

Reporting and Performance Review Processes for the Commonwealth Universal Research Enhancement (CURE) Program Grants

Overview

Chapter 9 of the Tobacco Settlement Act, Act 2001-77, authorized the Department of Health to establish a health research program called the Commonwealth Universal Research Enhancement (CURE) Program.

An applicant that receives a health research grant under the Tobacco Settlement Act must comply with annual and final progress reporting requirements and is subject to an evaluation via a performance review by the Department upon completion of the research grant, or more often if deemed necessary by the Department.

Annual Progress Reports are posted to the CURE Program's Web site in November as part of the Annual Report to the Legislature.

For grants ending after July 1, 2007, Final Progress Reports, Performance Review Reports and grantee responses to Performance Review Reports will be posted on the CURE Web site approximately 12-16 months after the end of the grant.

The performance review generally occurs at the end of the grant period, but additional performance reviews may occur prior to a project's end if deemed necessary. The performance review is conducted by experts in the area of research addressed by the research project and results in a rated assessment.

Grantees that receive an unfavorable Final Performance Review rating have a reconsideration process available to them. Unfavorable ratings for a grant may result in a reduction in or loss of CURE funding.

Annual and Final Progress Reports

The Annual Progress Report contains a brief status report on research activities conducted during the fiscal year. An Annual Progress Report for each state fiscal year ending June 30 must be submitted to the Department of Health within 30 days after the end of the state fiscal year or 60 days after the end of the grant in the year that the grant ends.

The Final Progress Report, which has no page limitations, is a detailed summary of research accomplishments for the entire grant award period and contains measures of performance as required by Act 2001-77. The Final Progress Report should provide a detailed description of methods and findings and include evidence of the data that was generated and analyzed, providing appropriate tables, graphs, and figures of the data. The Final Progress Report is due 60 days after the ending date of the grant award.

There are separate forms and instructions to be used for completing the Annual Progress Reports and for completing the Final Progress Reports.

The grantees' Annual Progress Reports are incorporated in the Department's Annual Report to the Legislature. This report is made available to the public when it is posted on the Department's CURE Web site in November, approximately five months after the end of the state fiscal year.

Final Progress Reports will be made available to the public when they are posted on the Department's CURE Web site approximately 12-16 months after the completion of the grant. This time lapse assures grantees adequate time to publish research results prior to public availability of project findings. Final Progress Reports are reviewed for completeness, but are NOT edited for spelling and grammar by Department of Health staff.

Publications

All publications that result from health research grants funded by the Department of Health must acknowledge that the project was funded, in part, under a grant from the Pennsylvania Department of Health. Grantees are required to provide the Department with a copy of each publication with the Final Progress Report.

Only publications that acknowledge the Pennsylvania Department of Health as a funding source are accepted by the Department for consideration during the performance review process.

Performance Review Process and Criteria

The performance review is based on requirements specified by Act 2001-77 and criteria developed by the Department in consultation with the Health Research Advisory Committee.

As part of the performance review process, each research project funded as part of a grant is reviewed by at least three experts who are physicians, scientists or researchers. Reviewers are from the same or a similar discipline as the research grant/project under review and are not from Pennsylvania. Reviewers use the applicant's proposed research plan (strategic plan), Annual Progress Reports, Final Progress Report, and publications that resulted from the project to conduct the review.

Upon completion of the performance review process, the Department will provide each grantee with a copy of the Performance Review Report containing the outcome of the review (outstanding, favorable, or unfavorable) for each project and for the grant as a whole, strengths and weaknesses of each research project, and recommendations for future improvement. Grantees will then be required to respond, in writing, to the reviewers' comments.

The Performance Review Report, as well as the grantee's written response to the Performance Review Report and the Final Progress Report will be posted on the CURE Web site approximately 12-16 months after the end of the grant.

For formula grants, the following criteria are applied to each and every project contained in the grant, using information submitted by research grant recipients. Note that the criteria for formula and nonformula grants are slightly different. Formula grants are not selected by a peer review process, whereas nonformula grants are subject to peer review prior to selection for funding by the Department. Therefore, for nonformula grants the performance reviewers are not asked to consider questions that were considered during peer review, e.g., questions concerning the significance of the project for improving health and adequacy of research design.

Formula Grant Evaluation Criteria:

- 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?

- 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 that are attributable to the completed research project.
 - What are the future plans for this research project?

- Did the project leverage additional funds or were additional grant applications submitted as a result of the project?
 - If leveraging of funds was expected, did these funds materialize?
 - Are the researchers planning to apply for additional funding in the future to continue or expand the research?

- 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.
- 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?
- Did the project lead to collaboration with research partners outside of 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.

Nonformula Grant Evaluation Criteria:

- How well did the grant meet its stated objectives? If objectives were not completely met, was reasonable progress made?
 - Did the grant meet the stated objectives?
 - Consider these questions about the 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, was it reasonable?
 - Consider (only for clinical research grants) 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 plan?
- What is the likely beneficial impact of this grant? If the likely beneficial impact is small, is it judged reasonable in light of the dollars budgeted?
 - 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 that are attributable to the completed research grant.
 - What are the future plans for this research grant?
- Did the grant leverage additional funds or were additional grant applications submitted?
 - If leveraging of funds was expected, did these funds materialize?
 - Are the researchers planning to apply for additional funding in the future to continue or expand the research?

- Did the grant 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 and what was proposed in the original application.
- Did the grant enhance the quality and capacity for research at the grantee's institution?
 - If any improvements in infrastructure were expected, were they made?
 - 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?
- Did the grant lead to collaboration with research partners outside of 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.

Assignment of Performance Review Ratings to Research Projects and Grants:

Each research project within each grant is reviewed and assigned an overall rating by a minimum of three reviewers. These reviewers are experts in the technical fields of the grant projects; they also have been screened for conflicts of interest. Reviewers are instructed not to compare research projects to each other, but to base all comments against the documented evaluation criteria.

The final overall rating for a research project is the average rating obtained from all of the reviewers of each project. If a grant consists of only one research project, the overall grant rating will be the average overall rating for the research project. If the grant consists of more than one research project, the overall grant rating is an average rating for all projects funded by the grant.

The performance review ratings are as follows:

1.00 – 1.33 = *Outstanding*

1.34 – 2.66 = *Favorable*

2.67 – 3.00 = *Unfavorable*

The rating is made according to the following guidelines:

- *Outstanding* indicates that: (1) major strengths were identified throughout the project with few, if any, weaknesses; (2) the project met all or most of its stated objectives; and (3) the project is likely to have some beneficial impact.
- *Favorable* indicates that: (1) strengths were identified within the project with one or more weaknesses; (2) the project met some of its stated objectives and/or made acceptable progress to do so; and/or (3) the project may or may not have a beneficial impact.

- *Unfavorable* indicates that: (1) major weaknesses were identified that are pervasive throughout the project; (2) the project did not meet any of its objectives or did not make any acceptable progress to meet the objectives; (3) the project is not likely to have any beneficial impact; (4) insufficient data and information were provided to support the fact that the project met any of its objectives or made acceptable progress; or (5) the information and data provided were not applicable to the project objectives listed in the strategic plan.

The overall rating reflects the adequacy of the research activities performed during the funding period, taking into consideration all of the significant attributes identified in the review, including the following categories:

- Major strength - an attribute of the project or grant that clearly distinguishes it well above the standards set by the program objectives and that provides compelling justification for continued funding.
- Strength - a noteworthy attribute of the project or grant compared to the objectives.
- Weakness - a noteworthy deficiency or flaw compared to program objectives.
- Major weakness - a very serious, if not fatal, flaw or deficiency compared to the objectives or common research practices.

Funding Impacts of Unfavorable Performance Reviews

Any grantee that receives an overall final performance review rating of “unfavorable” (rating of 2.67-3.00) will receive a warning that outlines the impacts of subsequent “unfavorable” performance review ratings. Specifically, grantees receiving two or more consecutive overall (grant-level) ratings of “unfavorable” will be subject to funding impacts. The recommended funding impacts will increase through consecutive years of “unfavorable” overall ratings, as shown in the table below. In referring to this table please note the following:

1. The term “grantee” refers to the lead institution listed in the grant. The funding impacts apply to the entire lead institution, and not just to the principal investigator of a research project.
2. The term “consecutive” applies to the end date for the grant, not the grant start date or the date when the grantee is notified of the outcome of the performance review.
3. For formula grants, both the grant coordinator and administrative officer named on the grant application will be notified. For the nonformula grants, both the principal investigator and administrative officer named in the grant application will be notified.
4. The considerations for future funding impacts apply regardless of whether the “unfavorable” performance review ratings were received for formula grants, non-formula grants or both.
5. All considerations for future funding impacts apply only to the lead institution listed in the grant. Collaborating or partnering institutions are not impacted.
6. The funding impacts would be effective during the next scheduled funding cycle.

Upon Receipt of “Unfavorable” Overall Grant Ratings (2.67-3.00)	Future Funding Impacts
First Unfavorable Grant Rating	A written warning outlining the future funding impacts of subsequent “unfavorable” ratings will be sent to the grantee. Further, Department of Health staff will directly contact the grantee to explain and discuss the implications of subsequent “unfavorable” ratings.
Second Consecutive Unfavorable Grant Rating	<ol style="list-style-type: none"> 1. In the next grant cycle, the grantee will receive a 25% reduction in the amount of formula grant funds that the grantee would have received if there were no reduction. 2. The grantee will not be eligible to receive any non-formula funds (as an applicant or as a collaborator or partner, etc.) in the next grant cycle.
Third Consecutive Unfavorable Grant Rating	<ol style="list-style-type: none"> 1. In the next grant cycle, the grantee will receive a 50% reduction in the amount of formula grant funds that the grantee would have received if there were no reduction. 2. The grantee will not be eligible to receive any non-formula funds (as an applicant or as a collaborator or partner, etc.) in the next grant cycle.
Fourth Consecutive Unfavorable Grant Rating	<ol style="list-style-type: none"> 1. In the next grant cycle, the grantee will receive a 100% reduction in the amount of formula grant funds that the grantee would have received if there were no reduction. In short, the grantee will not be eligible for any formula funding in the next grant cycle. 2. The grantee will not be eligible to receive any non-formula funds (as an applicant or as a collaborator or partner, etc.) in the next grant cycle.

Examples of funding impacts applied when grantees receive unfavorable performance reviews:

Example 1: FUNDING IMPACTS				
Grant end date	Type of grant	Date performance review report sent to grantee	Outcome of performance review	Would funding impacts apply?
1/31/2006	2001 formula	3/1/2006	unfavorable	Yes – 25% reduction in formula funds and ineligible for nonformula funds in next grant cycle.
6/23/2006	2001 nonformula	4/30/2007	unfavorable	
12/31/2006	2002 formula	3/15/2007	favorable	

Example 2: NO FUNDING IMPACTS				
Grant end date	Type of grant	Date performance review report sent to grantee	Outcome of performance review	Would funding impacts apply?
12/31/2007	2004 formula	9/1/2008	unfavorable	No
4/30/2008	2003 formula	6/30/2009	favorable	
6/30/2008	2005 formula	4/30/2009	unfavorable	

Reconsideration Process for Performance Reviews

A reconsideration process is available for grantees that receive an overall final performance rating of “unfavorable.” After examining the report of the “unfavorable” final performance review, a principal investigator may wish to contest the overall rating. If the grantee and then the Department of Health determine that the rating given during the final performance review needs to be reconsidered, the reconsideration process will consist of a second performance review using the same documentation that was submitted for the original performance review.

Scope

The reconsideration process is only available for grants that receive an overall “unfavorable” rating in the Final Performance Review Report. Differences of scientific opinion or limitations of the documentation already provided by the grantee in the Annual and Final Progress Reports (factual errors, excluded data, unclear narrative text, etc.) are not permitted to be used as the basis for the reconsideration request.

Procedures for Reconsideration

Step 1 - Grantee requests to discuss review outcomes with the Department of Health (DOH) Program Manager.

Before submitting a request for reconsideration, the principal investigator should speak with the DOH Program Manager responsible for the evaluation. The Program Manager can explain the options and their consequences, and is often in a position to help the principal investigator understand the evaluation.

The Program Manager must receive the request to discuss the performance review outcomes within 30 calendar days of the date that the grantee received the Final Performance Review Report. The request may be submitted by email (to ra-healthresearch@pa.gov) or in writing to the address listed below:

Program Manager
Health Research Office
Room 833, Health & Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701

Step 2 - Grantee submits written request for reconsideration.

For those cases that cannot be resolved by discussion, the next step is to submit a written letter of request for reconsideration. The principal investigator and his/her institution, represented by the institutional official authorized to sign grant applications, must jointly sign the request for reconsideration and send it to the DOH Program Manager. The official representative's signature indicates that the investigator's institution endorses both form and substance of the request for reconsideration. The letter must explain fully the reasons for the reconsideration request and must include any supporting documentation.

The Program Manager must receive the letter requesting reconsideration within 60 calendar days of the date that the grantee received the Final Performance Review Report. The request must be submitted in writing to the address listed above.

Step 3 - DOH acknowledges receipt of request for reconsideration.

The principal investigator will receive an acknowledgment letter/e-mail within 15 calendar days of receipt of his or her letter. The request for reconsideration will be submitted to the DOH Reconsideration Group consisting of the Program Manager, his/her supervisor or manager, and others as appropriate for deliberation. The DOH Reconsideration Group may seek advice or assistance as needed.

The timeline for the DOH Reconsideration Group to meet will depend on factors such as the complexity of the basis for the reconsideration request and the availability of the required individuals.

Step 4 - DOH Reconsideration Group determines merit of reconsideration request.

If the DOH Reconsideration Group determines that the reconsideration request should be granted, the investigator will be notified in writing, within 15 calendar days after the decision is made, that the documentation will be reconsidered during the next round of scheduled performance reviews.

If the DOH Reconsideration Group does not agree with the request for reconsideration, the principal investigator will be notified in writing within 15 calendar days after the DOH Reconsideration Group's decision.

Step 5 - Reconsideration.

If the Department determines that the rating given during the final performance review of a grant needs to be reconsidered, the reconsideration process will consist of a performance review using the same documentation that was submitted for the original performance review (i.e., the research plans, Annual Progress Reports and Final Progress Reports without any addition, revision, or modification). The reconsideration would typically occur during the next round of scheduled performance reviews.

Upon the completion of the reconsideration process, the Department will provide the grantee with a summary report, including the reconsidered performance rating. This report and rating may not be further appealed.

The reconsidered rating replaces the original rating, and funding impacts apply as though the reconsidered rating were the only rating assigned to the grant.

Final Authority

The DOH Reconsideration Group's recommendation is final and may not be appealed.

Overview of Timeline for Reconsideration

- The grantee must request to discuss review outcomes with the DOH Program Manager no later than 30 calendar days after receiving the Final Performance Review Report.
- The grantee must submit a written letter of request for reconsideration no later than 60 calendar days after receiving the Final Performance Review Report.
- DOH will acknowledge the written request for reconsideration within 15 calendar days of DOH receiving the signed letter.
- Notification of the DOH Reconsideration Group's decision will be made within 15 calendar days of the decision.

The timeline for the DOH Reconsideration Group to meet will depend on factors such as the complexity of the basis for the reconsideration request and the availability of the required individuals.