DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

January 11, 2018

TO: James M. Anderson, M.D., Ph.D.
Director
Division of Program Coordination, Planning, and Strategic Initiatives
National Institutes of Health

Donna Jones
Chief Financial Officer
National Institute on Drug Abuse
National Institutes of Health

Judit O'Connor
Chief Financial Officer
National Institute on Alcohol Abuse and Alcoholism
National Institutes of Health

FROM: /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

SUBJECT: Independent Attestation Review: National Institutes of Health Fiscal Year 2017 Detailed Accounting Submissions and Performance Summary Report for National Drug Control Activities and Accompanying Required Assertions (A-03-18-00352)

This report provides the results of our review of the attached National Institutes of Health (NIH) submissions as follows:

- detailed accounting submissions, which include the tables of Fiscal Year 2017 Actual Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2017, submitted by NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), respectively, and

- the Performance Summary Report for National Drug Control Activities and management's assertions for the fiscal year ended September 30, 2017, submitted by NIH for NIDA and NIAAA, collectively.

NIH management is responsible for, and prepared, the detailed accounting submissions and Performance Summary Report to comply with the Office of National Drug Control Policy Circular *Accounting of Drug Control Funding and Performance Summary*, dated January 18, 2013 (the ONDCP Circular).

We performed this review as required by 21 U.S.C. § 1704(d)(A) and as authorized by 21 U.S.C. § 1703(d)(7) and in compliance with the ONDCP Circular.

We conducted our attestation review in accordance with attestation standards established by the American Institute of Certified Public Accountants and the standards applicable to attestation engagements contained in *Government Auditing Standards* issued by the Comptroller General of the United States. An attestation review is substantially less in scope than an examination, the objective of which is to express an opinion on management's assertions contained in its report. Accordingly, we do not express such an opinion.

Based on our review, nothing came to our attention that caused us to believe that NIH's detailed accounting submissions and Performance Summary Report for fiscal year 2017 were not fairly stated, in all material respects, based on the ONDCP Circular.

NIDA's and NIAAA's detailed accounting submissions and NIH's combined Performance Summary Report are included as Attachments A, B, and C, respectively.

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Although this report is an unrestricted public document, the information it contains is intended solely for the information and use of Congress, ONDCP, and NIH. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Amy J. Frontz, Assistant Inspector General for Audit Services, at (202) 619-1157 or through email at Amy.Frontz@oig.hhs.gov. Please refer to report number A-03-18-00352 in all correspondence.

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

MEMORANDUM TO: Director
Office of National Drug Control Policy

THROUGH: Sheila Conley
Deputy Assistant Secretary of Finance
Department of Health and Human Services

FROM: Donna Jones Donna M Jones 11/2/17
Chief Financial Officer
National Institute on Drug Abuse

SUBJECT: Assertions Concerning Drug Control Accounting

In accordance with the requirements of the Office of National Drug Control Policy Circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached annual accounting of drug control funds:

Obligations by Budget Decision Unit

I assert that obligations reported by budget decision unit are the actual obligations from the NIH financial accounting system for this budget decision unit after using NIDA's internal system to reconcile the NIH accounting system during the year.

Drug Methodology

I assert that the drug methodology used to calculate obligations of Prior year budget resources by function for the institute was reasonable and accurate in accordance with the criteria listed in Section 6b(2) of the Circular. In accordance with these criteria, I have documented data which support the drug methodology, explained and documented other estimation methods (the assumptions for which are subject to periodic review) and determined that the financial systems supporting the drug methodology yield data that present fairly, in all material respects, aggregate obligations from which drug-related obligation estimates are derived (See Exhibit A).

Obligations of prior year drug control budgetary resources are calculated as follows:

FY 2017 actual obligations were determined by identifying NIDA support for projects that address drug prevention and treatment. Projects for inclusion in the ONDCP budget are identified from the NIDA coding system and database known as the "NEPS" system (NIDA Extramural Project System). Data are entered into this system by program staff. NIDA does not need to make any assumptions or estimates to isolate its total drug control obligations as the total appropriation is drug control.

As the supporter of most of the world's research on drug abuse and addiction, the National

Institute on Drug Abuse (NIDA) provides a strong science base for our Nation's efforts to reduce the abuse of drugs and their consequences. NIDA's comprehensive research portfolio addresses a broad range of drug abuse and addiction issues, ranging from the support of fundamental neurobiology to community-based research. As our Nation looks for science-based approaches to enhance its prevention and treatment efforts, NIDA's broad portfolio and its continuing efforts to work with other Agencies and NIH Institutes on a variety of transdisciplinary issues will provide the tools necessary to move these efforts forward. Research serves as the cornerstone of NIDA's efforts to disseminate research information and educate health professionals and the public, especially our Nation's youth, about the factors influencing drug use, its consequences, and about science-based and tested treatment and prevention techniques. These research and dissemination efforts to develop, test, and disseminate information on the basis of addiction, its consequences, and enhanced therapeutic techniques support the ONDCP Goal 3 (treatment). Efforts to enhance the science base and disseminate information on the factors that inhibit and facilitate drug use and its progression to addiction and other health consequences, and on science-based approaches for prevention interventions support the ONDCP Goal 1 (prevention).

NIDA obligations are allocated between prevention and treatment research based on the professional judgment of scientific program officials on specific grant and contract projects. These scientists review the grant application, project purpose and methodology, and/or progress report to determine whether the project meets NIDA's criteria for categorization as prevention or as treatment research. Projects are coded and entered into the NEPS system prior to funding.

NIDA's FY 2017 Annualized CR budget from the FY 2018 President's Budget (PB) was $1,075,440,000. In May of 2017, NIDA received the FY 2017 Enacted budget of $1,090,853,000, which was an additional $15,413,000 above the Annualized CR level. There was a Permissive Transfer in the amount of $2,474,000 and an HIV/AIDS transfer in the amount of $17,533,000. NIDA obligated $1,070,812,670 and $33,330 lapsed.

Application of Methodology

I assert that the drug methodology described in the preceding section was the actual methodology used to generate the table required by Section 6a. NIDA has not modified its drug methodology from the previous year. The difference between NIDA's actual obligations and the National Drug Control Strategy Budget summary number for FY 2017 are for the same reasons described above for the FY 2017 column of the FY 2018 PB.

Reprogrammings or Transfers

I assert that the obligation data presented are associated against a financial plan that, if revised during the fiscal year, properly reflects those changes, including ONDCP's approval of reprogrammings or transfers affecting drug-related resources in excess of $1 million that occurred during the fiscal year.

Fund Control Notices

I assert that the obligation data presented are associated against a financial plan that complied fully with all Fund Control Notices issued by the Director under 21 U.S.C. 1703(f) and with section 9 of the ONDCP Circular *Budget Execution*, dated January 18, 2013.

ATTACHMENT

Exhibit A

(1) **Drug Methodology** – Actual obligations of prior year drug control budgetary resources are derived from the NIDA Extramural Project System (NEPS) and the NIH nVision Balance of Accounts Report.

(a) **Obligations by Budget Decision Unit** – NIDA's budget decision units have been defined by ONDCP Circular, Budget Formulation, dated January 18th, 2013. NIDA reports its entire budget to ONDCP. This unit is referred to as:

- National Institute on Drug Abuse

(b) **Obligations by Drug Control Function** – NIDA distributes drug control funding into two functions, prevention and treatment:

- Research and Development Prevention
- Research and Development Treatment

(2) **Methodology Modifications** – none

(3) **Material Weaknesses or Other Findings** – none

(4) **Reprogrammings or Transfers -** The obligation data presented are associated against a financial plan that, if revised during the fiscal year, properly reflects those changes, including ONDCP's approval of reprogrammings or transfers affecting drug-related resources in excess of $1 million that occurred during the fiscal year.

(5) **Other Disclosures** - none

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE
FY 2017 Actual Obligations
(Dollars in Thousands)

I. RESOURCE SUMMARY

	FY 2017 Actual
Drug Resources by Decision Unit:	
National Institute on Drug Abuse	1,070,813
Total	1,070,813
Drug Resources by Function:	
Research and Development Prevention	380,513
Research and Development Treatment	690,300
Total	1,070,813

Difference Between the FY 17 Annualized CR column of the FY 18 PB and the National Drug Control Strategy Budget Summary and the Actual NIDA Obligations
(Dollars in Thousands)

FY 17 Annualized CR column of the FY 2018 PB; National Drug Control Strategy	1,075,440
Increase over FY 2017 Annualized CR level	15,413
Permissive Transfer	-2,474
HIV/AIDS Transfer	-17,533
Lapse of Funds	-33
Total Actual Obligations	1,070,813

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism 5635 Fishers Lane
Bethesda, MD 20892-9304

November 14, 2017

MEMORANDUM TO: Director Office of National Drug Control Policy

THROUGH: Sheila Conley
Deputy Assistant Secretary of Finance
Department of Health and Human Services

FROM: Judit O'Connor
Chief, Financial Management

Judit O'connor -S

Digitally signed by Judit O'connor -S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, cn=Judit O'connor -S, 0.9.2342.19200300.100.1.1=0013363641
Date: 2017.11.14 14:19:01 -05'00'

National Institute on Alcohol Abuse and Alcoholism

SUBJECT: Assertions Concerning Drug Control Accounting

In accordance with the requirements of the Office of National Drug Control Policy Circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached annual accounting of drug control funds:

Obligations by Budget Decision Unit

I assert that obligations reported by budget decision unit are the actual obligations from the National Institutes of Health (NIH) financial accounting system for this budget decision unit after using the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) internal system to reconcile the NIH accounting system during the year.

Methodology

I assert that the methodology used to calculate obligations of prior year budgetary resources by function for the institute was reasonable and accurate in accordance with the criteria listed in Section 6b(2) of the Circular. Obligations of prior year underage drinking control budgetary resources are calculated as follows:

The NIAAA prevention and treatment components of its underage drinking research are included in the ONDCP drug control budget. Underage drinking research is defined as research that focuses on alcohol use, abuse and dependence in minors (children under the legal drinking age of 21). It includes all alcohol related research in minors, including behavioral research, screening and intervention studies and longitudinal studies with the exception of research on fetal alcohol spectrum disorders resulting from alcohol use by the mother during pregnancy. Beginning with

the reporting of FY 2010 actual obligations, NIAAA's methodology for developing budget numbers uses the NIH research categorization and disease coding (RCDC) fingerprint for underage drinking that allows for an automated categorization process based on electronic text mining to make this determination. Once all underage drinking projects and associated amounts are determined using this methodology, NIAAA conducts a manual review and identifies just those projects and amounts relating to prevention and treatment. Contract expenditures supporting underage prevention activities are also included. This subset makes up the NIAAA ONDCP drug control budget. Prior to FY 2010, there was no validated fingerprint for underage drinking, and the NIAAA methodology was completely dependent upon a manual review by program officers.

Application of Methodology

I assert that the drug methodology described in this section was the actual methodology used to generate the table required by Section 6a of the Circular.

Reprogramming or Transfers

I assert that NIAAA did not reprogram or transfer any funds included in its drug control budget.

Fund Control Notices

I assert that the obligation data presented are associated against a financial plan that complied fully with all Fund Control Notices issued by the Director under 21 U.S.C. 1703(f) and with ONDCP Circular *Budget Execution,* dated January 18, 2013.

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
FY 2017 ACTUAL OBLIGATIONS
(Dollars in Thousands)

	FY 2017 Actuals
Drug Resources by Decision Unit:	
National Institute on Alcohol Abuse and Alcoholism	$50,639
Total Drug Resources by Decision Unit	$50,639
Drug Resources by Function:	
Research and Development: Prevention	$45,504
Research and Development: Treatment	$5,134
Total Drug Resources by Function	$50,639

ATTACHMENT

Exhibit A

(1) **Drug Methodology** – Actual obligations of prior year drug control budgetary resources are derived from the NIH research categorization and disease coding (RCDC) fingerprint for underage drinking and a manual review to identify projects related to prevention and treatment.

(a) **Obligations by Budget Decision Unit** – NIAAA's budget decision units have been defined by ONDCP Circular, Budget Formulation, dated January 18th, 2013. NIAAA reports only a portion of the budget dedicated to treatment and prevention to ONDCP. This unit is referred to as:

- National Institute on Alcohol Abuse and Alcoholism

(b) **Obligations by Drug Control Function** – NIAAA distributes drug control funding into two functions, prevention and treatment:

- Research and Development Prevention
- Research and Development Treatment

(2) **Methodology Modifications** – none

(3) **Material Weaknesses or Other Findings** – none

(4) **Reprogrammings or Transfers -** none

(5) **Other Disclosures** - none

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: November 13, 2017

MEMORANDUM TO: Director
Office of National Drug Control Policy

THROUGH: Norris Cochran
Deputy Assistant Secretary, Office of Budget, HHS

FROM: Director, Division of Program Coordination,
Planning, and Strategic Initiatives (DPCPSI), NIH

SUBJECT: Assertions Concerning Performance Summary Report

In accordance with the requirements of the Office of National Drug Control Policy circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached Performance Summary Report for National Drug Control Activities:

Performance Reporting System

I assert that NIH has a system to capture performance information accurately and that this system was properly applied to generate the performance data presented in the attached report.

Explanations for Not Meeting Performance Targets

I assert that the explanations offered in the attached report for failing to meet a performance target are reasonable and that any recommendations concerning plans and schedules for meeting future targets or for revising or eliminating performance targets are reasonable.

Methodology to Establish Performance Targets

I assert that the methodology used to establish performance targets presented in the attached report is reasonable given past performance and available resources.

Performance Measures Exist for All Significant Drug Control Activities

I assert that adequate performance measures exist for all significant drug control activities.

James. M. Anderson, MD, PhD
Director, DPCPSI

FY 2017 Performance Summary Report for National Drug Control Activities

Decision Unit 1: NIDA

Prevention

Measure SRO-5.15: By 2018, develop, refine, and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.

Table 1: NIDA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Target	FY 2017 Actual	FY 2018 Target
NIH-funded research tested multiple interventions to prevent drug use, drug use problems, and drug-related risky behaviors including HIV risk behaviors.	NIH-funded research tested over twenty strategies for improving the dissemination and implementation of evidence-based interventions to prevent drug use, drug use problems, and drug-related risky behaviors including HIV risk behaviors.	41 research articles were published examining the efficacy of a variety of prevention interventions to protect youths from initiation or escalation of substance use and associated negative health outcomes.	Assess the efficacy or effectiveness of at least two indicated/selective interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations.	The efficacy or effectiveness of three interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations was tested.	Assess the efficacy or effectiveness of at least two strategies or interventions to prevent prescription drug abuse in youth and young adult populations.

Note: SRO-5.15 began reporting in FY 2014.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

NIH's growing knowledge about substance use and addiction (including tobacco, alcohol, illicit, and nonmedical prescription drug use) is helping to inform the development of prevention strategies that are evidence-based and rooted in a growing understanding of the biological (e.g., genetics, neurobiology), psychosocial (e.g., support systems, stress resilience), and environmental (e.g., socioeconomic, cultural) factors that influence risk for substance use and related disorders. NIH-supported research is building the scientific knowledge base to advance the development of effective, tailored prevention strategies for youth.

NIH's prevention portfolio encompasses a broad range of research to increase our understanding of the factors that enhance or mitigate an individual's propensity to initiate drug use or to escalate from use to substance use disorders across different developmental stages. Understanding the mechanisms through which these factors influence substance use and addiction across individuals is critical for designing more effective prevention strategies. **Measure SRO-5.15 focuses on developing, refining, evaluating, and disseminating evidence-based intervention strategies to prevent substance misuse and substance use disorders and**

their consequences in underage populations and contributes to the *2016 National Drug Control Strategy Goal of Strengthening Efforts to Prevent Drug Use in Our Communities (Chapter 1)*.

The efficacy and cost-effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to substance use disorders—can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of taking drugs or becoming addicted.[1,2,3] For example, prevention programs designed for sensation-seeking youth are effective for these youth, but not for their peers who do not demonstrate a high level of sensation seeking.[4] High levels of sensation-seeking, and other traits known to be risk factors for substance misuse—such as high impulsivity or early aggressive behavior—may be identified early using genetic markers.

It is estimated that genetic factors account for approximately half of the risk for addiction.[5] A number of genetic markers have been identified that influence risk for addiction and recent research has shown that genetic risk factors can influence the effectiveness of school-based prevention interventions.[6] This information can be harnessed for improving prevention by personalizing interventions for optimal benefit. Such strategies would enable substance use prevention programs to target programs more precisely based on individual or group vulnerability, ultimately increasing their impact and cost-effectiveness. Combined with improved educational efforts to increase an individual's awareness of his or her personal risk, this preemptive prevention approach can empower people to make decisions that ultimately prevent substance use from starting or escalating.

The information gained from research on the factors that influence risk and resilience to substance use disorders will lay the foundation for improved and tailored prevention efforts in the future. As personalized risk (or protective) factors for substance use and addiction vulnerability are identified, NIH will encourage researchers to use that information to better understand how biological factors, combined with environmental ones, contribute to substance use disorder vulnerability, thereby enhancing its prevention portfolio. NIH will also encourage the scientific community to use this knowledge to develop and test targeted prevention interventions for populations with differing vulnerabilities to improve our Nation's intervention efforts, similar to the strategy now being used to prevent substance use in high sensation-seeking youth.

(2) Provide narrative that examines the FY 2017 actual performance results with the FY 2017 target, as well as prior year actuals. If the performance target was not achieved for FY 2017, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The performance target for SRO-5.15 was met for FY 2017. The efficacy or effectiveness of three interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations was tested. Prevention of the initiation of drug use and escalation to addiction continues to be one of NIDA's primary strategic goals (see NIDA's Strategic Plan).

NIDA continues to fund a robust prevention portfolio that builds upon solid epidemiological findings and insights from genetics and neuroscience research, applying this knowledge to develop effective strategies to prevent initiation of drug use and escalation of use to addiction among youth.

Substance use problems are highly prevalent among youth in foster care. Such problems in adolescence have long-lasting implications for subsequent adjustment throughout adulthood and even across generations. Although several programs have demonstrated positive results in reducing substance use in at-risk youth, few studies have systemically examined how such programs work for foster youth and whether they are effective for both genders. A NIDA-funded study examined the efficacy of KEEP SAFE, a family-based and skill-focused program designed to prevent substance use and other related health risking behaviors among youth in foster care. The authors hypothesized that improving the caregiver-youth relationship would lead to later reductions in youths' involvement with deviant peers, which subsequently would lead to less substance use, and that this mechanism would work comparably for both genders. 259 youth (105 boys and 154 girls, age range = 11-17) in foster care and their caregivers participated in a randomized controlled trial and were followed for 18 months post-baseline. Results indicated that the intervention significantly reduced substance use in foster youth at 18 months post-baseline and that the intervention influenced substance use through two processes: youths' improved quality of relationships with caregivers at 6 months post-baseline and fewer associations with deviant peers at 12 months post-baseline. This suggests that these two processes may be fruitful immediate targets in substance use prevention programs for foster youth. The authors also found little gender differences in the effects of the intervention, suggesting KEEP SAFE may be effective for both genders in foster care.[7]

Another NIDA-funded study evaluated the effectiveness of an evidence-based, parent-centered intervention called Familias Unidas. The intervention aimed to prevent substance use (alcohol, illicit drugs) and sex without a condom among Hispanic adolescents. School personnel, including social workers and mental health counselors, were trained to deliver the evidence-based intervention. A randomized controlled trial (n = 746) evaluated the effectiveness of Familias Unidas among Hispanic eighth graders (age range = 12-16), relative to prevention as usual, within a public school system. (Prevention as usual was defined as a six-lesson HIV risk reduction educational unit provided by science teachers in the classroom setting.) Familias Unidas was effective in preventing drug use from increasing and prevented greater increases in sex without a condom 30 months after baseline, relative to prevention as usual. Familias Unidas also had a positive impact on family functioning and parental monitoring of peers at six months after baseline. The study demonstrated the effectiveness of a parent-centered preventive intervention program in preventing risky behaviors among Hispanic youths. Findings highlight the feasibility of training community members to effectively deliver a manualized intervention in a real-world setting.[8]

Another study examined an intervention for disruptive behavior. Prior research suggests that under some conditions, interventions that aggregate high-risk youth may be ineffective, or at worst, may even exacerbate risk. However, group formats have considerable practical utility for delivery of preventive interventions, and thus it is crucial to understand child and therapist factors that predict which children who demonstrate increased aggressive behaviors benefit from

group intervention and which do not. To address these questions, researchers video-recorded group Coping Power intervention sessions (938 sessions) and analyzed both therapists' and children's behaviors in the sessions that predicted changes in teacher and parent reports of problem behavior at one-year follow up. The sample included 180 high-risk children (69% male) who received intervention in 30 separate Coping Power intervention groups (six children assigned per group). The evidence-based Coping Power prevention program consists of 32 sessions delivered during the 4th and 5th grade years. The behavioral coding system used in the analyses included two clusters of behaviors for children (positive; negative) and two for the primary therapists (group management; clinical skills). The analyses suggest that high levels of children's negative behaviors usually predicted increases in teacher and parent rated aggressive and conduct problem behaviors during the follow-up period. Therapist use of clinical skills (e.g., warmth, nonreactive) predicted less increase in children's teacher-rated conduct problems. These findings suggest the importance of clinical training in the effective delivery of evidence-based practices, particularly when working with high-risk youth in groups.[9]

(3) The agency should describe the performance target for FY 2018 and how the agency plans to meet this target. If the target in FY 2017 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2018.

The FY 2018 target is to assess the efficacy or effectiveness of at least two strategies or interventions to prevent prescription drug abuse in youth and young adult populations. Prevention of the initiation of drug use and the escalation to substance use disorders in those who have already initiated use is one of NIDA's primary strategic goals (see NIDA's Strategic Plan. To address this goal, NIDA funds a robust prevention portfolio to identify the characteristics and patterns of drug use; understand how biology, environment, behavior, and development influence the risk and protective factors for drug use; and to apply this knowledge towards the development and dissemination of more effective strategies to identify populations at "high risk" and prevent them from initiating drug use and from progressing to substance use disorders if they do. NIDA's Division of Epidemiology, Services, and Prevention Research also makes a significant investment in implementation science research to better understand the factors that influence successful dissemination and implementation of tested, effective interventions in real world settings. This implementation science research will be used to achieve this target.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness and Unbiased Presentation

The research field is guided by standard scientific methodologies, policies, and protocols. Any variation from these proven methodologies generates criticism that negates findings. The scientific process also has several benchmarks within it to ensure scientific integrity. For instance, research designs, such as qualitative, quantitative, and mixed methods, have each been tested, with evidence-based strategies established to guide the implementation of all scientific

research studies. In these processes, data collection, security, management, and structures are clearly defined to ensure optimum analyses.

Data analyses are guided by statistical methodologies, a mathematical science used to test assumptions. In addition, NIH has incorporated standardized policies and procedures for making funding announcements, assessing meritorious science, monitoring progress of grantees and scientists in achieving the expected outcomes, and assessing performance at the project's conclusion. Researchers are also expected to publish findings in peer-reviewed journals, which offer another layer of assessment and validation of the findings. In addition, all studies involving human subjects must receive Institutional Review Board (IRB) clearance, yet another form of review that ensures the relevance of the study and the safety of the subjects. NIH's research activities implement and practice all scientifically relevant procedures to ensure data quality and to substantiate findings.

In implementing scientific research, NIH uses established tools to develop and oversee programs and improve their performance, proactively monitoring grants, contracts, and cooperative agreements and assess their performance. The following briefly describes the NIH scientific process, which has been assessed by outside entities and is regarded as premier.

Assessment to fund meritorious science (peer review). NIH uses state-of-the-art assessment to determine scientific merit and make funding decisions based on the best science. In general, project plans presented in competing grant applications and contract proposals are subject to three levels of review focused on the strength and innovation of the proposed research, the qualifications of the investigator(s), and the adequacy of the applicant's resources:

- The first level of review, called peer review, ensures that the most meritorious science, as determined by the scientific field's experts, is identified for funding. NIH has over 11,000 external experts participating in peer review panels, each of whom is nationally recognized for his or her area of expertise. The applications are systematically reviewed and scored to inform funding decisions. NIH is one of the few Federal agencies with a legislative requirement for peer review.
- The second level of review is by the Institute's National Advisory Council, which is comprised of eminent scientists along with members of the general public. The Council serves as a useful resource to keep each Institute abreast of emerging research needs and opportunities, and to advise the Institute on the overall merit and priority of grant applications in advancing the research. All members of Council are appointed by the HHS Secretary.
- The third level of review is by the Institute Director, with input from Institute staff who have relevant expertise. The Director makes the final decision on whether an application will receive funding.

These layers of expert review assessing scientific methodologies and relevance to the field enable funding of the most promising research to advance the field. Consequently, funding decisions made at the agency level are conducted in a consistent, merit-based fashion, guided by scientific methodologies and relevance.

Performance monitoring of grants and contracts. Once an award is made, additional NIH policies and guidelines are implemented to ensure oversight of the proposed project aims and program goals. The NIH Grants Policy Statement (available at https://grants.nih.gov/policy/nihgps/index.htm) provides the standardized protocols for monitoring performance-based grants and contracts. Although there are many procedures, a few significant items include the timely submission of progress and final reports. These are assessed by NIH project officers and grants management staff to determine adherence to the approved scientific research plan and to appropriate cost principles and legislative compliance. Project officers may work closely with principal investigators to facilitate adherence, address barriers, and ensure quality programmatic achievements.

As a standard performance-based practice, the approved scientific aims and objectives formulate the terms and conditions of each grant award and become the focus of scientific monitoring. The NIH Grants Policy Statement, referenced as a term of every award, states the specific administrative requirements for project monitoring and enforcement actions when a grantee fails to comply with the terms and conditions of the award. NIH staff monitor scientific progress against the approved aims and scope of the project, as well as administrative and fiscal compliance through review of periodic progress reports, publications, correspondence, conference calls, site visits, expenditure data, audit reports (both annual institutional financial reports and project-specific reports), and conference proceedings. When a grantee fails to comply with the terms and conditions of an award, enforcement actions are applied. These may include modification to the terms of award, suspension, withholding support, and termination.

A further checkpoint for programmatic assessment occurs when the applicant requests renewal support of continuation research. A peer review group again assesses the merits of future research plans in light of the progress made during the previous project period, and any problems in grantee performance are addressed and resolved prior to further funding. This process further demonstrates use of assessments to improve performance.

Review of manuscripts. Ultimately, the outcomes of any scientific research are judged based on published results in a peer-reviewed journal. The peer-review publication process is another point in which the quality and innovation of the science undergoes a rigorous evaluation. For most scientific journals, submitted manuscripts are assigned to a staff editor with knowledge of the field discussed in the manuscript. The editor or an editorial board will determine whether the manuscript is of sufficient quality to disseminate for external review and whether it would be of interest to their readership. Research papers that are selected for in-depth review are evaluated by at least two outside referees with knowledge in the relevant field. Papers generally cannot be resubmitted over a disagreement on novelty, interest, or relative merit. If a paper is rejected on the basis of serious reviewer error, the journal may consider a resubmission.

Additional controls specific for genetics projects. For all genetics projects (i.e., both contracts and grants), a three-tier system ensures data accuracy. This system is based on sound, proven scientific methodology internally governed by the larger scientific research community (as described above). First, gene expression levels are validated using highly quantitative methods to measure ribonucleic acid (RNA) levels. Second, each study builds in a replication design using subsets of the study population or, sometimes, different study populations. Third, the

information gleaned from these studies is compared against previously collected data or, if not available, replicated and validated in models suited to evaluate the implications of the genetic findings.

Every effort is made to acquire complete data sets; however, several factors can limit a researcher's ability to do so. These factors are either intrinsic to the type of data being collected (inability to collect from all drug users, all ethnic minorities, every developmental stage, every comorbid association, etc.) or linked to the incompleteness of genetic information databases (considerable gaps in SNP collections, many genes yet unidentified or without known function, etc.). Some level of data incompleteness mires all human genomic programs in which population sampling, limited by cost considerations, must be used. These obstacles, however, do not necessarily jeopardize data quality, since many powerful post-hoc standard protocols are available and being deployed to clean the data sets and ensure accuracy and replicability.

Methodology Used to Establish Targets/Actuals

The targets are established based on the state of the science in a particular field and knowledge of the scientific process by which advances are made. NIDA supports a robust portfolio on implementation science research to better understand the factors that influence successful dissemination and implementation of tested and efficacious interventions in real world settings. The targets are established based on where the field stands in this process and on the next logical scientific step for moving the field forward

Data Sources

As described above, each grantee provides an annual progress report that outlines past-year project accomplishments, including information on patients recruited, providers trained, patents filed, manuscripts published, and other supporting documentation, depending on the goals of the study. This information allows NIH to evaluate progress achieved or to make course corrections as needed.

Treatment

Measure SRO-7.3: By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery and adherence for substance use disorders and related health consequences.

Table 2: NIDA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Target	FY 2017 Actual	FY 2018 Target
Research tested feasibility and efficacy of technology-based treatments, and measurement of real-time contextual feedback, and mobile-technology-based interactions in drug addiction; development of other approaches in the use of mobile technology continues.	Studies examined the efficacy of mobile technology-based treatments to enhance treatment for patients with mental illness, and for interactive treatment of patients with drug addiction; and the feasibility of improving HIV antiretroviral treatment adherence with cell phone reminders, counseling, and two-way personalized text messaging.	Five interventions utilizing HIT, including mobile health technology, addressing five research priority areas were developed. All interventions were found to be feasible and will undergo additional revision and efficacy testing in preparation for broad dissemination and implementation.	Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings.	Research testing the feasibility and efficacy of 3 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including research in 2 different care delivery settings.	Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities.

Note: SRO-7.3 began reporting in FY 2014.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

Addiction is a complex but treatable disorder that affects brain function and behavior. However, we have a significant and ongoing treatment gap in our Nation. Among those who need treatment for a substance use disorder (SUD), only about 10 percent receive specialty care.[10] Further, many treatment programs do not deliver current evidence-based practices –for example, less than fifty percent provide access to medications approved for the treatment of opioid use disorder[11], and they typically do not coordinate care with the patient's general health care providers. In addition, patients receiving treatment for SUD or related health conditions – such as HIV or mental health disorders – often do not fully adhere to the treatment plan recommended by their doctor. NIDA is committed to supporting health services and implementation research to develop and test technologies that aim to reduce these gaps.

An unacceptable gap also separates scientific discoveries from their implementation into community health care settings. A scientific approach is needed to develop and test implementation strategies to improve the reach of evidence-based treatments. Ultimately, NIH

strives to make research-based treatments user friendly, cost effective, and available to a broad range of practitioners and their patients. Health information technology (HIT) tools, including mobile technologies, represent one promising mechanism to achieve this goal.

The last few years have seen tremendous advances in the development and implementation of HIT tools that have great promise for improving the efficiency and quality of health care delivery for substance use disorders – ranging from electronic health records, telehealth, wearable sensors, and mobile health technologies.[12] These advances are revolutionizing health services research and presenting new opportunities to deliver innovative treatment and recovery interventions. HIT has the power to drive new treatment delivery models by supporting more effective integration of care, extending the reach of the SUD treatment workforce, enabling real-time patient monitoring and support, and engaging patients who are hesitant to participate in traditional behavioral health treatment systems. NIH-supported research is exploring how technology can best be leveraged to increase access to and quality of care to improve patient outcomes.

SRO-7.3 is focused on developing and testing treatment interventions using HIT tools to improve patient identification, treatment delivery, or adherence to treatment for substance use disorders and related health problems. This goal contributes to NIDA's long-term strategy for improving drug use disorder treatment nationwide, thereby contributing to the ***2016 National Drug Control Strategy's Goals of: Seeking Early Intervention Opportunities in Health Care (Chapter 2)*** by supporting screening for substance use and substance use disorders in healthcare settings using mobile technologies***; and Increasing Access to Treatment and Supporting Long Term Recovery (Chapter 3)*** *by supporting innovative research to develop and test mobile technologies to support the delivery of treatment and recovery services.*

NIH's health services research portfolio encompasses a broad array of studies exploring the use of HIT tools to deliver evidence-based treatments, support coordination of care, improve the organization and delivery of treatment services, educate patients to prevent common comorbidities such as HIV or Hepatitis C, improve adherence to treatment for both substance use disorders and comorbid health conditions, increase treatment engagement, and provide recovery support. Research in this area will lay the foundation for leveraging technology to improve health outcomes related to substance use and substance use disorders. As these technologies advance, NIH will continue to encourage innovative research to determine how they can best be applied to address gaps in access to and quality of care as well as treatment engagement to improve individual and public health.

(2) Provide narrative that examines the FY 2017 actual performance results with the FY 2017 target, as well as prior year actuals. If the performance target was not achieved for FY 2017, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The FY 2017 target for SRO-7.3 was met. NIDA funds a broad portfolio of research on the potential of HIT tools to improve health care delivery and health outcomes related to SUDs. In FY 2017, research testing the feasibility and efficacy of three technology-based strategies to

improve substance use disorder treatments and adherence was conducted, including research in two different care delivery settings. Research findings leveraging HIT to address NIDA research priority areas include:

Approval of the ReSET mobile application for SUD Treatment – A major development in mHealth in 2017 was the FDA approval of the reSET mobile app. ReSET – previously known as the Therapeutic Education System (TES) – is a mobile app that is approved for use in outpatient treatment for substance use disorders related to cocaine, other stimulants, cannabis, and alcohol. The mobile app delivers cognitive behavioral therapy, which aims to change behavior by changing an individual's cognitive processes. The app rewards users for continuing with therapy with various incentives, which can improve adherence. When adopted widely, evidence-based advances in digital therapeutics will broaden the spectrum of substance use disorder treatment options, particularly in rural and underserved communities.

This treatment tool was created through NIDA's behavior-therapy development program and validated through a major nationwide multi-site trial conducted in the NIDA Clinical Trials Network (CTN) program. In the clinical trial, the 12-week abstinence rate from drugs and alcohol for users of the app, 40 percent, was more than twice the abstinence rate for individuals who received standard care (18 percent). Pear Therapeutics, Inc. acquired the right to rebrand TES as reSET and used the CTN trial results as pivotal evidence to gain approval from the Food and Drug Administration as the first prescription digital therapeutic to improve clinical outcomes in a disease. The reSET app is not approved for treating opioid use disorder, but with a Small Business Innovation Research grant from NIDA, a new version of the app called reSET-O is currently being developed.

Implementation of Evidence-Based HIT Tools – A recent study by NIDA explored strategies to support the implementation of a combination of evidence-based technologies in the primary care setting – including both reSET and a mobile application that provides SUD recovery support (ACHESS). When these combined technologies, branded Seva, were pilot tested using proven implementation strategies (informed by quality improvement), researchers found that they supported patients' sustained, positive use of Seva.[13]

My Mobile Advice Program (MyMAP) – Other NIDA-funded research is exploring a mobile optimized website accessed via smartphone to improve medication adherence and provide tailored advice to manage symptoms to help users quit smoking. An initial pilot study in a large health system determined that MyMAP is a feasible, acceptable, and potentially effective means to support varenicline use to quit smoking.[14] Future studies are planned to determine the efficacy of this intervention for smoking cessation.

(3) The agency should describe the performance target for FY 2018 and how the agency plans to meet this target. If the target in FY 2017 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2018.

The FY 2018 target is to develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities. HIT is a rapidly advancing field that is poised to significantly improve the efficiency and efficacy of healthcare delivery. Based on the research

of relevance to SRO-7.3, along with other advances in HIT, NIDA recognizes the potential of an array of technologies to transform patient care through the secure sharing and use of health information. Through SRO-7.3 NIDA will support the development and evaluation of interventions that use HIT (e.g., mobile health tools, web applications, telehealth, and electronic health records) to improve patient identification, treatment delivery, or adherence for substance use disorders and related health consequences. To address this target, NIDA funds a significant research portfolio to examine the feasibility and efficacy of technology-based treatments for patients with SUDs. NIDA's ongoing efforts related to HIT will be used to achieve the FY 2018 target.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness, and Unbiased Presentation

As described above, the research field (including health services research) is guided by standard scientific methodologies, policies, and protocols to ensure the validity of its research results. NIH uses these established tools for program development; for actively monitoring grants, contracts, and cooperative agreements; and for assessing performance of grants and contracts in order to oversee the program and improve performance. These tools have been described in response to question 4 above.

For the SRO-7.3 FY 2017 target, NIDA relied on annual progress reports provided by each grantee that outline past-year project accomplishments, including information on patients recruited, providers trained, patents filed, manuscripts published, and other supporting documentation. This information allows NIH to evaluate progress achieved and to make course corrections as needed.

Decision Unit 2: NIAAA

Prevention

Measure SRO-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.

Table 1: NIAAA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Target	FY 2017 Actual	FY 2018 Target
NIAAA developed the College Alcohol Intervention Matrix (*CollegeAIM*), a decision tool to help colleges and universities select appropriate strategies to meet their alcohol intervention goals. *College-AIM* is being finalized and will be released in 2015.	NIAAA supported six studies to evaluate the effectiveness of the youth guide for alcohol screening and brief intervention in a variety of settings.	NIAAA promoted and disseminated the College Alcohol Intervention Matrix (*CollegeAIM*), and disseminated the youth screening guide through print and electronic media.	Continue to promote the College Alcohol Intervention Matrix (*CollegeAIM*).	NIAAA promoted and disseminated *CollegeAIM* and initiated efforts to update *CollegeAIM* to reflect the latest evidence-based alcohol interventions.	Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native).

Note: SRO-5.15 began reporting in FY 2014.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

Adolescence is the stage of life during which most people begin drinking, and it is also a time of considerable social, psychological, and physiological change. The brain, particularly the frontal cortex, continues to develop throughout adolescence and does not fully mature until early adulthood. Adolescents are particularly vulnerable to the adverse consequences of alcohol misuse. Adolescent alcohol exposure can affect normal brain development, compromise short- and long-term cognitive functioning, and increase the likelihood of developing alcohol-related problems during adolescence and later in life. Adolescent alcohol misuse also increases the risk for other adverse outcomes such as blackouts, physical and sexual assault, risky sexual behavior, alcohol overdose, injuries, and death. Given the pervasive use of alcohol among young people, the potential impact on their developmental trajectories, and the increased risk for alcohol use disorder (AUD) and other harmful consequences, effective strategies are needed to prevent the initiation and escalation of youth alcohol use and the associated adverse outcomes.

SRO-5.15 is focused on developing, evaluating, and promoting evidence-based intervention strategies to prevent substance misuse and substance use disorders and their consequences in underage populations, thereby contributing to the ***2016 National Drug Control Strategy Goal of***

Strengthening Efforts to Prevent Drug Use in Our Communities (Chapter 1). NIAAA supports research on preventing and reducing alcohol misuse, including underage alcohol use, as well as preventing and treating AUD and other alcohol-related problems. NIAAA's underage alcohol prevention efforts focus on risk assessment and screening, universal and selective prevention, early intervention (i.e., before problems escalate and/or become chronic), and timely treatment as appropriate. NIAAA supports a range of interventions designed for multiple levels (e.g., individual, school/college, family, and community) in support of this goal.

(2) Provide narrative that examines the FY 2017 actual performance results with the FY 2017 target, as well as prior year actuals. If the performance target was not achieved for FY 2017, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The target for FY 2017 was met. In September 2015, NIAAA released the *College Alcohol Intervention Matrix* (*CollegeAIM*) guide and website, important new resources to help colleges address harmful and underage student drinking. Developed with input from researchers and college staff, *CollegeAIM* is an easy-to-use and comprehensive tool to help colleges and universities identify evidence-based alcohol interventions. *CollegeAIM* rates nearly 60 alcohol interventions in terms of effectiveness, costs, and other factors, and presents the information in a user-friendly and accessible way. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address student drinking.

With the release of *CollegeAIM*, NIAAA embarked on a multifaceted promotion and dissemination effort to introduce college and university officials to this new resource. NIAAA senior staff and selected researchers from the *CollegeAIM* development team made numerous presentations, including at national higher education conferences and regional workshops, to demonstrate how to use the guide and website. For example, in FY 2017, NIH staff presented *CollegeAIM* at a special workshop of the New Jersey Higher Education Consortium on Alcohol and Other Drug Prevention at Rutgers University and at the Substance Abuse and Mental Health Services Administration Prevention Day, which was held at the Community Anti-Drug Coalitions of America (CADCA) National Leadership Forum. NIAAA also continued to promote *CollegeAIM* through it communication outlets, including Twitter and the NIAAA website. Since its launch in 2015, the *CollegeAIM* website has received over 47,000 visitors (16,146 in FY 2017), the digital *CollegeAIM* booklet was downloaded more than 8,000 times (2,275 in FY 2017), and NIAAA distributed more than 14,000 print copies of the booklet (2,824 in FY 2017). NIAAA is also in the process of updating *CollegeAIM* to ensure that it reflects the latest research on evidence-based alcohol interventions for college-age individuals. The Institute reconvened the original group of developers to begin working on the updated *CollegeAIM*, which is scheduled to be completed in 2018.

(3) The agency should describe the performance target for FY 2018 and how the agency plans to meet this target. If the target in FY 2017 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2018.

The FY 2018 target is to develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native). NIAAA is currently supporting several studies to develop culturally-tailored interventions for preventing or reducing alcohol use and adverse alcohol-related consequences among underserved youth. Ongoing studies include culturally-tailored, family-based interventions for Latino emerging adults and rural African American youth transitioning to middle and high school.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness and Unbiased Presentation

To promote the use of evidence-based intervention strategies for harmful and underage college student drinking, NIAAA engaged a team of premier researchers with expertise in college drinking interventions to assess the state of the science on the effectiveness, cost, and barriers to implementation of existing interventions. This process informed the development of *CollegeAIM*, a decision tool designed to help college and university administrators more easily navigate and select alcohol interventions for their campuses.

The team first searched the research literature through 2012 to find studies and reviews for each strategy. Seminal studies from 2013 were added following the first round of reviews. Researchers used quantitative methods to estimate the effectiveness and amount of research for individual-level strategies, as well as the amount and quality of research for the environmental-level strategies. For estimated effectiveness for the environmental strategies, as well as estimated costs and barriers for all strategies, they used a qualitative process of assigning rating codes independently – based on literature reviews, direct knowledge of strategies in practice, or both – then resolving discrepancies through discussion and referral to the literature to reach a consensus. Once the *CollegeAIM* analysis was completed, an additional group of prominent college drinking researchers served as peer reviewers for the data analysis underlying the decision tool. Analyses of the data underlying *CollegeAIM* are guided by statistical methodologies, a mathematical science used to test assumptions.

To ensure the accuracy of reporting on *CollegeAIM* promotion and dissemination efforts, NIAAA conducted a comprehensive search for relevant activities conducted throughout FY 2017, including *CollegeAIM* presentations delivered by NIAAA staff and posts on the NIAAA Twitter feed and website. NIAAA has awarded contracts for the management of its website and print publications, and the Institute receives regular reports from its contactors on the number visitors to the *CollegeAIM* website and the number of times the digital *CollegeAIM* booklet was downloaded. These figures are calculated using Google Analytics software. NIAAA contractors also report on the number of print copies of the *CollegeAIM* booklet that have been distributed.

Performance monitoring of support contracts. As with NIH research and development contracts, once a support contract award is made, NIH policies and guidelines are implemented to ensure

oversight of the proposed project aims and program goals. The Federal Acquisition Regulation provides the standardized protocols for monitoring performance-based grants and contracts. Although there are many procedures, a few significant items include the timely submission of progress and final reports. These are assessed by NIH program officials and contracting staff to determine adherence to the approved statement of work. Program officials may work closely with contractors to facilitate adherence, address barriers, and ensure quality programmatic progress.

As a standard performance-based practice, the approved statement of work formulates the requirements of each contact award. The products outlined in the statement of work comprise the deliverables to be provided by the contractor, which are reviewed by NIH contracts staff. The Federal Acquisition Regulation state the specific administrative requirements for project monitoring and enforcement actions when a contractor fails to comply with the requirements of the award. NIH staff monitor progress against the approved statement of work for the project, as well as administrative and fiscal compliance through review of periodic progress reports, publications, correspondence, conference calls, site visits, expenditure data, audit reports (both annual institutional financial reports and project specific reports), and conference proceedings. When a contractor fails to comply with the terms and conditions of an award, enforcement actions are applied. These may include modification to the terms of award, suspension, withholding of support, and termination.

Methodology Used to Establish Targets/Actuals

The targets are established based on the state of the science and public health needs in a particular field. As a result, a target may represent the next logical step for advancing a particular scientific field or initiative, or fulfilling a public health or research need.

Data Sources

Progress reports that outline project accomplishments allow NIH to evaluate progress achieved and/or to make course corrections as needed. NIAAA contractors provide monthly and annual Web metrics reports that document web traffic and downloads, as well as a monthly report documenting the distribution of NIAAA print publications. NIAAA's Twitter feed and website provide records of NIAAA distribution activities through those particular channels. In addition, NIAAA staff conduct searches of their email and calendar entries for relevant talks and presentations they may have given related to the performance targets.

Treatment

Measure SRO-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health systems.

Table 2: NIAAA Annual Targets

FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Target	FY 2017 Actual	FY 2018 Target
NIAAA supported two additional studies to evaluate its youth alcohol screening guide and developed continuing medical education (CME) training through Medscape for physicians, nurses and physicians' assistants.	NIAAA continued to support research to evaluate the underage drinking screening guide in emergency department, juvenile justice, school, and primary care settings, and for youth with chronic conditions.	NIAAA promoted alcohol screening and brief intervention in primary care by offering online continuing medical education (CME) on the underage guide to primary care providers, and by collaborating with federal and non-federal stakeholders to facilitate integration of prevention and early intervention of alcohol misuse in primary care training and practice.	NIAAA encouraged youth alcohol screening and referral to treatment by supporting and promoting continuing medical education training on the use of the guide, organizing or participating in symposia addressing youth alcohol screening, and supporting studies to evaluate the youth screening guide in various settings and populations.	Continue to support studies evaluating screening and brief alcohol interventions in underage or young adult populations.	NIAAA supported a multi-site, school-based study to evaluate *NIAAA's Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*, and another study to evaluate a brief alcohol intervention for adolescents hospitalized for a suicide plan or attempt who report co-occurring alcohol use.	Disseminate findings from studies evaluating the effectiveness of alcohol screening and brief intervention.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

NIAAA has a strong focus on preventing and reducing underage drinking, recognizing the pervasive use of alcohol among young people and the association between early initiation of alcohol use and future alcohol problems. A major focus is to integrate alcohol screening and brief intervention for youth into healthcare practice. Research shows that while many youth are willing to discuss alcohol use with their doctors when assured of confidentiality, too few clinicians follow professional guidelines to screen their young patients. Clinicians often cite insufficient time, unfamiliarity with screening tools, the need to triage competing problems, and uncertainty about how to manage a positive screen, as barriers to alcohol screening. As a result, they may miss the opportunity to express concern about early alcohol use, allow their young

patients to ask questions about alcohol use, and intervene before or after drinking starts or problems develop. NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide* was devised to help health care providers identify risk for alcohol use, current alcohol use, and alcohol use disorder (AUD) in children and adolescents. It includes a brief two-question screener and support materials about brief intervention and referral to treatment that are designed to help surmount common obstacles to youth alcohol screening in primary care. This tool was developed for use in the primary care setting, and NIAAA is supporting research to evaluate its use in primary care and other settings. Recognizing the importance of training health care providers in identifying, preventing, and addressing youth alcohol misuse and the associated consequences, NIAAA partnered with Medscape to develop an online training course based on the guide to familiarize clinicians with the screening and brief intervention process and increase their skill and comfort level with it.

SRO-8.7 is focused on identifying the key factors influencing the scaling up of research-tested interventions across large networks of services systems such as primary care, specialty care and community practice. SRO-8.7 represents NIAAA's long-term strategy for improving AUD treatment nationwide, thereby contributing to the ***2016 National Drug Control Strategy's Goal of: Seek Early Intervention Opportunities in Health Care (Chapter 2)*** **by** ***Evaluating Screening for Substance Use in Healthcare Settings*** **and** ***Enhancing Healthcare Providers' Skills in Screening and Brief Intervention.***

(2) Provide narrative that examines the FY 2017 actual performance results with the FY 2017 target, as well as prior year actuals. If the performance target was not achieved for FY 2017, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The target for FY 2017 was met. NIAAA continued to support studies evaluating screening and brief alcohol interventions in underage populations. In one ongoing study, researchers are performing a multisite, school-based evaluation of *NIAAA's Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*. The evaluation is designed to assess the extent to which the questions in NIAAA's youth screening guide predict current and subsequent alcohol use, alcohol-related problems, and AUD, as well as illicit drug use, sexual risk behavior, and problem behaviors (e.g., aggression, rule breaking), in a diverse sample of 6th, 8th, and 10th graders attending public schools in Miami-Dade County, Florida and the Maryland suburbs of Washington, D.C. The study will also examine the extent to which the validity of the screening tool varies based on contextual factors, such as the density of alcohol outlets near participants' homes and schools, neighborhood socioeconomic factors, family characteristics, as well as the gender and ethnicity of participants.

NIAAA is also supporting the development of a brief alcohol intervention, iASIST (integrated Alcohol and Suicide Intervention for Suicidal Teens), for adolescents hospitalized for a suicide plan or attempt who report co-occurring alcohol use. Alcohol can play a significant role in suicidal ideation and attempts as disinhibition caused by alcohol can increase the likelihood of acting on suicidal thoughts. The iASIST emphasizes the assessment and initial treatment of alcohol use in adolescent inpatient psychiatric settings and involves three components: 1) an

individual intervention with the adolescent using motivational enhancement techniques to explore alcohol use as a risk factor for continued suicide-related thoughts and behaviors, build his or her motivation to reduce or stop drinking, and create a complementary change plan; 2) a family intervention to facilitate a discussion between the adolescent and parent about the change plan and strengthen the adolescent's commitment to the plan and the parent's ability to support the adolescent in their plan; and 3) a post-discharge mobile health "booster" intervention to strengthen the child's commitment to the plan and the parent's ability to support him or her. The investigators are planning to conduct a randomized trial with 50 adolescents and their parents to test the feasibility and acceptability of iASIST, as well as alcohol- and suicide-related outcomes among adolescents three months after discharge from the hospital.

(3) The agency should describe the performance target for FY 2018 and how the agency plans to meet this target. If the target in FY 2017 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2018.

The FY 2018 target is to disseminate findings from studies evaluating the effectiveness of alcohol screening and brief intervention. NIAAA has funded six studies to evaluate its youth alcohol screening guide, and the last of those studies are expected to conclude in FY 2018. NIAAA will work with the researchers leading these and other NIAAA-funded youth screening and brief intervention projects to disseminate the results of these studies to the scientific and public health communities. NIAAA has multiple mechanisms for promoting research findings, including through news releases and scientific presentations at national conferences and workshops, and through engagement with relevant stakeholder groups. For example, NIAAA has an ongoing effort to encourage the integration of addiction medicine into medical care. As part of this effort, NIAAA will continue to work with medical education groups to raise awareness about the effectiveness of alcohol screening and brief intervention and encourage the adoption of evidence-based practices in healthcare settings.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness and Unbiased Presentation

The research field (including health services research) is guided by standard scientific methodologies, policies, and protocols to ensure the validity of its research results. Moreover, NIH has incorporated standardized policies and procedures for making funding announcements, identifying meritorious science, monitoring progress of grantees and scientists in achieving the expected outcomes, and assessing performance at the project's conclusion. Researchers are also expected to publish findings in peer-reviewed journals, which offer another layer of assessment and validation of the findings. In addition, all studies involving human subjects must receive Institutional Review Board (IRB) clearance, yet another form of assessment that ensures the relevance of the study and the safety of the subjects. NIH's research activities implement and practice all scientifically relevant procedures to ensure data quality and to substantiate findings.

In implementing scientific research, NIH uses established tools to develop and oversee programs and improve their performance, proactively monitoring grants, contracts, and cooperative agreements and assessing their individual performance. The following briefly describes the NIH scientific process, which has been assessed by outside entities and is regarded as premier.

Assessment to fund meritorious science (peer review). NIH uses state-of-the-art assessment to determine scientific merit and make funding decisions based on the best science. In general, project plans presented in competing grant applications and contract proposals are subject to three levels of review focused on the strength and innovation of the proposed research, the qualifications of the investigator(s), and the adequacy of the applicant's resources:

- The first level of review, called peer review, ensures that the most meritorious science, as determined by the scientific field's experts, is identified for funding. NIH has over 11,000 external experts participating in peer review panels, each of whom is nationally recognized for his or her area of expertise. The applications are systematically reviewed and scored to inform funding decisions. NIH is one of the few Federal agencies with a legislative requirement for peer review.
- The second level of review is by the Institute's National Advisory Council, which comprises eminent scientists along with members of the general public. The Council serves as a useful resource to keep each Institute abreast of emerging research needs and opportunities, and to advise the Institute on the overall merit and priority of grant applications in advancing the research. All members of Council are appointed by the HHS Secretary.
- The third level of review is by the Institute Director, with input from Institute staff who have relevant expertise. The Director makes the final decision on whether an application will receive funding.

These layers of expert review assessing scientific methodologies and relevance to the field enable funding of the most promising research to advance the field. Consequently, funding decisions made at the agency level are conducted in a consistent, merit-based fashion, guided by scientific methodologies and relevance.

Performance monitoring of research and development grants and contracts. Once an award is made, additional NIH policies and guidelines are implemented to ensure oversight of the proposed project aims and program goals. The NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm) provides the standardized protocols for monitoring performance-based grants and contracts. Although there are many procedures, a few significant items include the timely submission of progress and final reports. These are assessed by NIH program officials and grants management staff to determine adherence to the approved scientific research plan, appropriate cost principles, and legislative requirements. Program officials may work closely with principal investigators to facilitate adherence, address barriers, and ensure quality programmatic progress.

As a standard performance-based practice, the approved scientific aims and objectives formulate the terms and conditions of each grant award and become the focus of scientific monitoring. The NIH Grants Policy Statement, referenced as a term of every award, states the specific

administrative requirements for project monitoring and enforcement actions when a grantee fails to comply with the terms and conditions of the award. NIH staff monitor scientific progress against the approved aims and scope of the project, as well as administrative and fiscal compliance through review of periodic progress reports, publications, correspondence, conference calls, site visits, expenditure data, audit reports (both annual institutional financial reports and project specific reports), and conference proceedings. When a grantee fails to comply with the terms and conditions of an award, enforcement actions are applied. These may include modification to the terms of award, suspension, withholding of support, and termination.

A further checkpoint for programmatic assessment occurs when the applicant requests renewal support to continue a project. A peer review group again assesses the merits of future research plans in light of the progress made during the previous project period, and any problems in grantee performance are addressed and resolved prior to further funding. This process further demonstrates use of assessments to improve performance.

Review of manuscripts. Ultimately, the outcomes of any scientific research are judged based on published results in a peer-reviewed journal. The peer-review publication process is another point in which the quality and innovation of the science undergoes a rigorous evaluation. For most scientific journals, submitted manuscripts are assigned to a staff editor with knowledge of the field discussed in the manuscript. The editor or an editorial board will determine whether the manuscript is of sufficient quality to disseminate for external review and whether it would be of interest to their readership. Research papers that are selected for in-depth review are evaluated by at least two outside referees with knowledge in the relevant field.

Methodology Used to Establish Targets/Actuals

The targets have been established based on the existing protocols. As discussed above, these protocols undergo a rigorous review process to determine which research areas hold the most promise for filling gaps and should therefore be prioritized for testing. The target values are based on sound methodological procedures and related timelines set for each protocol. While these methodologies cannot precisely predict the course of a study, the likely path of implementation and timing is based on knowledge gained from earlier research and will be used to generate the targets for this measure.

Data Sources

Progress reports that outline project accomplishments allow NIH to evaluate progress achieved and/or to make course corrections as needed.

Endnotes Related to Decision Unit 1: NIDA

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