was ever submitted.

Reviewer 2:

The researcher claims to have a manuscript in preparation and has shown many of the results she plans to submit in this manuscript. It is clear that work has been done, and the work completed matches the work proposed in the application.

Reviewer 3:

A paper is intended for submission shortly to a peer-reviewed journal. It appears to be an interesting paper that will be of interest to the field.

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

STRENGTHS AND WEAKNESSES

Reviewer 1:

The project did not provide support to improve infrastructure or to enhance training of young scholars. As a result, the overall impact on the grantee's institution is quite limited.

Reviewer 2:

No infrastructure or training was proposed in this application and none was performed.

Reviewer 3:

Major strength: The modest funding was used to leverage more information from an already existing data set. This is quite valuable and should happen more often.

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 evolved as a result of the project.

Reviewer 2:

No collaborations were proposed or formed in carrying out this research.

Reviewer 3:

The project did not lead to collaboration, and this is fine.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

1. Theoretical Framing: The relations between drug use and sexual risk taking must be examined with a more holistic theoretical frame.
2. Methodological: More sophisticated statistical analyses need to be undertaken to explore relations between various drugs used and how these combinations manifest across various person factors and relate to sexual risk taking.
3. Innovation: The overall work is not particularly innovative, nor does it advance our knowledge. More nuanced investigations, framed in a more conceptual manner (e.g., syndemics theory) could help advance knowledge in the field.

Reviewer 2:

1. It is unclear whether this research, while clearly novel, is needed given the number of papers found in the literature on associations between other drugs and sexual risk behavior; however, this may be obvious to someone more familiar with the field. Perhaps all that is needed is better defense of the objectives in order for this project to receive an outstanding rating.

Reviewer 3:

1. The investigator should ask for more funding and time for this excellent proposal and should continue with the analysis of Aim 2. This would be of value and build on this valuable initial effort. The investigator is to be commended for the work to date.

2. To better understand the situation within the black sample, the investigator should compare to the Hispanic cohort as well. This would also require more funding and time.

ADDITIONAL COMMENTS

Reviewer 1:

The project that was undertaken was not high-scholar quality. Work on this level is undertaken by master's level graduate students.

Reviewer 3:

More secondary analyses such as this should be encouraged. These are quite valuable, and many data sets are collected and then lie fallow without having their full complement of information ever fully exposed.

Encourage investigators in secondary analyses such as these to have access to a senior Ph.D. level biostatistician (not an epidemiologist, and not a master's degree only) preferably with experience in the analysis of sex and drug behaviors.

If it is possible, it would be beneficial to have extra funding set aside to help researchers finish worthy research projects such as this one. Of course, that may also encourage people to under budget and rely on additional funding.