



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



January 8, 2021

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

Nathaniel Davis
Budget 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: /Amy J. Frontz/
Deputy Inspector General for Audit Services

SUBJECT: Independent Attestation Review: National Institutes of Health Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00352)

This report provides the results of our review of the attached National Institutes of Health (NIH) Office of National Drug Control Policy (ONDCP):

- Detailed Accounting Reports, which include the tables of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2020, submitted by NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), respectively;

- Performance Summary Report, which includes management's assertions and related performance information for the fiscal year ended September 30, 2020, submitted by NIH for NIDA and NIAAA, collectively; and
- Budget Formulation Compliance Reports, which includes budget formulation information for the fiscal year ending September 30, 2022¹, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

NIH management is responsible for, and submitted, the Detailed Accounting Report, Performance Summary Report, and Budget Formulation Compliance Report, which were prepared in accordance with the ONDCP Circular *National Drug Control Program Agency Compliance Reviews*, dated October 22, 2019 (ONDCP Circular). It is our responsibility to express a conclusion about the reliability of management's assertions based on our review.

We performed this review as required by 21 U.S.C. § 1704(d)(1) and as authorized by 21 U.S.C. § 1703(d)(7) and in compliance with the ONDCP Circular.

We conducted our review in accordance with attestation standards established by the American Institute of Certified Public Accountants and the standards applicable to attestation engagements, as described in the U.S. Government Accountability Office (GAO) publication, *Government Auditing Standards* (July 2018). Those standards require that we plan and perform the review to obtain limited assurance about whether any material modifications should be made to management's assertions to be in accordance with the criteria. A review is substantially less in scope than an examination, the objective of which is to obtain reasonable assurance and express an opinion about whether management's assertions are in accordance with the criteria in all material respects. Accordingly, we do not express such an opinion. We believe that our review provides a reasonable basis for our conclusion.

Based on our review, we are not aware of any material modifications that should be made to NIH's Detailed Accounting Reports and Performance Summary Report for fiscal year 2020 and NIH's Budget Formulation Compliance Reports for fiscal year 2022 for them to be in accordance with the ONDCP Circular.

NIDA's and NIAAA's Detailed Accounting Reports, NIH's combined Performance Summary Report, and NIDA's and NIAAA's Budget Formulation Report assertions² are included as Attachments A, B, and C, respectively.

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. It is not intended

¹ Although NIAAA's Budget Formulation Compliance Report was provided to ONDCP as of FY20, the budget figures reflect the FY22 funding request.

² Only the Budget Formulation report assertions are included as Attachment C since the report contains prospective information.

to be, and should not be, used by anyone other than those specified parties. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Carla J. Lewis, Assistant Inspector General for Audit Services, at (202) 205-9125 or at Carla.Lewis@oig.hhs.gov. Please refer to report number A-03-21-00352 in all correspondence.

Attachments



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

December 14, 2020

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 Branch
National Institute on Alcohol Abuse and Alcoholism

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O'Connor -S

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Date: 2020.12.14
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SUBJECT: Assertions Concerning Drug Control Accounting

In accordance with the requirements of the Office of National Drug Control Policy Circular "National Drug Control Program Agency Compliance Reviews," 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 7 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 misuse and alcohol use disorder in minors (youth under the legal drinking age of 21). It includes all alcohol related research involving youth, 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 7 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 October 22, 2019.

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM FY 2020 ACTUAL OBLIGATIONS
(Dollars in Thousands)

	FY 2020 Actual
Drug Resources by Decision Unit:	
National Institute on Alcohol Abuse and Alcoholism	<u>\$60,591</u>
Total Drug Resources by Decision Unit	<u>\$60,591</u>
Drug Resources by Function:	
Research and Development: Prevention	\$51,145
Research and Development: Treatment	<u>\$9,446</u>
Total Drug Resources by Function	<u>\$60,591</u>

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 October 22nd, 2019. 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



MEMORANDUM TO: Director
Office of National Drug Control Policy

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

FROM: Nathaniel Davis Nathaniel M. Davis -S
Chief Financial Officer National Institute on Drug Abuse

SUBJECT: Assertions Concerning Drug Control Accounting

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M. Davis -S
Date: 2020.12.03 10:39:02
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In accordance with the requirements of the Office of National Drug Control Policy Circular “National Drug Control Program Agency Compliance Reviews,” 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 National Institute on Drug Abuse’s (NIDA) 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 7 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 2020 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, 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 2020 Enacted budget from the FY 2021 President's Budget (PB) was \$1,457,724,000. In December of 2019, NIDA received the FY 2020 Enacted budget of \$1,462,016,000 (\$1,195,695,000 for direct and \$266,321,000 for research relating to the Opioid Crisis) which was an increase of \$4,292,000 above the FY 2020 CJ. There was an HIV/AIDS transfer in the amount of \$4,292,000. NIDA obligated \$1,457,682,887 of the Annual Appropriation and \$41,113 lapsed.

Application of Drug Methodology

I assert that the drug methodology described in the preceding section was the actual methodology used to generate the table required by Section 7 of the Circular. NIDA has not modified its drug methodology from the previous year. Any differences between NIDA's actual obligations and the National Drug Control Strategy Budget summary number for FY 2020 are described above for the FY 2020 column of the FY 2021 PB.

Material Weaknesses or Other Findings

I assert that that all material weaknesses or other findings by independent sources, which may affect the presentation of prior year drug-related obligations as required by Section 7.a.(4) have been disclosed.

Methodology Modifications

I assert that no modifications were made to methodology for reporting drug control resources

from the previous year's reporting.

Reprogrammings or Transfers

I assert that the data presented are associated with obligations against a financial plan that, if revised during the fiscal year, properly reflects those changes, including ONDCP's approval of all reprogrammings or transfers affecting drug-related resources that individually or in aggregate for the fiscal year exceed \$5 million or 10 percent of a specific program or account included in the National Drug Control Budget (21 U.S.C. § 1703(c)(4)(A)).

Fund Control Notices

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

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 October 22th, 2019. 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 2020 Actual Obligations
(Dollars in Thousands)**

I. RESOURCE SUMMARY - ANNUAL APPROP

	FY 2020 Actual
Drug Resources by Decision Unit:	
National Institute on Drug Abuse	1,457,683
Total	1,457,683
Drug Resources by Function:	
Research and Development Prevention	483,158
Research and Development Treatment	974,525
Total	1,457,683

**Differences Between (1) Actual Obligations and (2) the FY 20 Column of the FY
21 CJ and the National Drug Control Strategy Budget Summary
(Dollars in Thousands)**

Total 2020 Column of the FY 2021 CJ; National Drug Control Strategy	1,457,724
Adjustment for Enacted FY 2020 Budget	5,206
Permissive Transfer	-914
HIV/AIDS Transfer	-4,292
Lapse of Funds	<u>-41</u>
Total Annual Obligations	1,457,683

NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	\$1,419,844	\$1,462,016	\$1,431,770
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-3,249	0	0
Subtotal, adjusted appropriation	\$1,416,595	\$1,462,016	\$1,431,770
OAR HIV/AIDS Transfers	-8,379	-4,292	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$1,408,216	\$1,457,724	\$1,431,770
Unobligated balance, start of year ²	213,124	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,621,340	\$1,457,724	\$1,431,770
Unobligated balance lapsing	-6	0	0
Total obligations	\$1,621,334	\$1,457,724	\$1,431,770

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2019 - \$16,549 FY 2020 - \$12,931 FY 2021 - \$12,850

² Reflects HEAL Initiative funding not obligated in FY 2018, and carried over into FY 2019.

FY 20 Appropriations Language:

<http://docs.house.gov/billsthisweek/20191216/BILLS-116HR1865SA-RCP116-44.PDF>

NIH starts on page 69, NIDA on 72:

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS 16 Act with respect to drug abuse,
\$1,462,016,000.

Current Congressional Justification: http://officeofbudget.od.nih.gov/insti_center_subs.html



DATE: November 25, 2020

MEMORANDUM TO: Associate Director for Performance and Budget
Office of National Drug Control Policy

THROUGH: Office of the Assistant Secretary for Financial Resources
Department of Health and Human Services

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 “National Drug Control Program Agency Compliance Reviews,” I make the following assertions regarding the attached Performance Summary Report:

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 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 -S Digitally signed by James M.
Anderson -S
Date: 2020.11.25 17:29:52 -05'00'

James M. Anderson, MD, PhD
Director, DPCPSI

FY 2020 Performance Summary Report for National Drug Control Activities

Decision Unit 1: National Institute on Drug Abuse (NIDA)

Prevention

Measure SRO-5.2: By 2025, develop or evaluate the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD).

NIDA began reporting on this measure in FY 2020.

Table 1: NIDA Annual Targets

SRO-5.15*			SRO-5.2		
FY 2017 Actual	FY 2018 Actual	FY 2019 Actual	FY 2020 Target	FY 2020 Actual	FY 2021 Target
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.	The effect of an intervention to prevent prescription drug abuse in youth and young adult populations was tested, and several ongoing studies are assessing the efficacy or effectiveness of strategies to prevent prescription drug abuse in this target population.	NIDA supported at least three projects focused on developing, tailoring and/or adapting interventions to prevent prescription drug misuse and/or OUD in older adolescent and young adult populations.	Conduct 3-5 pilot studies to test the efficacy of promising prevention interventions for SUD.	Nine prevention pilot studies were conducted as part of the HEAL.	Launch 1-2 clinical trials, based on pilot study results, to test the effects of a prevention intervention for opioid use disorder.

*NIDA’s contribution to SRO-5.15 (By 2025, 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) ended in FY 2019 as planned.

(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 (SUD) across different developmental stages.

FY 2020 Performance Summary Report for National Drug Control Activities

Understanding the mechanisms through which these factors influence substance use and addiction across individuals is critical for designing more effective prevention strategies. SRO-5.2 focuses on developing or evaluating the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD) and contributes to the objective of “Enhancing Research and the Development of Evidence-Based Prevention Programs” in the [2020 National Drug Control Strategy](#). NIDA’s prevention efforts, in particular, advance the goal of supporting the research and development of innovative technologies and additional therapies to prevent addiction.

Preventing the initiation of substance use and minimizing the risks of harmful consequences of substance use is an essential part of addressing SUD. To this end, NIDA funds a portfolio of prevention research to understand and intervene upon mechanisms that underlie risk and resilience for addiction and common comorbidities. NIDA’s prevention research portfolios encompass a broad range of research on how biological, psychosocial, and environmental factors operate to enhance or mitigate an individual’s propensity to initiate substance use or to escalate from use to misuse to SUD across different developmental stages. This information, along with rapidly 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) risk and protective factors. NIH-supported research is building the scientific knowledge base needed to advance our goal of developing effective and efficient prevention strategies.

As such factors are identified, NIDA also supports research to develop and test innovative prevention interventions that target underlying risk and protective factors, as well as strategies for effectively and sustainably implementing evidence-based prevention interventions. One example is a multi-site collaborative project between NIDA, CDC, SAMHSA and the Appalachian Regional Commission that works with communities to reduce opioid use and its consequences, with the goals of increasing uptake of evidence-based practices, including medication-assisted treatment (MAT), HIV/hepatitis C screening, and overdose prevention.

A robust evidence base exists for a variety of prevention interventions, including:

- School-based models, such as Life Skills Training, that help students develop social, emotional, cognitive, and substance refusal skills;
- Family-based models, such as Strong African American Families, that provide parents with tools and practices that help their children learn problem-solving and self-regulation skills to support healthy social and emotional development; and
- Implementation frameworks, such as Communities That Care that engages a coalition of local community organizations and leaders to identify and intervene on local risk and protective factors.

These prevention models have proven effective, but more research is required to determine whether new interventions are required to impact targets specific to the prevention of non-medical use of opioids and opioid use disorder (OUD), particularly during the transition from adolescence to young adulthood initiation of opioid misuse. In response to this need, NIDA’s

FY 2020 Performance Summary Report for National Drug Control Activities

Division of Epidemiology, Services, and Prevention Research (DESPR) is supporting a series of studies to develop and test effective strategies to prevent opioid misuse and OUD among older adolescents and young adults. The focus of these studies is on strategies within settings that can identify and reach at-risk individuals and populations, such as health care, justice, school, and child welfare systems.

In addition to opioid-focused efforts, DESPR supports research on integrating prevention and treatment services into healthcare and community systems to reduce the burden of drug problems across the lifespan. DESPR supports prevention specific portfolios of research and training grants that span efficacy, effectiveness and services-related questions. Within DESPR, the Prevention Research Branch (PRB) cultivates research to understand mechanisms of action of effective prevention approaches, to develop preventive interventions for understudied populations, and to address emerging public health crises. In addition to opioid related research, PRB funds research to develop and test interventions to address factors underlying risk for substance misuse while also enhancing protective factors.

(2) Provide narrative that examines the FY 2020 actual performance results with the FY 2020 target, as well as prior year actuals. If the performance target was not achieved for FY 2020, 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 2020 target was met. NIDA funded nine prevention pilot studies that were conducted in FY 2020, under the auspices of the Helping to End Addiction Long-term (HEALSM) Initiative. These grants used the two-phase, milestone-based UG3-UH3 grant mechanism, which allows for grants that successfully complete pilot-study progress milestones to apply to advance into larger clinical studies. Of those nine pilot studies, seven completed their pilots and were eligible for transition. (Two of the studies had planned for two-year pilot phases, so were not eligible for transition.) Three of the seven transitioning studies are highlighted as examples below.

One transitioning study involves modifying an existing alcohol and drug prevention intervention designed for American Indian/Alaska Native youth to be appropriate for opioid prevention in young adults¹. The study conducted focus groups to determine how best to engage the target population, adapted and enhanced the intervention to specifically address opioid use, and pilot-tested the intervention. The scaled-up study will test the intervention in larger groups over a 12-month period, examine the mechanisms by which it produces change, and explore approaches to making it sustainable over time.

Another transitioning study is focused on preventing OUD among adolescents/young adults ages 18-24 years experiencing homelessness, and explores whether providing housing in addition to opioid and related risk reduction services could improve outcomes². The pilot study demonstrated feasibility of recruitment, locating housing and placement into housing, and

¹ UH3 DA050235-01: Development and Implementation of a Culturally Centered Opioid Prevention Intervention for American Indian/Alaska Native Young Adults in California

² UH3 DA050174-02: Prevention of OUD: The HOME (Housing, Opportunities, Motivation and Engagement) Randomized Trial

FY 2020 Performance Summary Report for National Drug Control Activities

delivery of prevention services through strengths-based outreach and advocacy. Partnerships with community-based homeless youth service providers and landlords have been established for the post-pilot phase, housing has been identified, and Institutional Review Board (IRB) approval has been obtained. The scaled-up study will compare individuals randomly assigned to receive housing alongside opioid and related risk prevention services to individuals who receive those services alone.

A third study developed a plan to leverage technology that is appealing to adolescents and young adults to facilitate delivery of an emergency department-based intervention via health coaches. In their transitioning pilot, researchers were able to adapt promising health coach-delivered interventions³ and pilot test feasibility/acceptability in adolescents and young adults, as well as actively engage hospital administration leadership in the study. As the project transitions to the next phase, it will begin testing the intervention in a sample of over 1,000 adolescents and young adults in emergency department settings.

(3) The agency should describe the performance target for FY 2021 and how the agency plans to meet this target. If the target in FY 2020 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2021.

The FY 2021 target is to launch 1-2 clinical trials, based on pilot study results, to test the effects of a prevention intervention for opioid use disorder. As stated above, of the nine pilot studies funded in FY 2020, seven reached their milestones and were eligible for transition into clinical trials, with others likely to do so in the next year. NIDA awarded these transition grants at the end of FY 2020, and expects the relevant trials to begin in FY 2021, which should allow the target to be met.

(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. 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

³ UH3 DA050173-01: Optimized Interventions to Prevent Opioid Use Disorder among Adolescents and Young Adults in the Emergency Department

FY 2020 Performance Summary Report for National Drug Control Activities

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 rigorous 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](#) 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

FY 2020 Performance Summary Report for National Drug Control Activities

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 of 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 at 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 about novelty, interest, or relative merit. If a paper is rejected on the basis of serious reviewer error, the journal may consider a resubmission.

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

Each grantee provides an annual progress report that outlines past-year project accomplishments, including information on patients recruited, providers trained, patents filed, manuscripts

FY 2020 Performance Summary Report for National Drug Control Activities

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.

FY 2020 Performance Summary Report for National Drug Control Activities

Treatment

Measure SRO-4.9: By 2023, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD).

NIDA began reporting on this measure in FY 2019.

Table 2: NIDA Annual Targets

SRO-7.3*		SRO-4.9			
FY 2017 Actual	FY 2018 Actual	FY19 Actual	FY 2020 Target	FY 2020 Actual	FY 2021 Target
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.	Research testing the feasibility and efficacy of 2 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including (1) reSET-O which is under expedited review by FDA and (2) a web-delivered cognitive behavior therapy for veterans who screen positive for PTSD and SUD.	A pre-clinical study of a novel opiate withdrawal therapy was conducted, and a clinical trial of a therapy for both opioid withdrawal and associated insomnia was also conducted.	Conduct one pre-clinical and one clinical study of a longer acting formulation of a medication for the treatment of OUD or opioid overdose.	NIDA conducted a pre-clinical development study of a novel long-acting formulation of nalmefene for treating OUD, and a clinical study of a novel long-acting implant that delivers naltrexone, an effective treatment for OUD.	Conduct a Phase I clinical trial of an anti-opioid vaccine and a new medication to treat OUD.

*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) was replaced by SRO-4.9 in FY 2019 to reflect the Institute's enhanced focus on finding new or improved strategies for treating OUD.

(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.

Opioid misuse, addiction, and overdose is an ongoing and rapidly evolving public health crisis. Millions of Americans have an OUD, and millions more suffer from chronic pain. There are multiple factors that contribute to poor treatment uptake for OUD, and NIDA is taking a multi-pronged approach to mitigate these factors. NIDA is playing a major role in the HEAL Initiative, launched in April 2018 to provide scientific solutions to the national opioid overdose crisis, including improved treatment strategies for pain as well as OUD. This Congress-funded initiative brings new hope for people, families, and communities affected by this devastating crisis. This measure reflects NIDA's commitment to finding innovative solutions to this crisis, and contributed to the objectives of "Improving the Response to and Monitoring of Overdose" and "Enhancing Evidence-Based Addiction

FY 2020 Performance Summary Report for National Drug Control Activities

Treatment” in the [2020 Strategy](#).

(2) Provide narrative that examines the FY 2020 actual performance results with the FY 2020 target, as well as prior year actuals. If the performance target was not achieved for FY 2020, 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 2020 target was met. NIDA funded⁴ the pre-clinical development of a new implant that will deliver nalmefene, a drug that blocks opioid signaling, over a six-month period. The goal is to advance this compound to be tested in humans for the prevention of relapse to opioid addiction in patients following opioid detoxification. This long-acting formulation will use the Proneura® technology that has been successful in an FDA-approved long-acting formulation of buprenorphine. This long-acting nalmefene is completing the necessary nonclinical safety, toxicology, pharmacokinetic and manufacturing activities to start studies in humans (clinical trials) and begin the process of applying for FDA approval.

In FY 2020, NIDA also funded⁵ a clinical trial to evaluate the safety and efficacy of GM0017, an implant that delivers the opioid antagonist naltrexone for six months. This compound is being developed for prevention of opioid relapse in individuals with OUD who have been detoxified. Recruitment for this study has been delayed due to COVID-19, but it is expected that clinical results will soon be presented to the FDA.

(3) The agency should describe the performance target for FY 2021 and how the agency plans to meet this target. If the target in FY 2020 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2021.

The FY 2021 target is to conduct a Phase I clinical trial of an anti-opioid vaccine and a new medication to treat OUD. Based on its investments in focused medications development under the HEAL Initiative, NIDA expects that these trials will be conducted in FY 2021.

(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

⁴ UG3DA047707 “Nalmefene Implant for the Long-Term Treatment of Opioid Use Disorder”
https://projectreporter.nih.gov/project_info_description.cfm?aid=9778798&icde=52216417

⁵ UG3DA047720 “Evaluation of Safety and Pharmacokinetics of Naltrexone Implant”
https://projectreporter.nih.gov/project_info_description.cfm?aid=9778810&icde=52216423&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=

FY 2020 Performance Summary Report for National Drug Control Activities

As described above, the research field 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.

Data Sources

For SRO-4.9's FY 2020 target, NIDA relied on annual progress reports provided by each grantee that outlined past-year project accomplishments, such as information on patients recruited, providers trained, patents filed, manuscripts published, and other supporting documentation. This information allowed NIH to evaluate progress achieved and to make course corrections when needed.

FY 2020 Performance Summary Report for National Drug Control Activities

Decision Unit 2: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Prevention

Measure SRO-5.15: By 2025, 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 2017 Actual	FY 2018 Actual	FY 2019 Actual	FY 2020 Target	FY 2020 Actual	FY 2021 Target
NIAAA promoted and disseminated <i>CollegeAIM</i> and initiated efforts to update <i>CollegeAIM</i> to reflect the latest evidence-based alcohol interventions.	Researchers supported by NIAAA developed and evaluated the effects of combined individual- and community-level interventions to reduce underage drinking by Native American youth on rural California reservations.	Researchers demonstrated the efficacy of interventions involving brief motivational interviewing and a supplemental activity for reducing alcohol misuse among college age individuals.	Develop a digital technology-based intervention to prevent or reduce alcohol misuse in underage individuals.	Researchers developed and tested three technology-based interventions to prevent and reduce underage drinking.	Disseminate information about evidence-based interventions for underage populations.

(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.

Alcohol use is commonly initiated during adolescence, a developmental period characterized by complex social, physiological, behavioral, and neurobiological changes. Adolescents are especially vulnerable to the adverse consequences of alcohol use. The brain, particularly the frontal cortex, continues to develop throughout adolescence, reaching maturity around age 25. A growing body of evidence demonstrates that 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 consumption also increases the risk for other adverse outcomes such as blackouts, physical and sexual assault, unsafe 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. NIAAA's underage alcohol prevention efforts focus on risk assessment and screening, universal and selective prevention, and early intervention (i.e., before problems escalate and/or become chronic). NIAAA supports research on a range of preventive

FY 2020 Performance Summary Report for National Drug Control Activities

interventions at the individual-, school/college-, family-, community-, and policy-level in support of this effort. Many intervention strategies involve an educational component in which information about consequences of underage drinking is shared with participants, thereby contributing to the objective of “Enhancing Research and the Development of Evidence-Based Prevention Programs” in the [2020 Strategy](#).

(2) Provide narrative that examines the FY 2020 actual performance results with the FY 2020 target, as well as prior year actuals. If the performance target was not achieved for FY 2020, 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 2020 target was met. NIAAA-funded researchers developed and evaluated digital technology-based interventions to prevent or reduce alcohol misuse among underage college and high school students.

Research indicates that perceived norms about alcohol use are a strong correlate of alcohol misuse that predict alcohol consumption over time. Perceived norms among college students tend to be exaggerated relative to actual drinking norms and may have adverse effects on both individuals and the community. NIAAA-supported researchers recently created a text messaging intervention for heavy drinking, underage college students that was designed to realign perceived drinking norms with actual drinking norms of their campus peers. Heavy drinking in the study was defined as more than four drinks per day or more than 14 drinks per week for males, and more than three drinks per day or more than seven drinks per week for females in the past 30 days. Participants were assigned to either an experimental or control condition. The experimental group received text messages containing information about campus-specific drinking norms while the control group received text messages containing unique facts unrelated to alcohol. Text messages were sent daily to participants over a period of 10 weeks. The intervention was shown to be effective at reducing peak alcohol consumption and alcohol-related consequences three months after the beginning of the study. These intervention effects, however, were not maintained another three months later. This study demonstrates the feasibility of text-based norms interventions in reducing alcohol use and its consequences around the time of engagement with the intervention.

In FY 2020, NIAAA also supported research to develop and test digital, school-based interventions aimed at preventing and reducing alcohol use among high school students. One ongoing study focuses on developing and testing the efficacy of an e-learning intervention to improve school staff’s knowledge, skills, and self-efficacy in supporting sexual minority youth and protecting them from bullying victimization. Prior research has demonstrated that sexual minority youth have an increased risk of future alcohol and other substance use and supportive school environments can help reduce substance use.

Another school-based study recently demonstrated that eCHECKUP TO GO is effective in reducing alcohol-related cognitive risk factors and alcohol use in both male and female high school seniors. eCHECKUP TO GO is a brief, web-based personalized feedback intervention designed to reduce alcohol use by targeting cognitive risk factors (e.g., perceived drinking norms

FY 2020 Performance Summary Report for National Drug Control Activities

among peers) and protective behavioral strategies (e.g., behaviors that minimize the risk of alcohol-related consequences).

In combination with the FY 2019 actual performance which demonstrated the efficacy of interventions designed to prevent alcohol misuse among college-age individuals, the digital interventions described above contribute to the Institute's goal of evaluating and promoting evidence-based intervention strategies to prevent substance misuse in underage populations.

References

- Carey KB, Merrill JE, Boyle HK, Barnett NP. Correcting exaggerated drinking norms with a mobile message delivery system: Selective prevention with heavy-drinking first-year college students. *Psychol Addict Behav*. 2020 May;34(3):454-464. doi: 10.1037/adb0000566.
- Doumas GM, Esp S, Turrisi R, Bond L, Flay B. Efficacy of the eCHECKUP TO GO for high school seniors: sex differences in risk factors, protective behavioral strategies, and alcohol use. *J Stud Alcohol Drugs*. 2020 Mar;81(2):135-143. doi: 10.15288/jsad.2020.81.135.
- Developing and piloting a school staff-based intervention to reduce alcohol and drug use among sexual minority youth. K01AA027564.
https://projectreporter.nih.gov/project_info_description.cfm?aid=9928861&icde=52127944

(3) The agency should describe the performance target for FY 2021 and how the agency plans to meet this target. If the target in FY 2020 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2021.

The FY 2021 target is to disseminate information about evidence-based interventions for underage populations. Disseminating evidence-based information is a key component of NIAAA's mission and the Institute will pursue multiple strategies for sharing evidence-based information to prevent underage drinking in FY 2021.

(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 field of alcohol 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

FY 2020 Performance Summary Report for National Drug Control Activities

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](#) 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.

FY 2020 Performance Summary Report for National Drug Control Activities

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. Peer-reviewed publications are also used as indicators of performance.

FY 2020 Performance Summary Report for National Drug Control Activities

Treatment

Measure SRO-4.15: By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations.

NIAAA began reporting on this measure in FY 2019.

Table 2: NIAAA Annual Targets

SRO-8.7*		SRO-4.15			
FY 2017 Actual	FY 2018 Actual	FY 2019 Actual	FY 2020 Target	FY 2020 Actual	FY 2021 Target
NIAAA supported a multi-site, school-based study to evaluate <i>NIAAA's Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide</i> , and another study to evaluate a brief alcohol intervention for adolescents hospitalized for a suicide plan or attempt who report co-occurring alcohol use.	NIAAA-supported investigators published research findings from an evaluation of NIAAA's Youth Guide, and NIAAA staff disseminated information about studies evaluating the effectiveness of alcohol screening and brief intervention.	Researchers supported by NIAAA tested NIAAA's Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide's two-question screening tool to determine its predictive ability in identifying future risk for alcohol-related problems in an underage population.	Test a behavioral therapy for intervening with alcohol misuse in an underage population.	Researchers tested the effectiveness of multiple behavioral interventions for reducing alcohol use and other harmful behaviors in underaged incarcerated and homeless youth.	Test another behavioral therapy for intervening with alcohol misuse in an underage population.

*NIAAA's contribution to SRO-8.7 (By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health systems) ended in 2018 as planned.

(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 supports efforts to facilitate treatment of alcohol misuse in underage populations, from integration of alcohol screening and brief intervention for youth into routine healthcare to evaluation of interventions to reduce alcohol misuse in youth and adolescent populations. Research shows that while many youths are willing to discuss alcohol use with their doctors when assured of confidentiality, too few clinicians conduct alcohol screening with 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. 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

FY 2020 Performance Summary Report for National Drug Control Activities

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. NIAAA is supporting research to evaluate the use of the *Guide* in primary care as well as in other settings and encourages new studies to improve the effectiveness and uptake of alcohol screening and brief intervention. NIAAA is also developing a resource that will contain information that every health professional should know about alcohol to help them better recognize its effects in their patients and deliver improved care for those whose drinking may be affecting their health.

SRO-4.15 is focused on the evaluation of treatment interventions for alcohol misuse in underage populations. This measure contributes to the objective of “Enhancing Evidence-Based Addiction Treatment” in the [2020 Strategy](#). The development of evidence-based interventions for alcohol-related problems is a major priority for NIAAA, and the Institute’s underage drinking portfolio includes research projects that are developing and testing behavioral and other therapies for intervening with underage drinking.

(2) Provide narrative that examines the FY 2020 actual performance results with the FY 2020 target, as well as prior year actuals. If the performance target was not achieved for FY 2020, 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 2020 target was met. NIAAA-supported researchers evaluated a treatment invention in an underage, incarcerated population. Research suggests that combining evidence-based behavioral interventions – e.g., motivational interviewing plus cognitive behavior therapy (MI/CBT) – that focus on motivation, problem-solving, communication, mental health, and substance use may be useful in improving outcomes for incarcerated youth. In the current study, NIH-supported researchers conducted a randomized controlled clinical trial to evaluate the effectiveness of MI/CBT in mitigating alcohol and marijuana use and aggression among incarcerated youth. The control condition, RT/SET, was a combined intervention consisting of relaxation training (a mindfulness approach) and treatment as usual (substance-education and twelve step programming). Eligibility criteria included using alcohol or marijuana at least monthly; heavy drinking (defined as more than five standard drinks for boys, more than four standard drinks for girls) at least once; or alcohol or marijuana use in the four weeks before either the offense for which they were incarcerated, or before they were incarcerated. The researchers found RT/SET to be slightly more effective than MI/CBT in reducing percent of heavy drinking days and significantly more effective in reducing alcohol-related aggression after the youths’ release from incarceration. RT/SET and MI/CBT both reduced aggression after release but neither showed significant effects on marijuana-related behavioral outcomes. These results suggest that RT/SET may be a viable, lower-cost intervention for delivery in youth correctional settings; however, additional research on RT/SET is needed.

Homeless youth have high rates of alcohol and other substance use which is associated with unsafe sexual behavior. In FY 2020, NIAAA supported an ongoing study that is conducting a large-scale evaluation of AWARE, a brief motivational interviewing-informed group risk reduction intervention focused on reducing alcohol and other substance use and sexual risk

FY 2020 Performance Summary Report for National Drug Control Activities

behaviors among homeless individuals aged 18-25. AWARE is being evaluated in settings where homeless youth often seek health-related and other services.

NIAAA is making progress toward facilitating treatment for alcohol misuse in underage populations, from development and evaluation of screening and brief intervention tools (FY 2019 actual performance) to evaluation of treatment interventions that target alcohol and other substance use in vulnerable underage populations as described above.

References

- Stein LAR, Martin R, Clair-Michaud M, Lebeau R, Hurlbut W, Kahler CW, Monti PM, Rohsenow D. A randomized clinical trial of motivational interviewing plus skills training vs. Relaxation plus education and 12-Steps for substance using incarcerated youth: Effects on alcohol, marijuana and crimes of aggression. *Drug and Alcohol Dependence*. 2020 Feb 1;207:107774. doi: 10.1016/j.drugalcdep.2019.107774.
- Brief group MI intervention for AOD and sexual risk behavior in homeless youth. R01AA025641.
https://projectreporter.nih.gov/project_info_description.cfm?aid=9915820&icde=52125688

(3) The agency should describe the performance target for FY 2021 and how the agency plans to meet this target. If the target in FY 2020 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2021.

The FY 2021 target is to test another behavioral therapy for intervening with alcohol misuse in an underage population. Behavioral interventions have the potential to reduce alcohol misuse and the associated consequences among youth and adolescents. NIAAA anticipates meeting this target as the Institute currently supports multiple projects that involve evaluating behavioral therapies, such as motivational interviewing, motivational enhancement, and cognitive-behavioral therapy, in adolescent populations.

(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 field of alcohol 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 programs and improve performance. These tools have been described in response to question 4 above.

Data Sources

FY 2020 Performance Summary Report for National Drug Control Activities

Progress reports that outline project accomplishments allow NIH to evaluate progress achieved and/or to make course corrections as needed. Peer-reviewed publications are also used as indicators of performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of HealthNational Institute on Alcohol
Abuse and Alcoholism 5635
Fishers Lane
Bethesda, MD 20892-9304

December 15, 2020

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 Branch
National Institute on Alcohol Abuse and AlcoholismJudit
O'Connor -SDigitally signed by Judit
O'Connor -S
Date: 2020.12.15
10:10:27 -05'00'**SUBJECT:** Budget Formulation Compliance Report for FY 2020

In accordance with the requirements of the Office of National Drug Control Policy (ONDCP) Circular: *National Drug Control Program Agency Compliance Reviews*, dated October 22, 2019, I make the following assertions regarding the attached Budget Formulation Compliance Report:

Timeliness of Summer Budget Submission

I assert that the summer drug budget submitted to ONDCP under the cover letter provided in response to Section 6.a.(1) in response to ONDCP Circular: Budget Formulation, Section 9.a.(1) was provided to ONDCP at the same time as the budget request was submitted to our superiors in accordance with 21 U.S.C. § 1703(c)(1)(A).

Funding Levels Represent Bureau-Level Request

I assert that the funding request in the submission provided in Section 6.a.(2) of this circular represent the funding levels in the budget submission made by the bureau to the Department without alteration or adjustment by any official at the Department.



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: Nathaniel Davis
Chief Financial Officer
National Institute on Drug Abuse

SUBJECT: National Institute on Drug Abuse
Budget Formulation Compliance Report for FY 2022

Nathaniel
M. Davis -S

Digitally signed by
Nathaniel M. Davis -S
Date: 2020.12.09
14:41:28 -05'00'

In accordance with the requirements of the Office of National Drug Control Policy (ONDCP) Circular: National Drug Control Program Agency Compliance Reviews, dated October 22, 2019, I make the following assertions regarding the attached Budget Formulation Compliance Report:

Timeliness of Summer Budget Submission

I assert that the summer drug budget in response to ONDCP Circular Budget formulation, Section 9.a.(1) was provided to the NIH Office of Budget who then provided it to ONDCP in accordance with 21 U.S.C. § 1703(c)(1)(A).

Funding Levels Represent Bureau-Level Request

I assert that the funding request in the submission provided to the NIH Office of Budget represents the funding levels in the budget submission made by the National Institute on Drug Abuse without alteration or adjustment by any official at the Department.