

	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Drug Resources by Budget Decision Unit and Function:			
Decision Unit 1: National Institute on Drug Abuse			
Research and Development: Prevention	\$380.513	\$385.002	\$404.176
Research and Development: Treatment	\$690.300	\$698.443	\$733.227
Total, Decision Unit 1	\$1,070.813	\$1,083.445	\$1,137.403
Decision Unit 2: National Institute on Alcohol Abuse and Alcoholism			
Research and Development: Prevention	\$45.504	\$45.281	\$44.240
Research and Development: Treatment	\$5.134	\$4.883	\$4.441
Total, Decision Unit 2	\$50.638	\$50.164	\$49.011
Total Funding	\$1,121.451	\$1,133.609	\$1,186.414
Drug Resources Personnel Summary			
Total FTEs (direct only)	380	382	382
Drug Resources as a Percent of Budget			
Total Agency Budget (in Billions)	\$34.2	\$34.1	\$34.8
Drug Resources percentage	3.28%	3.33%	3.41%

Program Summary

MISSION

The National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), two of NIH's Institutes and Centers, support *the National Drug Control Strategy*:¹ NIDA, by funding research on the prevention and treatment of drug use, addiction, and its harmful consequences; and NIAAA, by funding research on the prevention and treatment of underage drinking and its harmful consequences.

The societal impact of the misuse of illicit drugs in 2007 was estimated at \$193 billion in health care, crime-related, and productivity losses.² Knowledge is the foundation of the transformative agenda needed to strike at the heart of this stubborn and costly challenge. To provide a comprehensive public health response, NIDA will continue to build on science advances from the Institute's investments in genetics, neuroscience, pharmacotherapy, and behavioral and health services research that have led to innovative strategies for preventing and treating substance use disorders (SUDs) in this country and worldwide.

Studying drug use, SUDs, and their causes is a complex challenge compounded by societal stigma and misunderstanding that most other illnesses do not face. The landscape of drug

¹ <https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs>

² U.S. DOJ National Drug Intelligence Center. *The Economic Impact of Drug Use in American Society*. April 2011

addiction in America evolves from year to year; we are currently seeing the terrible results of a decades-long epidemic of prescription drug misuse that is leading to a rise in heroin use as well as new HIV and Hepatitis C outbreaks. A growing number of states are legalizing marijuana for medical or recreational use, producing natural experiments whose outcomes cannot yet be predicted. New synthetic drugs as well as new delivery systems such as electronic cigarettes (e-cigarettes) are changing how people use drugs. NIDA is supporting research to address today's drug use-related challenges in several key areas, including supporting the Secretary of HHS to respond to opioid abuse and overdose; spearheading a landmark longitudinal study of adolescent substance use and brain development³; studying the impact of the changing marijuana landscape⁴; studying the impact of new synthetic drugs⁵; and contributing to scientific and public understanding of the brain mechanisms underlying addiction.

Alcohol misuse has profound effects on the health and well-being of individuals, families, and communities, and costs the United States \$249 billion per year.⁶ Since its creation, NIAAA has led the national effort to define alcohol problems as medical in nature and address them using evidence-based findings. The research supported by the Institute has transformed the understanding and treatment of alcohol misuse and its consequences, including alcohol use disorder (AUD). NIAAA is working to reduce the considerable burden of alcohol misuse for individuals at all stages of life by supporting research on: the neurobiological mechanisms underlying alcohol misuse, AUD, and co-occurring disorders; fetal alcohol spectrum disorders; the effects of alcohol misuse on the developing adolescent brain and on other tissues and organs; the development of strategies to prevent and treat alcohol misuse and its consequences. NIAAA also supports efforts to translate and implement research findings into improved health care for individuals with AUD and with co-occurring conditions, as well as to disseminate research-based information to health care providers, researchers, policy makers, and the public.

METHODOLOGY

NIDA's entire budget is drug-related and scored as a part of the National Drug Control Budget.

The prevention and treatment components of NIAAA's underage drinking research program are scored as a part of the national drug control budget. Underage drinking research is defined as research that focuses on alcohol use by youth (individuals under the legal drinking age of 21), as well as the negative consequences of underage alcohol use (e.g., alcohol-related injuries, impact on adolescent development, including on the developing brain, and risk for AUD).⁷ It includes basic research, epidemiological studies, behavioral research, screening and intervention studies,

³ NIDA ABCD Study description: <https://www.drugabuse.gov/related-topics/adolescent-brain/longitudinal-study-adolescent-brain-cognitive-development-abcd-study>

⁴ NIDA's marijuana research is described here: <https://www.drugabuse.gov/drugs-abuse/marijuana/nida-research-marijuana-cannabinoids>

⁵ NIDA NDEWS System: <https://www.drugabuse.gov/related-topics/trends-statistics/national-drug-early-warning-system-ndews>

⁶ Sacks, J. J., Gonzales, K. R., Bouchery, E. E., Tomedi, L. E., & Brewer, R. D. (2015). 2010 national and state costs of excessive alcohol consumption. *American Journal of Preventive Medicine*, 49(5), e73-e79.

⁷ U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking. U.S. Department of Health and Human Services, Office of the Surgeon General, 2007.

and the development and testing of preventive interventions. NIAAA's methodology for developing budget estimates for the *Budget and Performance Summary* is a two-step process. First, NIAAA identifies its underage drinking projects using NIH's automated, electronic text mining system for research, condition, and disease categorization. Once all underage drinking projects are identified through this process, NIAAA conducts a manual review of the project listing and identifies only those projects and amounts that are relevant to prevention and treatment. This is used to generate the NIAAA drug control budget estimate.

BUDGET SUMMARY

The FY 2019 President's Budget request for drug-related activities at NIH is \$1,186.4 million (\$1,137.4 million for NIDA and \$49.0 million for NIAAA), an increase of \$52.8 million compared with the FY 2018 Annualized CR level.

NIH-supported research has and will continue to provide the scientific basis for budget policy. For example, NIH continues to explore the many biological, behavioral, and environmental influences on drug addiction vulnerability, which will allow the development of more targeted and effective prevention approaches. Research reveals that universal prevention programs not only reduce drug use, underage drinking, and other risky behaviors that can lead to HIV and other adverse outcomes, but can also promote other positive outcomes, such as strengthening young people's sense of community or "connection" to school—key to reducing substance misuse, violence, and mental health problems.

Another top priority continues to be the development of therapeutic interventions to treat SUDs, including medications, biologics, and non-pharmacological interventions such as transcranial magnetic stimulation or neurofeedback. NIH is now poised to capitalize on a greater understanding of the neurobiology underlying addiction, and of newly identified candidate molecules and brain circuits that show promise as potential targets for the treatment of SUDs. NIH is also exploring ways of improving the dissemination and implementation of evidence-based practices (implementation science) in real world settings to improve the prevention and treatment of SUDs and co-occurring conditions such as HIV, thereby enhancing the public health impact of NIH-supported research.

National Institute on Drug Abuse

FY 2019 Request: \$1,186.4 million
(\$53.9 million above the FY 2018 Annualized CR level)

NIDA's efforts consist of Neuroscience and Behavioral Research; Epidemiology, Services and Prevention Research; Pharmacotherapies and Medical Consequences; Clinical Trials Network; Intramural Research Program (IRP); and Research Management and Support (RMS).

Neuroscience and Behavior Research

The Division of Neuroscience and Behavior (DNB) seeks to expand our understanding of the fundamental neurological, genetic/epigenetic, and behavioral processes that underlie SUDs.

Central to this goal are efforts to delineate the multiple neurobiological factors that contribute to drug use and addiction risk, with particular emphasis on individual differences in vulnerability and drug sensitivity. NIDA is supporting research to develop advanced technologies that improve our ability to study the organization of the living brain from cells to networks. This is helping to elucidate the interactions of complex neural circuits and how they encode reward, craving, compulsive behavior, and related decision making that drive substance use. Ongoing pharmacological research is developing and testing new compounds that target the neurobiological factors that underlie addiction, as is research on the development of novel non-pharmacological strategies such as transcranial magnetic stimulation (TMS), transcranial direct current stimulation (tDCS), deep brain stimulation (DBS), and neurofeedback. NIDA also supports research on the interactions between HIV infection and addiction to understand how this comorbidity influences outcomes for both illnesses. Finally, NIDA is working to support big data science to promote efficient analysis of large, diverse data sets on a scale not previously possible. Collectively, this research will provide new perspectives on the effects of drugs on multiple biological systems and improve our understanding of the basic neural and genetic mechanisms that underlie drug use and addiction, thus guiding the development of novel therapies for treating addiction.

In addition, under the Collaborative Research on Addiction at the NIH (CRAN) initiative, NIDA and NIAAA, along with other components of NIH and the Centers for Disease Control and Prevention, are supporting a longitudinal study to examine the neurodevelopmental consequences of substance use. The Adolescent Brain Cognitive Development (ABCD) study will follow the biological and behavioral development of more than 10,000 children beginning at ages 9-10 through adolescence into early adulthood. Over the course of the next decade, scientists will use advanced brain imaging, interviews, and behavioral testing to determine how childhood experiences interact with each other and with a child's changing biology to affect brain development and—ultimately—social, behavioral, academic, health and other outcomes. Understanding these relationships may help reveal the biological and environmental building blocks that contribute to successful and resilient young adults. This enhanced knowledge also may lead to ways to predict potential developmental problems including mental illness and SUD so that they can be prevented or reversed. Families that volunteer will be part of groundbreaking research that promises to inform future substance use prevention strategies, educational priorities, child development innovations, research priorities, and public health interventions.

Epidemiology, Services, and Prevention Research

NIDA's Division of Epidemiology, Services, and Prevention Research (DESPR) supports integrated approaches to understanding and developing strategies to address the interactions between individuals and environments that contribute to drug use, addiction, and related health problems. The Division supports the annual Monitoring the Future survey, which tracks drug use and related attitudes among adolescent students nationwide, and the National Drug Early Warning System (NDEWS), a surveillance network that monitors emerging trends related to illicit drug use around the country so that rapid, informed, and effective public health responses can be developed and implemented when and where they are needed. DESPR also supports research on integrating prevention and treatment services into healthcare and community systems to reduce the burden of drug problems across the lifespan. For example, ongoing research is

exploring SUD treatment in the criminal justice system, including studies on implementation of medication-assisted treatment (MAT) and seek, test, treat, and retain (STTR) strategies for people with SUDs who are also at risk for HIV. NIDA also funds research into the efficacy of screening brief intervention and referral to treatment (SBIRT) in primary care settings for reducing drug use and SUD.

Program efforts also focus on research to optimize implementation of evidence-based prevention interventions and treatment services in real-world settings. For instance, NIDA is funding researchers to partner with states as they use the State Targeted Response funding from the 21st Century Cures Act to test approaches for expanding access to MAT for opioid use disorder and naloxone for the reversal of overdose.⁸ NIDA is also partnering with Appalachian Regional Commission (ARC), the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA), to address the opioid crisis in rural U.S. regions. Nine grants issued over the past year aim to help communities develop comprehensive approaches to prevent and treat substance use disorder, overdose, and HIV.⁹ These projects will work with state and local communities to develop best practices that can be implemented by public health systems in the nation's rural regions.

Therapeutic and Medical Consequences

NIDA's Division of Therapeutics and Medical Consequences is focused on developing therapeutics for the treatment of SUDs. Since the pharmaceutical industry has traditionally made limited investment in the development of medications to treat SUDs, the responsibility for supporting their development has rested largely with NIDA. To most effectively leverage NIDA resources, this program encourages the formation of alliances between strategic partners (pharmaceutical and biotechnology companies, as well as academic institutions) with the common goal of advancing medications through the development pipeline toward FDA approval in a timely manner. NIDA conducts research to decrease the risks associated with medications development to make it more feasible for pharmaceutical companies to complete costly phase IIb and III clinical studies. Preclinical studies with this class of molecule indicate they could be effective for treating cannabis use disorders and possibly sleep and anxiety disorders, which are highly common in individuals with substance use disorders. NIDA also invests in research supporting the development of vaccines and monoclonal antibodies for the treatment of SUDs. For example, an ongoing collaboration with Selecta Biosciences is working to develop a novel nicotine vaccine¹⁰ and another with Intervexion Therapeutics is working to develop a monoclonal antibody to treat methamphetamine addiction, both of which are now being evaluated in clinical trials.¹¹

⁸ More information about the SAMHSA grants is available here: <https://www.samhsa.gov/grants/grant-announcements/ti-17-014>

⁹ More information about this funding is available here: <https://www.drugabuse.gov/news-events/news-releases/2017/08/grants-awarded-to-address-opioid-crisis-in-rural-regions>

¹⁰

https://projectreporter.nih.gov/project_info_description.cfm?aid=9110936&icde=37966795&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=

¹¹ https://projectreporter.nih.gov/project_info_description.cfm?aid=9067432&icde=37966812

Clinical Trials Network

The CTN comprises 13 research nodes with 25 principal investigators affiliated with academic medical centers and large health care networks, two research coordinating centers, and more than 240 community anchored treatment programs and/or medical settings in over 40 States plus the District of Columbia and Puerto Rico. The overarching mission of the CTN is to improve the effectiveness of, and accelerate the adoption of, evidence-based SUD prevention and treatment interventions. The network evaluates interventions, implementation strategies, and health system approaches to addressing SUDs and related disorders, such as co-occurring mental health disorders and HIV, in randomized controlled trials (RCTs) and other clinical studies that are conducted in diverse treatment settings and patient populations. Another pilot study is developing and testing a clinical decision support (CDS) tool to treat opioid use disorder for use in electronic health record (EHR) systems. Additional studies are investigating the effectiveness and safety of a combination pharmacotherapy for treatment of methamphetamine use disorder. The CTN has also undertaken a multi-pronged initiative to develop effective methods for using the big healthcare data generated via EHRs to speed the pace and reduce the costs of SUD RCTs and to improve clinical care for SUDs. These efforts include developing a pilot patient registry to follow outcomes for opioid use disorder patients longitudinally; investigating patient- and system-level factors associated with quality measurement across health systems; and exploring methods for capturing health and behavioral data from mobile technology and linking those data to EHRs to facilitate monitoring and longitudinal follow-up of hard-to-reach patient populations.

Intramural Research Program

In addition to funding extramural scientists, NIDA conducts research in high priority areas through our IRP. Intramural research at NIDA focuses on conducting multidisciplinary cutting-edge research to: 1) elucidate the underlying causes of addiction; 2) evaluate the potential of emerging new therapies for SUDs, including pharmacological and non-pharmacological (e.g. psychosocial, biofeedback, brain stimulation technologies); and 3) evaluate the long-term consequences of drug use on health, with particular emphasis on the brain and its development. For example, the IRP is collaborating with pharmaceutical industry partners to study a potential medication that can decrease methamphetamine craving and collaborating with researchers in Italy to study the efficacy of TMS for treatment of cocaine use disorders. In addition, the IRP is working to understand and develop interventions to reverse the impact of deficits in the prefrontal cortex caused by cocaine and heroin use. The IRP is also working to develop clinically useful indicators (biomarkers) of addiction severity or treatment efficacy that will support the development of more effective treatments. IRP scientists are also working to better understand factors that contribute to cravings and relapse. Researchers are developing interventions that might be used in humans to selectively impair harmful addiction memories. The IRP is also planning a large translational study of a novel medication, with promising results in animal studies, to treat opioid use disorder and compare the efficacy with buprenorphine. In addition, IRP scientists are developing a mobile health toolbox to collect data on the daily-life reality of addiction with the goal of developing tools that can predict relapse and deliver help just when a person needs it.

Research Management and Support

RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. Additionally, the functions of RMS encompass strategic planning, coordination, and evaluation of NIDA's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. NIDA currently oversees more than 1,662 research grants and more than 82 research and development contracts. NIDA also provides evidence-based resources and educational materials about SUDs and to raise awareness of the science relating to cutting-edge issues such as opioid overdose prevention, marijuana research, synthetic drug trends and MAT. The RMS portfolio also incorporates education and outreach activities to inform public health policy and practice by ensuring the institute is the primary trusted source for scientific information on drug use and addiction. NIDA is also committed to being at the forefront of training the next generation of innovative researchers by supporting both pre-doctoral and postdoctoral-level scientists interested in drug use and addiction research. NIDA leads the NIH Pain Consortium Centers of Excellence in Pain Education (CoEPEs); these twelve centers work to enhance patient outcomes by improving the education of healthcare professionals about pain and its treatment. The CoEPEs act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools to improve how health care professionals are taught about pain and its treatment.

Program Portrait: NIH Public-Private Partnerships to End the Opioid Crisis

Opioid misuse and addiction is an ongoing and rapidly evolving public health crisis. Millions of Americans suffer from opioid use disorder, and millions more suffer from chronic pain. The urgency and scale of this crisis calls for innovative scientific solutions. As part of a government-wide effort to address this crisis, the NIH is planning to supplement existing research efforts with a public-private collaborative research initiative to develop new, safe, and effective strategies to prevent and treat pain, opioid use disorder, and overdose in half the time it currently takes. The totals above include \$50 million for pain research funded through the National Institute of Neurological Disorders and Stroke (NINDS). These funds are not part of the drug control budget.

In collaboration with the Food and Drug Administration (FDA), NIH is moving forward with establishing public-private partnerships to address the opioid crisis facing the Nation. Three major areas for advancement have been targeted: (1) *safe, more effective, and non-addictive strategies* for chronic pain management to improve pain care and reduce reliance on opioids; (2) *new and innovative opioid addiction treatments and overdose reversal interventions* to promote access to treatment and reduce mortality.

To identify the scientific strategies with the greatest potential for solutions to the opioid crisis, NIH brought together innovative experts from government, industry, and academia for a series of three cutting-edge science meetings in 2017. The meetings explored how to accelerate our understanding of the neurological mechanisms of pain; the development of safe, effective, non-addictive pain treatments; and medications development to treat opioid use disorders and for overdose prevention and reversal.

The initiative will focus on a few key areas related to treatment of OUD and overdose prevention and reversal including:

- Developing new treatments for opioid use disorder – such as extended release formulations of existing medications used to treat OUD (methadone, buprenorphine, and naltrexone) and alternative therapeutics including vaccines and antibodies.

- Overdose prevention and reversal – such as stronger formulation of naloxone to reverse overdose from powerful synthetic opioids like fentanyl and carfentanyl, and devices to detect and reverse overdose (i.e. naloxone autoinjectors).

National Institute on Alcohol Abuse and Alcoholism

FY 2019 Request: \$49.0 million

(\$1.2 million below the FY 2018 Annualized CR level)

Alcohol screening and brief intervention in primary care has been recognized as a leading preventive service for reducing harmful alcohol use in adults, and a growing body of evidence demonstrates its effectiveness in preventing and reducing alcohol misuse in youth. Yet research indicates that adolescents are not routinely asked about drinking when they interface with the health care system. NIAAA supports research on the implementation of alcohol screening and brief intervention among youth and young adult populations, including those disproportionately affected by alcohol misuse. NIAAA also supports efforts to encourage the adoption of alcohol screening and brief intervention in healthcare and other appropriate settings.

Reducing alcohol misuse among college students, many of whom are underage, continues to be a high priority for NIAAA. Binge drinking (drinking 4 or more drinks for women and 5 or more drinks for men, in approximately two hours) and extreme binge drinking (drinking at levels two or more times the binge drinking threshold) are especially pervasive among college students; these practices are particularly troubling as they increase risks for alcohol-related blackouts, alcohol overdoses, sexual assault, sexually transmitted diseases, AUD, and other detrimental consequences. To assist college and university officials in addressing alcohol misuse on their campuses, NIAAA developed the College Alcohol Intervention Matrix (*CollegeAIM*), a user-friendly guide and website that rates nearly 60 evidence-based alcohol interventions in terms of effectiveness, costs, and other factors. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address harmful and underage student drinking.

NIAAA's investment in underage drinking research also includes studies to understand how alcohol affects the developing brain. For example, NIAAA supports the National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA), an accelerated longitudinal study of more than 800 youth ages 12-21 to assess the vulnerability of the adolescent brain to alcohol exposure. NCANDA has laid the methodological foundation for the NIH Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of brain development and child health in the United States. Over 10,000 9- to 10-year olds are being invited to participate in the ABCD study, which will use brain imaging and neuropsychological and behavioral assessments to track the biological and behavioral development of youth before and after they start to use alcohol and/or other addictive substances. These two studies are expected to illuminate the neurobiological, cognitive, and behavioral precursors of alcohol and other drug misuse and ultimately inform preventive and treatment strategies. Complementing NCANDA and ABCD, NIAAA's Neurobiology of Adolescent Drinking in Adulthood Initiative is enabling investigators to examine, in animal models, the molecular, cellular, and circuit-level mechanisms by which adolescent drinking affects brain structure and function in the short- and long-term and how the changes observed during this critical period persist into adulthood.

PERFORMANCE

Information regarding the performance of the drug control efforts of NIH is based on agency GPRMA documents and other information that measures the agency's contribution to the *National Drug Control Strategy*.¹² NIH's performance measures are representative of Institute contributions to NIH's priorities regarding specific scientific opportunities, identified public health needs, and Presidential priorities. Such measures, reflecting NIH's broad and balanced research portfolio, are not Institute-specific. Many measures are trans-NIH, encompassing lead and contributing institutes and centers. This approach reflects NIH's commitment to supporting the best possible research and coordination of research efforts across its institutes and centers. All performance results reported were achieved in FY 2017.

NIDA and NIAAA lead and support a number of trans-NIH measures in the Scientific Research Outcome (SRO) functional area. While NIDA and NIAAA engage in many research and related activities, three measures best reflect the breadth of their efforts in the prevention and treatment of substance use, misuse, addiction, and its consequences.

One of these measures, led by NIAAA and supported by NIDA, is 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." This measure, which began in FY 2014, is indicative of NIDA's and NIAAA's efforts to support research to foster the development and implementation of prevention-based strategies for reducing substance misuse and addiction. NIH's prevention portfolio encompasses a broad range of research on the efficacy and cost effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to misuse or addiction—and how these programs can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of substance use or SUDs.

NIDA created and leads 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." This measure began in FY 2014 and has been updated to reflect NIDA's current focus in exploring and leveraging technological advances to improve the efficiency and quality of health care delivery for SUDs.

In addition to developing and leading SRO-5.15, NIAAA contributes to SRO-8.7: "By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems." This measure, which began in FY 2008 and has been updated over time, reflects NIH's ongoing commitment to supporting research on the implementation of preventive and treatment interventions and improving the translation of research into practice.

¹² <https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs>

National Institute on Drug Abuse		
Selected Measures of Performance	FY 2017 Target	FY 2017 Achieved
» Scientific Research Outcome- 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.	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.
» Scientific Research Outcome- 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.	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.

Prevention – Scientific Research Outcome-5.15

The 2017 target for SRO-5.15 was met. 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.¹³

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.¹⁴

Treatment—Scientific Research Outcome-7.3

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

¹³ <https://www.ncbi.nlm.nih.gov/pubmed/28523585?dopt=Summary>

¹⁴ Lochman, John E; Dishion, Thomas J; Boxmeyer, Caroline L; Powell, Nicole P; Qu, Lixin. J Abnorm Child Psychol. 2017; Jan. 5. <https://www.ncbi.nlm.nih.gov/pubmed/28058517>

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.¹⁵

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.¹⁶ Future studies are planned to determine the efficacy of this intervention for smoking cessation.

¹⁵ Mares, M.L., et al., *Implementing an mHealth system for substance use disorders in primary care: a mixed methods study of clinicians' initial expectations and first year experiences*. BMC Med Inform DECIS Mac, 2016. 16:126.

¹⁶ McClure, J.B., et al., *Evaluating an Adaptive and Interactive mHealth Smoking Cessation and Medication Adherence Program: A Randomized Pilot Feasibility Study*. JMIR Mhealth Uhealth, 2016. 4(3): p. e94.

National Institute on Alcohol Abuse and Alcoholism		
Selected Measures of Performance	FY 2017 Target	FY 2017 Achieved
» Scientific Research Outcome-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.	Continue to promote the <i>College Alcohol Intervention Matrix (CollegeAIM)</i> .	NIAAA promoted and disseminated <i>CollegeAIM</i> and initiated efforts to update <i>CollegeAIM</i> to reflect the latest evidence-based alcohol interventions.
» Scientific Research Outcome-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems.	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 <i>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.

Prevention – Scientific Research Outcome-5.15

The FY 2017 target for SRO-5.15 was met.

In September 2015, NIAAA released the *College Alcohol Intervention Matrix (CollegeAIM)* guide and website, important new resources to 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 its 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.

Treatment – Scientific Research Outcome-8.7

The FY 2017 target for SRO-8.7 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.