

Response Form for the Final Performance Review Report— Treatment Research Institute 2008F*

1. Name of Grantee: Treatment Research Institute
2. Year of Grant: 2008 Formula Grant

A. For the overall grant, briefly describe your grant oversight process. How will you ensure that future health research grants and projects are completed and required reports (Annual Reports, Final Progress Reports, Audit Reports, etc.) are submitted to the Department in accordance with Grant Agreements? If any of the research projects contained in the grant received an “unfavorable” rating, please describe how you will ensure the Principal Investigator is more closely monitored (or not funded) when conducting future formula funded health research.

Adherence to funding and other oversight requirements, in terms of quality of work and timeliness of communications are of utmost importance to our organization, and were reflective in our favorable score on this grant. We are excited about the prospect of future health research grants and projects through the Pennsylvania Department of Health, and appreciate the opportunity to describe our highly successful grant oversight process.

At the Treatment Research Institute (TRI), all project reports (Annual Reports, Final Progress Reports, Audit Reports, etc.) are prepared in advance of their deadlines, and are reviewed by the Research Coordinator, PI, and the Associate Director of TRI prior to submission. The Principal Investigator (PI) is responsible for monitoring the safety and efficacy of this study, executing the Data and Safety Monitoring Plan (DSMP), and complying with the reporting requirements. Additionally, we have a Quality Assurance Officer, who, under the direction of the Principal Investigator, is responsible for compliance monitoring of all human subject issues, including IRB submissions, data safety and monitoring, HIPAA compliance, and annual reports.

The Associate Director is responsible for compliance monitoring of all contract provisions including expenditure reporting. Expenditures are reviewed with, and approved by the Associate Director. Under direction of the Associate Director, TRI's Financial Manager meets at least quarterly with the PI and Research Coordinator to discuss study progress and verify proper allocation of expenditures.

Approval and continuing ethics review for all of our studies is obtained by at least one IRB, the TRI IRB. All of the Investigators, Research Assistants (RAs), Project Coordinators, and Site Coordinators for our studies complete the NIH Internet training course on Protection of Human Research Subjects. Copies of the completion certificates for these personnel are on file at the Treatment Research Institute. We hold regularly scheduled staff meetings, which are attended by the research team, including the Principal Investigator, Statistician, Coordinator, and RAs. These meetings discuss the progress of the study, improvements to procedures when necessary, and upcoming tasks and deadlines. During the implementation phase of each grant, detailed plans are developed, and are revised throughout the course of the grant as necessary.

* Please note that for grants ending on or after July 1, 2007, grantees' Final Performance Review Reports, Response Forms, and Final Progress Reports ***will be made publicly available on the CURE Program's Web site.***

For each research project contained in the grant, please provide a response to items B-D as listed on the following page(s). When submitting your response please include the responses for all projects in one document. The report cannot be submitted as a ZIP file, because the Department's exchange server will remove it from the email. If the report exceeds 2MB, please contact the Health Research Program for transmittal procedures: 717-783-2548.

Project Number: 0865301
Project Title: Program Quality Measures for a Consumer Guide to
Adolescent Addiction Treatment
Investigator: Cacciola, John

B. Briefly describe your plans to address each specific weakness and recommendation in Section B using the following format. As you prepare your response please be aware that the Final Performance Review Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer 1:

1. The inability to recruit sufficient adolescents for reliability testing of DSI-P is a weakness. Parental consent in these settings is notoriously difficult to obtain and could reasonably have been anticipated. The plan for waiver of consent for non-involved parents is a good plan going forward. Another approach might be to seek a waiver of consent by administering the instrument anonymously and using an anonymized identifier to link the forms across time.

Response: The waiver of non-involved parents has had a positive impact as we have moved forward with NIDA funding for this work. True anonymity is really not an option as clients must be contacted, tracked, followed, and reimbursed over multiple time points.

2. Analyses of reliability should include not only percent agreement, but also agreement beyond chance.

Response: We plan such reliability analyses [e.g., *kappa (k)*, intraclass correlation coefficient (ICC)] in the future when larger samples are obtained.

Reviewer 2:

1. Specific weakness: The recruitment of programs and directors (see page 13 of the final progress report) was not described clearly and contained inconsistencies.
Recommendation: Develop a flowchart that describes the flow of participants through the project.

Response: Recruitment is now recorded in a detailed manner using an electronic tracking system.

2. Specific weakness: The inability to recruit adolescents for the focus groups and for testing the DSQI-P is a weakness.
Recommendation: Obtain waiver of parental consent. This is the approach subsequently used as part of the NIDA grant.

Response: As noted by Reviewer 1, this recommendation has already been implemented in ongoing work.

3. Specific weakness: The inability to recruit parents for interviews is a weakness.
Recommendation: If parents are not responding to telephone or mail attempts, try going to their homes.

Response: Adolescents and program directors provide the information of primary importance in this work; information from parents is secondary and not essential. For recruiting adolescents, contact with an involved parent is essential and is now occurring either over the phone or in person at the treatment program. Also, for these parents, data/information is now being collected. Non-involved parents are now needless for adolescent participation. Also, data is unnecessary from these parents. For all of these reasons, as well as costs and time associated with home visits, there is no current plan to implement them.

4. Specific weakness: No manuscripts had been submitted at the time the final progress report was written.

Recommendation: It is understandably difficult to submit a manuscript when the number of participants is very low. Nevertheless, it may be possible to submit a descriptive paper for publication. Surely, publications will result from the NIDA grant.

Response: A current largely descriptive manuscript is in progress [and has advance interest from the Journal of Child and Adolescent Substance Abuse (JCASA)] detailing the work done on this project as well as the ongoing and planned work on the related NIDA project.

Reviewer 3:

1. The sample size was significantly lower than the stated goal, and the problems encountered with recruitment dramatically slowed the progress of the project. However, the problems proved to be informative, leading to solutions that are likely to improve recruitment efforts in the future. As a result, there are no recommendations for improvements in this area.

Response: These are lessons learned from this project, supported the development and implementation of effective solutions going forward.

2. There were no publications at the time the final report was generated. The investigators suggest that they will publish results following completion of the NIDA project. The lack of publications is not unreasonable given the length of the project, but there appears to be no plan for additional dissemination of information gained from the current project beyond a couple of completed presentations. It is recommended that the investigators discuss other possible avenues for dissemination of information from the current project.

Response: As mentioned, a current largely descriptive manuscript is in progress detailing this work. Additionally, the results of this and the NIDA work to date are being shared with the Partnership at DrugFree.org to enhance their website related materials informing parents how to choose a good treatment center. We have also made presentations of our work

at the 2012 meeting of the Joint Meeting of Adolescent Treatment Effectiveness (JMATE) in Washington, DC. Finally, other presentations and manuscripts are in the planning stages.

3. This project did not appear to enhance significantly the quality and capacity for research at the grantee's institution. This is a slight weakness because it is unclear to what extent there was potential to use project funds to hire and train new investigators. The investigators should provide comments on why there was no hiring or training of new investigators.

Response: This work did support TRI's growing capacity to conduct research involving youth. Kathleen Meyers, PhD, an adolescent expert who developed the Comprehensive Adolescent Severity Inventory (CASI), was hired at TRI as a Senior Scientist on October 25, 2010 after serving on this project's Scientific Advisory Panel. Her extensive knowledge of adolescent substance abuse and treatment has been of great benefit in this project and in distilling the lessons learned to support the related NIDA project. The PI, John Cacciola, Ph.D., became much more knowledgeable about adolescent and family issues around substance abuse as well as the adolescent substance abuse treatment system both nationally and locally. Finally, members from the Scientific Advisory Panel for this project have continued to provide guidance for TRI in other youth and family initiatives.

C. If the research project received an "unfavorable" rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive "unfavorable" ratings.

Response: Not Applicable

D. Additional comments in response to the Final Performance Review Report (OPTIONAL):

Response: This project provided invaluable pilot work that is now supporting a larger NIDA-funded project. In conjunction with the Final Performance Review, the preparatory work, the scientific consultation, the implementation issues, and the data collected all resulted in knowledge and lessons learned to move the work on developing a Consumer Guide to Adolescent Addiction Treatment forward.