

The National Institute on Drug Abuse

CONGRESSIONAL JUSTIFICATION FY 2022

Department of Health and Human Services National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

National Institute on Drug Abuse (NIDA)

FY 2022 Budget Table of Contents	Page No.
Director's Overview	3
IC Fact Sheet	9
Major Changes in Budget Request	11
Budget Mechanism Table	12
Appropriations Language	13
Summary of Changes.	14
Budget Graphs	
Organization Chart	16
Budget Authority by Activity	17
Justification of Budget Request	18
Program Descriptions	18
Appropriations History	26
Authorizing Legislation	27
Amounts Available for Obligation	28
Budget Authority by Object Class	29
Salaries and Expenses	30
Detail of Full-Time Equivalent Employment (FTE)	31
Detail of Positions	32

^{*} Cover: "Electrical lines and streetlights depicted as firing neurons illuminate an American neighborhood in a moment of silence" Courtesy of Laili Xie, Staff member, NIH Adolescent Brain Cognitive Development Study, University of California, San Diego

Director's Overview

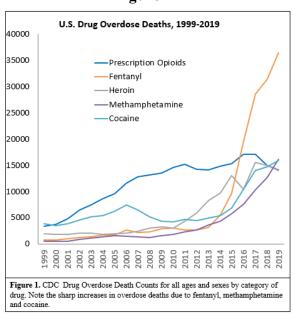
The National Institute on Drug Abuse (NIDA) is the lead federal agency supporting scientific research on drug use and its consequences. Its mission is to advance science on drug use and addiction and apply that knowledge to improve individual and public health. After decades of research, addiction is now understood to be a chronic, treatable brain disorder from which one can recover. NIDA-supported research has led to the development of effective prevention and treatment interventions, providing hope for the more than 20 million people in the United States diagnosed with substance use disorders and their loved ones. Although significant strides have been made, there is more work to be done. New and improved interventions and effective strategies for implementing them will be essential to combatting this evolving public health crisis.



Dr. Nora Volkow, NIDA Director

NIDA Research Responds to Urgent Public Health Needs

Figure 1



While drug overdoses in the United States have been increasing exponentially for at least 40 years, different substances have driven this increase over time. The 21st century has been marked by overdoses involving opioids. Data from the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths reached a record high in 2019; of nearly 71,000 overdose deaths, over 70 percent involved opioids (see **Figure 1**). The crisis was initially driven by prescription opioids, and later by heroin use. However, since 2016, synthetic opioids, such as fentanyl, account for the largest fraction of overdose deaths. The National Institutes of Health (NIH) Helping to End Addiction LongtermSM (HEAL) Initiative is an aggressive, transagency effort to speed scientific solutions to stem the national opioid public health crisis. Within

HEAL, NIDA leads numerous programs aimed at treating opioid use disorder (OUD) and reducing overdose mortality.

Stimulants have also emerged as an overdose threat. From 2012 through 2019, the number of deaths involving methamphetamine increased more than 6-fold (from around 2,600 to more than 16,100); the number involving cocaine more than tripled (from around 4,400 to nearly 16,000) (see **Figure 1**).² Given the urgent need to confront these dramatic increases, NIDA has prioritized the development of medications to treat stimulant use disorders.

¹ www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

² www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

The collision of the overdose crisis with the coronavirus disease 2019 (COVID-19) pandemic puts people with substance use disorders (SUD) at particular risk. Early data show increases in drug use and overdose since the pandemic began,³ and the highest number of overdose deaths (over 83,000) ever recorded occurred in the 12 months ending in June 2020.⁴ Individuals with SUD, especially Blacks/African Americans and those with OUD, are at higher risk for COVID-19 and its adverse outcomes.⁵ NIDA is supporting dozens of studies on the intersection of SUD and COVID-19. (See Program Portrait "Intersection of COVID-19 and Substance Use Disorders.")

Recently, there has been a dramatic increase in vaping cannabinoids and nicotine, particularly among teens and young adults. Nicotine vaping among 12th graders increased from 27.8 percent in 2017 to 37.3 percent in 2018, which is the largest one-year increase for any substance reported in the 45-year history of the Monitoring the Future (MTF) study, an annual NIDA-supported survey that assesses substance use behaviors and attitudes in adolescents and young adults. The second largest increase occurred for marijuana vaping among 12th graders, increasing from 7.5 percent in 2018 to 14 percent in 2019.6,7 NIDA continues to monitor and analyze these and other trends through its portfolio of epidemiology research. Data from MTF and NIDA's Population Assessment of Tobacco and Health (PATH) study, which assesses patterns of tobacco and nicotine use, showed that flavored e-cigarette products particularly appeal to youth 8,9 and informed a 2020 U.S. Food and Drug Administration (FDA) policy prioritizing enforcement against certain unauthorized flavored cartridge-based products that appeal to youth.¹⁰

The National Drug Early Warning System (NDEWS), launched in 2014, allows NIDA to monitor patterns of drug use across the nation and rapidly recruit research resources to study them. NDEWS was able to expand in its second iteration in April 2020, incorporating real-time surveillance to detect early signals of emerging crises. The new system, which includes 18 sentinel sites and a coordinating center, uses novel surveillance methods and rapidly harmonizes and disseminates data. NDEWS is currently harnessing its network to collect data on substance use-related consequences of COVID-19, including data from novel informants such as funeral directors, emergency medical service personnel, and syringe exchange service workers.

Addressing Health Disparities and Diversifying the Workforce

Disparities in access to SUD treatment exacerbate the negative impact of addiction on minority populations and individuals in under-resourced settings. ¹¹ For example, people of color who are charged with drug-related crimes are more likely to go to prison than White individuals, charged with similar crimes. ¹² NIDA is investing in research to develop and test interventions that can help address these disparities. Through HEAL, the Justice Community Opioid Innovation

³ https://emergency.cdc.gov/han/2020/han00438.asp

⁴https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

⁵ pubmed.ncbi.nlm.nih.gov/32929211/

⁶ www.drugabuse.gov/news-events/news-releases/2018/12/teens-using-vaping-devices-in-record-numbers

⁷ www.drugabuse.gov/news-events/news-releases/2020/09/vaping-marijuana-use-in-2019-rose-in-college-age-adults

⁸ pubmed.ncbi.nlm.nih.gov/31783934/

⁹ pubmed.ncbi.nlm.nih.gov/31688891/

¹⁰ www.fda.gov/media/133880/download

¹¹ www.drugabuse.gov/about-nida/noras-blog/2019/07/access-to-addiction-services-differs-by-race-gender

www.ncbi.nlm.nih.gov/pmc/articles/PMC3670657/, pubmed.ncbi.nlm.nih.gov/16327107/, www.ncbi.nlm.nih.gov/pmc/articles/PMC3665009/

Network (JCOIN)¹³ supported 10 grants and \$22 million in FY 2020 to test strategies to increase high quality OUD treatment in legal settings. To address disparities among African American/Black communities in SUD treatment initiation and completion, NIDA supports research on culturally-sensitive intervention strategies. NIDA's Intervention Research to Improve Native American (NA) Health program focuses on health-promotion and disease-prevention interventions tailored to the needs of NA populations. NIDA's broad health disparities portfolio also targets treatment disparities for SUD and infectious conditions in sexual and gender minorities and addresses challenges associated with preventing and treating OUD in rural areas. Several approaches leverage technology, including machine learning approaches to analyze electronic health record data to inform personalized, culturally-appropriate treatment.

Scientists and trainees from diverse backgrounds bring different perspectives, creativity, and individual enterprise to address complex scientific problems. Recognizing that the research enterprise requires superior intellect, creativity, and a wide range of skill sets and viewpoints, NIDA participates in the NIH diversity supplement program and supports the NIDA Diversity Scholars Network aimed at improving the funding success of early-stage investigators from underrepresented minority populations. NIDA is also developing an Action Plan to Promote Racial Equity, consisting of specific strategies to ameliorate racial discrimination in the NIDA workplace, increase diversity in NIDA's scientific workforce, and fill gaps in research related to minority health, health disparities, and the health effects of racism on SUD.

Building on Basic Science to Advance Prevention, Treatment, and Recovery

Decades of research have demonstrated the complex social and biological factors that contribute to substance misuse and addiction, including the long-lasting effects that addictive drugs have on the brain. Advances in genetics, neuroscience, and behavioral science, made possible through NIDA-supported research, have illuminated the factors that influence drug use, how individuals develop SUDs, and how those disorders manifest over time. NIDA supports research to translate findings from basic and epidemiological research into prevention and treatment interventions. For example, studying how opioids interact with their neural receptors led to the development of drugs like naloxone, which can reverse overdoses and save lives, and which researchers further refined into an easy-to-use, quick acting nasal formulation in 2018. Similarly, studying role of the noradrenergic system in stress reactivity informed the development of the adrenergic drug Lofexidine, a medication that specifically targets the physiological symptoms of opioid withdrawal. Lofexidine was developed with NIDA support and approved by the FDA in 2018.

The NIH Helping to End Addiction Long-termSM (HEAL) Initiative

In FY 2018, NIH launched the HEAL InitiativeSM, a trans-agency research effort to improve the prevention and treatment of opioid misuse and addiction and enhance pain management. As part of HEAL, NIDA supported over \$250 million annually focused on: translating research into practice for the treatment of opioid addiction in healthcare and legal settings; developing new strategies to prevent and treat opioid addiction; enhancing outcomes for infants and children exposed to opioids; and developing novel medications for OUD and overdose.

¹³ heal.nih.gov/research/research-to-practice/jcoin

Under HEAL, NIH is poised to launch the HEALthy Brain and Child Development (HBCD) Study, which will be the most comprehensive study of early brain development ever conducted. Led by NIDA, this study will enroll 7,500 pregnant and postpartum women and follow them and their children from the prenatal period through early childhood (age 9-10) to determine how diverse factors, including maternal drug exposures, influence brain and child development. The study, which will be conducted at multiple research sites across the country and in diverse ethnic and socioeconomic backgrounds, is expected to begin enrollment in 2022, and is currently soliciting applications for study sites, a data coordinating center, and an administrative core.

There is also a vital need to develop preventive strategies that can decrease the incidence and prevalence of opioid misuse and OUD during key periods of vulnerability. NIDA is administering nine studies to develop and test strategies to prevent opioid misuse and OUD among high-risk adolescents and young adults (ages 16-30), which is the age group at highest risk for opioid initiation, misuse, OUD, and overdose fatalities. The studies target this high-risk group in primary care, school-based health centers, 15 youth treatment centers, and legal system settings 16 in areas most affected by the opioid crisis or with indicators of an emerging crisis.

While effective medications exist for OUD, these medications are underutilized. Suboptimal patient retention in treatment regimens, policy barriers that limit opioid prescribing, and stigma around opioid agonist medications all contribute to their underutilization. More options are needed to help people with OUD achieve long-term recovery. NIDA administered over 40 HEAL grants in FY 2020 focused on medications development research for OUD and overdose. Since HEAL began, 16 Investigational New Drug applications were filed with the FDA and authorized to for human studies. These studies focus on a variety of drug targets, as well as vaccines that could prevent opioids from entering the brain. Others are repurposing existing medications for OUD indications, such as the FDA-approved insomnia medication, suvorexant, based on known overlaps between brain signaling systems involved in sleep and addiction.

To help commercialize the results of NIDA research, the Institute supports translational initiatives to turn research into products for SUD and related indications or attract companies with potentially useful approaches to expand into this traditionally underserved space. Products under development in these programs help deliver counseling via mobile devices, use virtual reality to reduce the need for opioid pain relief, identify the signs of overdose to automatically alert first responders, and provide automated gentle, soothing stimulation to babies born in opioid withdrawal. (See Program Portrait "NIDA's Innovative Technology Program.")

NIDA-supported research has revolutionized our understanding of the biological, social, environmental, and systems-level factors that confer risk for or resilience against development of SUDs, and leveraged that understanding to advance prevention, treatment, and recovery. Continued support, both for NIDA and HEAL, will be crucial to realizing the promise of the public investment in addiction research and to addressing this deadly public health crisis.

¹⁵ projectreporter.nih.gov/project info description.cfm?aid=9969974&icde=51760156

¹⁴ heal.nih.gov/research/infants-and-children/healthy-brain

¹⁶ projectreporter.nih.gov/project_info_details.cfm?aid=10022112&icde=51760006

Overall Budget Policy: The FY 2022 President's Budget request is \$1,852.5 million, an increase of \$372.2 million or 25.1 percent above the FY 2021 Enacted level. Within this funding level, funding for the HEAL Initiative will increase by \$135.1 million or 50.0 percent above the FY 2021 Enacted level. In addition, funding for research into opioids and pain management outside the HEAL Initiative will increase by an additional \$196.3 million.



Nora D. Volkow, M.D. Director since 2003

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The Addiction Public Health Crisis



20.4 million people in the United States were diagnosed with SUD in the past year*



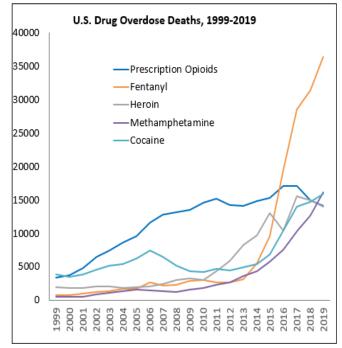
Only 10.3 percent of people with pastyear SUD received SUD treatment*



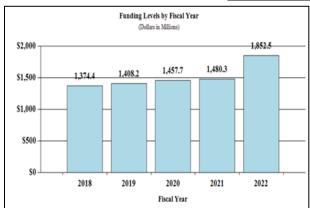
Nearly 71,000 people died of drug

overdoses in 2019[†]
* 2019 National Survey on Drug Use and Health
† 2010 The Contour for Dinagra Control and Properti

[†] 2019 The Centers for Disease Control and Prevention WONDER database



NIDA's Research Investment



- **363** Full-time equivalents (FTEs)
- 354 FY 2020 New Research Project Grants
- 477 Unique investigators in FY 2020
- 73 Early stage investigators
- \$266M for FY 2020 HEAL projects
- \$10.9M for FY 2020 COVID-19 studies
- \$261M for FY 2020 HIV/AIDS projects

- Basic Neuroscience: Understanding how drugs affects the cells and circuits of the brain, how addiction occurs, and how genes and environment affect the brain
- **Epidemiology**: Monitoring emerging trends in drug use
- Risk and Protective Factors: Identifying the factors that influence drug use, addiction, access to care, and related health outcomes
- Prevention: Developing and testing approaches to mitigate risk factors, promote resilience, and prevent drug use, addiction, and their consequences
- Treatment: Developing and testing medications, devices, and behavioral treatments for addiction and its consequences
- Implementation: Optimizing approaches for scaling-up and enhancing access to evidence-based treatment and prevention strategies

Recent Accomplishments

- Lofexidine: first medication for opioid withdrawal symptoms approved by FDA in 2018.
- ReSET-O: first smartphone app to deliver behavioral treatment for opioid use disorder (OUD) approved by FDA in 2018.
- ADAPT-2 Trial: multi-site clinical trial showed effectiveness of a combination of naltrexone and bupropion in reducing methamphetamine use.
- Tobacco Research and Policy: findings from NIDA-supported studies demonstrating the appeal of flavored e-cigarettes to youth informed FDA's 2020 policy prioritizing enforcement against certain unauthorized vaping products.
- NIDA Clinical Trials Network: with HEAL funds, added 5 new research nodes and supported the development of 26 new protocols to develop and test substance use interventions. Below: Pre-existing network nodes shown in blue, new nodes shown in red.



Current Activities

- Adolescent Brain Cognitive
 Development Study: the largest long-term study of brain development and child health ever conducted in the United States is continuing to track brain and behavioral development of nearly 12,000 9-10 year-olds through early adulthood.
 - NIH HEAL Initiative : administering over \$250M/year to prevent and treat opioid misuse, addiction, and overdose, including studies to develop and test new interventions and effective strategies for implementing proven interventions across settings.
- Medications Development: supporting over 40 grants in FY 2020 to develop medications and other treatments for OUD and over 25 to develop treatments for stimulant use disorders.
- Cannabis Research: supporting over 250 studies in FY 2019 to understand the basic science, health effects, and therapeutic potential of cannabis and cannabinoids.
- NIDA Technology Portfolio: advancing research on cutting-edge technologies for preventing and treating substance misuse, addiction, and overdose.
- COVID-19 and SUD: supporting over 90 studies to understand how COVID-19 may affect people with SUD and child health outcomes.



Future Initiatives

- HEALthy Brain and Child Development (HBCD) Study: participant recruitment for the most comprehensive study of early brain development ever conducted will begin in FY 2022. The study will enroll 7,500 pregnant and postpartum women and follow them and their children through early childhood to determine how maternal drug exposure and other factors influence development.
- **HEALing Communities Study**: researchers are on track to the deploy the intervention of this multisite implementation study across 67 communities in four states, aimed at reducing opioid overdose deaths by 40 percent in participating communities.
- **HEAL Prevention**: nine studies focused on preventing opioid use during the transition from high school to early adulthood are completing their pilot phase and transitioning to larger clinical trials.
- **Justice Community Opioid Innovation Network**: 10 grants and \$22 million in FY 2020 to test SUD prevention and treatment interventions will begin data collection.

Major Changes in the Fiscal Year 2022 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2022 President's Budget. The FY 2022 President's Budget for NIDA is \$1,852.5 million, an increase of \$372.2 million above the FY 2021 enacted level.

Research Project Grants (RPGs) (+\$348.5 million; total \$1,296.7 million): NIDA will significantly increase funding for competing RPGs in support of the additional funding requested for the HEAL Initiative and related research into opioids and pain management. The number of noncompeting RPGs will decrease by 215 in FY 2022 as previously awarded projects complete their performance period, but the number of competing RPGs is expected to increase by over 480 in comparison to the FY 2021 level of 261 awards. The amount of support to competing awards will be increased by \$410.6 million from FY 2021, a 213 percent increase.

<u>Research Centers (+\$2.5 million; total \$56.5 million):</u> NIDA will increase support to new specialized/comprehensive centers projects.

Other Research (+\$10.6 million; total \$182.1 million): NIDA will increase support to research career development awards, research training awards, and cooperative clinical research.

Ruth L Kirchstein Training (+\$1.1 million; total \$29.1 million): NIDA will maintain a level of 515 trainees in FY 2022, unchanged from FY 2021.

Budget Mechanism - Total¹

MECHANISM	FY 20	020 Final	FY 20	021 Enacted	FY 2022 P	resident's Budget	F	Y 2022 +/-	
			112021 23				FY 2021 Enacted		
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	
Research Projects:									
Noncompeting	949	\$635,899	1,020	\$709,701	805	\$633,057	-215	-\$76,644	
Administrative Supplements	(113)	12,666	(61)	5,528	(57)	6,000	(-4)	472	
Competing:	(113)	12,000	(01)	5,520	(57)	0,000	()	.,_	
Renewal	47	37,174	66	53,862	69	56,556	3	2,693	
New	293	208,458	179	135,821	658	543,374	479	407,553	
Supplements	14	2,267	16	2,658	18	3,000	2	342	
Subtotal, Competing	354	\$247,899	261	\$192,341	745	\$602,929	484	\$410,588	
Subtotal, RPGs	1,303	\$896,464	1,281	\$907,570	1,550	\$1,241,986	269	\$334,416	
SBIR/STTR	92	43,082	86	40,610	114	54,730	28	14,120	
Research Project Grants	1,395	\$939,546	1,367	\$948,180	1,664	\$1,296,717	297	\$348,537	
research Project Grand	1,575	ψ,σ,σ,σ.ισ	1,507	\$ 10,100	1,001	\$1,250,717	277	ψ3 10,037	
Research Centers:									
Specialized/Comprehensive	26	\$53,417	26	\$53,800	28	\$56,252	2	\$2,452	
Clinical Research	0	0	0	0	0	0	0	C	
Biotechnology	0	250	0	200	0	200	0	C	
Comparative Medicine	0	0	0	0	0	0	0	C	
Research Centers in Minority Institutions	0	0	0	0	0	0	0	C	
Research Centers	26	\$53,667	26	\$54,000	28	\$56,452	2	\$2,452	
Other Research:									
Research Careers	229	\$42,063	229	\$42,621	244	\$44,725	15	\$2,104	
Cancer Education	0	0	0	0	0	0	0	C	
Cooperative Clinical Research	28	99,126	27	95,244	29	100,244	2	5,000	
Biomedical Research Support	0	0	0	0	0	0	0	C	
Minority Biomedical Research Support	0	1,270	0	1,311	0	1,311	0	C	
Other	92	29,872	100	32,256	112	35,790	12	3,534	
Other Research	349	\$172,330	356	\$171,432	385	\$182,070	29	\$10,638	
Total Research Grants	1,770	\$1,165,543	1,749	\$1,173,612	2,077	\$1,535,239	328	\$361,627	
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs		
Individual Awards	124	\$5,615	172	\$7,946	172	\$8,320	0	\$374	
Institutional Awards	388	20,871	343	20,054	343	20,743	0	689	
Total Research Training	512	\$26,486	515	\$28,000	515	\$29,063	0	\$1,063	
		4_0,000		4_0,000		4-2,000		4-,000	
Research & Develop. Contracts	93	\$89,653	93	\$99,623	93	\$104,739	0	\$5,116	
(SBIR/STTR) (non-add)	(5)	(3,601)	(4)	(6,695)	(4)	(6,495)	(0)	(-200)	
Intramural Research	117	100,748	121	102,098	121	105,161	0	3,063	
Res. Management & Support	246	75,293	267	76,975	267	78,301	0	1,326	
SBIR Admin. (non-add)	(0)	(311)	(0)	(274)	(0)	(274)	(0)	(0)	
Construction		0		0		0		(
Buildings and Facilities	 	0		0		0		. (
Total, NIDA	363	\$1,457,724	388	\$1,480,309	388	\$1,852,503	0	\$372,194	

¹ All items in italics and brackets are non-add

NATIONAL INSTITUTE ON DRUG ABUSE

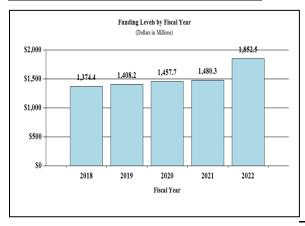
For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [\$1,479,660,000]\$1,852,503,000.

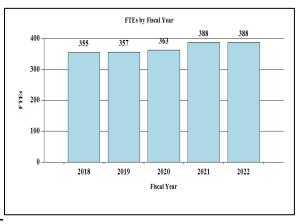
Summary of Changes

(Donars in Thousands)					r		
FY 2021 Enacted FY 2022 President's Budget				\$1,480,309 \$1,852,503			
Net change				\$1,852,503			
	FY202	1 Enacted	FY 2	2022 President's Budget	IC Adjustment Amount		in Change from 2021 Enacted
CHANGES	FTEs Bu	dget Authority	FTEs	Budget Authority	Budget Authority	FTEs 1	Budget Authority
A. Built-in:							
1. Intramural Research:							
a. Annualization of January 2021 pay increase & benefits		\$29,162		\$30,023	\$0		\$8
b. January FY 2022 pay increase & benefits		29,162		30,023	0		78
c. Paid days adjustment		29,162		30,023	0		
d. Differences attributable to change in FTE		29,162		30,023	0		
e. Payment for centrally furnished services		12,481		13,105	0		62
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		60,456		62,033	0		1,67
Subtotal					\$0		\$3,16
2. Research Management and Support:							
a. Annualization of January 2021 pay increase & benefits		\$40,268		\$41,493	\$0		\$109
b. January FY 2022 pay increase & benefits		40,268		41,493	0		1,11
c. Paid days adjustment		40,268		41,493	0		
d. Differences attributable to change in FTE		40,268		41,493	0		(
e. Payment for centrally furnished services		6,221		6,032	0		-18
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		30,486		30,775	0		853
Subtotal					\$0		\$1,890
Subtotal, Built-in					\$0		\$5,054
	FY202	1 Enacted	FY 2	2022 President's Budget	IC Adjustment Amount		m Change from 2021 Enacted
CHANGES	No.	Amount	No.	Amount	Amount	No.	Amoun
B. Program:							
1. Research Project Grants:							
a. Noncompeting	1,020	\$715,229	735	\$639,057		-285	-\$76,17
b. Competing	261	192,341	745	602,929		484	410,588
c. SBIR/STTR	86	40,610	114	54,730		28	14,12
Subtotal, RPGs	1,367	\$948,180	1,594	\$1,296,717	\$0	227	\$348,53
2. Research Centers	26	\$54,000	28	\$56,452		2	\$2,452
3. Other Research	356	171,432	385	182,070		29	10,633
4. Research Training	515	28,000	515	29,063		0	1,06
5. Research and development contracts	93	99,623	93	104,739		0	5,11
Subtotal, Extramural		\$1,301,236		\$1,669,041	\$0		\$367,80
	FTEs		<u>FTEs</u>			<u>FTEs</u>	
6. Intramural Research	121	\$102,098	121	\$105,161	\$0	0	-\$102
7. Research Management and Support	267	76,975	267	78,301	0	0	-564
8. Construction		0		0			
9. Buildings and Facilities		0		0			
Subtotal, Program	388	\$1,480,309	388	\$1,852,503	\$0	0	\$367,140
Total built-in and program changes					\$0		\$372,194

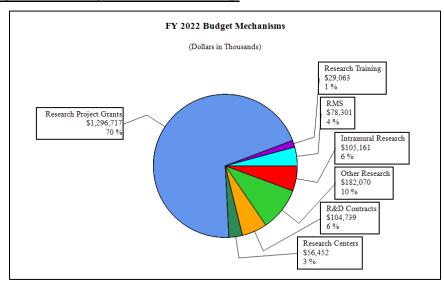
Fiscal Year 2021 Budget Graphs

History of Budget Authority and FTEs:

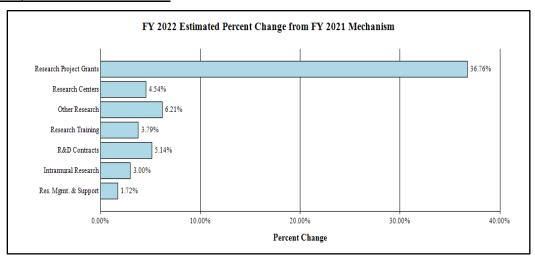




Distribution by Mechanism (dollars in thousands):

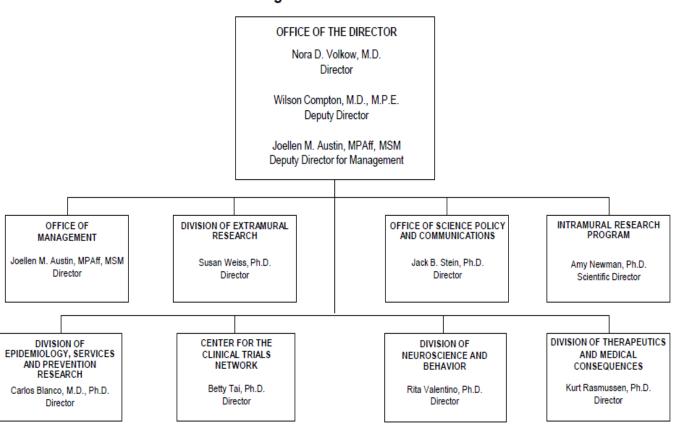


Change by Selected Mechanism:



National Institutes of Health

National Institute on Drug Abuse Organizational Structure



Budget Authority by Activity¹ (Dollars in Thousands)

	FY 2	020 Final	FY 2	021 Enacted		2 President's Budget		7 2022 +/- 21 Enacted
Extramural Research	FTE	Amount	FTE	Amount	FTE	<u>Amount</u>	FTE	Amount
<u>Detail</u>								
Division of Therapeutics and Medical Consequences		\$114,238		\$116,131		\$142,295		\$26,164
Division of Neuroscience and Behavior		480,779		492,754		603,769		111,015
Division of Epidemiology, Services and Prevention Research		335,590		341,150		418,009		76,859
Center for the Clinical Trials Network		39,001		39,647		48,580		8,932
Office of Translational Initiatives and Program Innovations		48,859		45,659		55,945		10,287
HEAL Initiative ²		263,216		265,895		400,443		134,548
Subtotal, Extramural		\$1,281,682		\$1,301,236		\$1,669,041		\$367,805
Intramural Research	117	\$100,748	121	\$102,098	121	\$105,161	0	\$3,063
Research Management & Support	246	\$75,293	267	\$76,975	267	\$78,301	0	\$1,326
TOTAL	363	\$1,457,724	388	\$1,480,309	388	\$1,852,503	0	\$372,194

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
 Total for HEAL Initiative including RMS is (in thousands) \$266,321 in FY 2020, \$270,295 in FY 2021, and \$405,443 in FY 2022.

Justification of Budget Request

National Institute on Drug Abuse (NIDA)

Authorizing Legislation: Section 301 and Title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

			FY 2022	
	FY 2020	FY 2021	President's	FY 2022 +/-
	Final	Enacted	Budget	FY 2021
BA	\$1,457,724,000	\$1,480,309,000	\$1,852,503,000	+372,194,000
FTE	363	388	388	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Program Descriptions

Neuroscience and Behavior Research

NIDA's Division of Neuroscience and Behavior (DNB) advances knowledge of the basic biological mechanisms that underlie drug use and guide the development of novel prevention strategies and treatments for SUD. This includes identifying the effects of illicit substances on brain structure and function throughout the lifespan and across stages of drug use and SUD. Areas of support include studies to identify genetic variants and epigenetic modifications that influence vulnerability to SUD, the effects of drugs on gene expression and brain development and function; the interaction of genes with environmental conditions, including how they influence brain development; and basic processes underlying vulnerability and resilience to SUD. DNB supports research to elucidate the pharmacology of drugs and to leverage this knowledge towards the development of therapeutics to treat SUD, the adverse consequences of illicit drugs, and pain. One recent DNB-supported study found that prenatal exposure to cannabinoids altered the ways the brains of male, but not female, adolescent rats respond to cannabis, and identified a drug that could normalize those responses.¹⁷ The DNB portfolio also includes research on non-pharmacological SUD treatments including transcranial magnetic stimulation, transcranial direct current stimulation, deep brain stimulation, and neurofeedback. Research on the interactions of complex neural circuits that underlie substance use, aversive responses to drugs that can inhibit drug-seeking, and interactions between neural and nonneuronal cells in these circuits is also supported in this portfolio. DNB funds technology development that enables studies of the functional organization of the living brain from cells to

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¹⁷pubmed.ncbi.nlm.nih.gov/31611707/

circuits to networks, and advanced computational approaches including theoretical modeling and novel methods for analyzing large, diverse data sets. One recent study found that activity in two different brain regions is linked with nicotine addiction severity and nicotine withdrawal, which is of particular interest because current smoking cessation treatments only affect one of those areas. 18 Such studies can help inform the creation of new and improved treatments with basic data on neural circuits. Finally, DNB supports mechanistic research to address realworld challenges faced in clinical care of SUD, such as polysubstance use, co-occurring conditions, and sex and gender differences in the development of SUDs.

One of NIDA's flagship basic science projects is the Adolescent Brain Cognitive Development (ABCD) study, which will follow children over 10 years, beginning at ages 9-10. Scientists are using techniques such as advanced brain imaging, interviews, and behavioral testing to determine how childhood experiences interact to affect brain development and—ultimately—social, behavioral, academic, and health outcomes. including substance use. Understanding how drugs interact with individual genetic, neurobiological, environmental, social, and developmental factors is essential to understanding what puts a person at risk for or confers resilience to addiction. Enrollment is complete with a total of 11,878 youth and their families participating. The study has already released baseline and one-year follow-up data from the full cohort, and more than 70 research papers have been published using these data, leading to a better understanding of the association between certain traits and experiences and brain structure and function, cognitive ability, and mental health. For example, a recent study has found that certain measures of obesity

<u>Intersection of COVID-19 and Substance Use</u> <u>Disorders</u>

Significant increases in drug use and overdoses have been reported since March 2020, when the coronavirus disease 2019 (COVID-19) pandemic emerged and physical distancing policies were put into place. Recent findings show that people with SUD are more likely to develop COVID-19 and to experience worse outcomes than people without SUD. An analysis of a large nationwide sample of urine drug tests by Millennium Health showed steep increases following mid-March in the use of non-prescribed fentanyl (32 percent), methamphetamine (20 percent). heroin (13 percent), and cocaine (10 percent). Overdose reports increased an average of 18 percent following mid-March for 62 percent of counties in the Overdose Detection Mapping Application Program. Data from the CDC suggest an acceleration of overdose deaths during the pandemic, and the 12months ending in May 2020 marked the highest number of overdose deaths ever recorded.

In March 2020, shortly after COVID-19 mitigation guidelines were released, NIDA issued a Notice of Special Interest for research on the intersection of COVID-19 and SUD. NIDA is supporting over 90 studies under this and other NIH COVID-19 funding opportunities, including basic research on severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) infection, the effect of COVID-19 on people who use drugs, the effect of COVID-19 on child and adolescent development, and the impact of pandemicrelated policy changes on access to SUD treatment. The latter includes studies on how telemedicine affects OUD treatment and the impact of policies facilitating at-home methadone dosing on OUD treatment adherence. NIDA is supports four studies on COVID-19 through its intramural program, including research to develop novel therapeutics for SARS-CoV-2 and assess the effects of pandemic-related psychosocial stress on patients in treatment for OUD.

NIDA leads an effort under the trans-NIH Rapid Acceleration of Diagnostics-Radical (RADx-Rad) initiative on methods to detect SARS-CoV-2 in wastewater to improve community-level surveillance of the virus. This project takes advantage of NIDA expertise on wastewater surveillance of drug use. NIDA also participates in the RADx-Underserved Populations (RADx-UP) initiative, which aims to expand COVID-19 testing among underserved populations, including those with SUD.

Continued investment in research on COVID-19 is vital for reducing devastating SUD and overdose outcomes, and NIDA continues to welcome applications to address the intersection of COVID-19 and SUD.

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¹⁸ europepmc.org/article/med/22493758

Medications Development for Stimulant Use Disorder

Stimulants, including methamphetamine and cocaine, are highly addictive and associated with serious physical and mental health consequences. From 2012 - 2019, overdose deaths involving methamphetamine increased more than 6-fold, and overdose deaths involving cocaine more than tripled. The only currently available treatments for stimulant use disorders are behavioral therapies such as contingency management. Although cognitive behavioral therapy is often used, its effectiveness for treating methamphetamine use disorder has not been demonstrated. There are no U.S. Food and Drug Administration (FDA)-approved medications for stimulant use disorders or overdose.

NIDA's portfolio in medications development for stimulant use disorders is multifaceted, spanning novel biological targets for new medications, to anti-cocaine and anti-meth vaccines, to the repurposing of existing medications. For example, NIDA-supported researchers are developing and testing novel compounds that target VMAT2, a protein that plays an important role in the transport and release of neurotransmitters including dopamine, which enables the reinforcing and addictive effects of stimulants. VMAT2 has been shown to decrease methamphetamine-seeking in animal models. Researchers are also working to develop vaccines that sequester stimulants in the blood so they do not reach the brain. As one example, a monoclonal antibody (IXTm200, developed by InterveXion) for the treatment of methamphetamine use disorder and overdose is being studied in a Phase II clinical trial and received Fast Track designation from the FDA. Additional studies focus on long-acting enzymes that block the physiological and toxic effects of stimulants, such as cocaine hydrolase for cocaine use disorder. NIDAsupported researchers are also exploring medications approved for other indications to test their effectiveness in treating stimulant use disorders. For example, the recently completed Accelerated Development of Additive Pharmacology Treatment (ADAPT-2) trial demonstrated that bupropion plus naltrexone was effective for reducing methamphetamine use and craving in individuals with moderate to severe methamphetamine use disorder. In addition, numerous agonists and antagonists are being studied including mirtazapine, a drug approved for the treatment of depression, that has been shown to decrease methamphetamine use in a small randomized control

Developing effective medications for stimulant use disorders is one of NIDA's highest priorities and is critical to improving the treatment of people addicted to methamphetamine. cocaine. and other stimulants.

correlate with measurements of the density of an area of the brain responsible for motivation and reward, suggesting a possible neural mechanism for behavioral changes that lead to obesity. ¹⁹

Budget Policy: The FY 2022 President's Budget request is \$603.8 million, an increase of \$111.0 million or 22.5% percent compared with the FY 2021 Enacted level.

<u>Epidemiology, Services, and Prevention</u> Research

NIDA's Division of Epidemiology, Services, and Prevention Research (DESPR) supports integrated approaches to understanding and addressing the interactions between individuals and environments that contribute to drug use, addiction, and related health problems. Through Monitoring the Future, the Population Assessment of Tobacco and Health study, and other studies, DESPR monitors trends in drug use, including marijuana, vaping/e-cigarettes, and other drugs, as well as the potential risks and health outcomes related to these behaviors.

Preventing the initiation of substance use to minimize risks of harmful consequences is an essential part of addressing SUD. To this end, DESPR funds a portfolio of prevention research to understand and intervene upon mechanisms that underlie risk for and resilience to addiction and common comorbidities. This includes studies 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, is helping to inform the development of evidence-based prevention strategies.

¹⁹ pubmed.ncbi.nlm.nih.gov/31816020/

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 examining efforts to implement evidence-based SUD treatment in jails and prisons, expand the use of effective medications for OUD in primary care settings, develop strategies to reduce transmission of viral infections related to substance use (e.g., HIV, and Hepatitis C), and increase uptake and retention in treatment for SUD and HIV. DESPR also funds research into the efficacy of screening, brief intervention, and referral to treatment in primary care settings for reducing drug use and SUD.

<u>Budget Policy:</u> The FY 2022 President's Budget request is \$418.0 million, an increase of \$76.9 million or 22.5 percent compared with the FY 2021 Enacted level.

Therapeutics and Medical Consequences Research

NIDA's Division of Therapeutics and Medical Consequences (DTMC) supports research to evaluate the safety and efficacy of pharmacotherapies and devices to treat SUD. This work spans all phases of medical product development including synthesis and preclinical evaluation of potential therapeutics, clinical trial design and execution, and preparing regulatory submissions. Through these investments, NIDA helps to mitigate risks of developing new treatments for SUD. For example, in collaboration with US WorldMeds, DTMC supported clinical trials on LUCEMYRATM, the first medication targeted specifically to treat the physical symptoms associated with opioid withdrawal,²⁰ which was approved by the FDA in May 2018. NIDA also supports research to identify promising compounds and make them more feasible for pharmaceutical companies to complete costly clinical studies for SUD indications. As part of the HEAL InitiativeSM, described below, DTMC leads efforts to develop new and repurposed medications to treat OUD.

NIDA is also prioritizing the development of pharmacological treatments for stimulant use disorders. This portfolio includes approaches from repurposing approved medications for other SUDs, to developing a novel monoclonal antibody that could prevent or reduce methamphetamine intoxication (see program portrait "Medications Development for Stimulant Use Disorder").

<u>Budget Policy:</u> The FY 2022 President's Budget request is \$142.3 million, an increase of \$26.2 million or 22.5 percent compared with the FY 2021 Enacted level.

Clinical Trials Network Research

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The overarching mission of the NIDA Clinical Trials Network (CTN) is to allow medical and specialty treatment providers, treatment researchers, patients, and NIDA to cooperatively develop, validate, refine, and deliver new treatment options to patients. The CTN comprises: 16 research nodes with 31 principal investigators affiliated with academic medical centers and large health care networks; two research coordinating centers; and more than 240 community-anchored treatment programs. This unique partnership enables the CTN to conduct studies of behavioral, pharmacological, and integrated treatment interventions in multisite clinical trials to

 $^{^{20}\} www.drugabuse.gov/about-nida/noras-blog/2018/05/nida-supported-science-leads-to-first-fda-approved-medication-opioid-withdrawal$

determine effectiveness across a broad range of settings and populations. It also allows the CTN to ensure the transfer of research results to providers and patients. The network evaluates interventions, implementation strategies, and health system approaches to addressing SUD and

co-occurring conditions such as mental illnesses and HIV. Using support from HEAL, the CTN has been able to expand its geographical reach (see **Figure 2**), adding 5 new nodes in 2020 that can develop and test interventions in new populations.

The CTN is conducting studies to evaluate strategies for integrating OUD screening and treatment into emergency departments, primary care clinics, and American Indian/Alaska Native



Figure 2: Expansion of NIDA's Clinical Trial Network. Existing nodes are shown in blue, and new nodes from the HEAL-supported expansion in red.

communities. The CTN is also conducting a study to examine the effects of medications for OUD in pregnant women. It has supported studies to capture important data for research on SUD in electronic health record (EHR) systems in primary care and emergency departments, and is currently developing and testing a clinical decision support tool that integrates with EHR systems to help doctors diagnose OUD and provide treatment or refer patients to appropriate care. Complementing the work supported through NIDA's DTMC, CTN studies are investigating the effectiveness and safety of pharmacotherapies (e.g., ADAPT-2; see program portrait, "Medications for Stimulant Use Disorder"), and transcranial magnetic stimulation for methamphetamine and cocaine use disorders.

<u>Budget Policy:</u> The FY 2022 President's Budget request is \$48.6 million, an increase of \$8.9 million or 22.5 percent compared with the FY 2021 Enacted level.

Research Responding to the Opioid Crisis

Through the HEAL InitiativeSM, NIDA continues to expand its support for research to combat opioid addiction. For example, NIDA is supporting a study to prevent the high rate of opioid misuse initiation associated with the transition from adolescence to adulthood. HEAL funds are also being used to accelerate the availability of novel treatments for OUD and overdose, including to develop longer-acting formulations of existing OUD drugs like buprenorphine, repurpose approved drugs for other indications for OUD, and develop novel antibodies to prevent the action of opioids in the brain.

The HEAL InitiativeSM leveraged NIDA's existing CTN to expand the network by adding 5 new nodes that are supporting the development of 26 new research protocols. Two large projects address knowledge gaps around treatment initiation and retention. The first is a study of the efficacy of prevention interventions to halt the progression from risky opioid use to OUD. Researchers will test the efficacy of a Subthreshold Opioid Use Disorder Prevention (STOP)

intervention in primary care settings to identify and address early-stage opioid misuse. The second is a study to test strategies to improve retention in medication treatment for OUD, as well as strategies to improve outcomes for patients stabilized on OUD medications who want to stop

taking them. This will be the first study of medications to treat OUD to follow prospectively a large sample of patients through discontinuation.

HEAL also supports studies that are developing effective implementation strategies for evidence-based interventions. The Justice Community Opioid Innovation Network (JCOIN) is testing strategies to expand effective OUD treatment and care for people in justice settings in partnership with local and state justice systems and community-based treatment providers, which will fully launch as clinical trials in early 2021. The HEALing Communities Study, a multisite implementation research study, is investigating coordinated approaches for deploying evidence-based strategies to prevent and treat opioid misuse and OUD tailored to the needs of local communities. The goal of the study is to reduce opioidrelated overdose deaths by 40 percent over three years. Research sites are partnering with 67 communities highly affected by the opioid crisis in four states to measure the impact of these efforts.

Finally, the HEALthy Brain and Child Development Study is a NIDA and HEAL-led, trans-NIH effort to add to our understanding of early brain development trajectories. This study will establish a cohort of pregnant women and follow their children through the first decade of their lives to determine how environmental factors, including maternal drug exposure and

NIDA's Innovative Technology Portfolio

Twenty-first century problems require 21st century solutions, and addiction is no exception. New trends in technology, including mobile apps, GPS, portable biosensors, and virtual reality offer opportunities to innovate new approaches to both research and delivery of addiction prevention interventions and treatments. Unfortunately, the addiction space is relatively underserved when it comes to product development and commercialization. To address this critical gap, NIDA invests in a variety of translational initiatives, in order to help researchers commercialize their research or to encourage companies with promising technologies to expand to the addiction space.

Some of these products deliver evidence-based therapies in novel ways. For example, OpenBeds, a smartphone app originally designed to connect patients to open acute care beds, has been expanded with NIDA support to facilitate referrals to residential. inpatient, and outpatient addiction treatment facilities, and is currently being used by several state governments and hospital systems. One technology, a novel app developed by Sound Life Sciences, turns a user's smartphone into a portable respiratory monitor capable of detecting changes in breathing associated with an overdose, sounding an alarm and alerting emergency services. Other apps help doctors and patients monitor and maintain their OUD medication, and connect individuals to behavioral therapies, peer support groups, and community interventions.

NIDA also supports the development of entirely novel technologies. One such technology is a hospital bassinet pad called Prapela SVS that applies gentle vibrations to soothe babies born dependent on opioids, which is currently seeking FDA approval. Another technology, applied VR, uses virtual reality as an alternative form of pain relief to opioids. Others help hospitals monitor their controlled substances for theft or diversion, identify illicit drug transactions on the internet, or find innovative new approaches to measuring pain via brain activity patterns.

genetics, influence early brain development and behavioral and clinical outcomes such as mental illnesses and addiction.

<u>Budget Policy</u>: The FY 2022 President's Budget request for HEAL Initiative extramural research is \$400.4 million, an increase of \$134.5 above the FY 2021 Enacted level. Including \$5.0 million for Research Management and Support, total NIDA funding in FY 2022 for the

HEAL initiative is \$405.4 million, an increase of \$135.1 million or 50.0 percent compared to the FY 2021 Enacted level.

High-Tech Biomedical Product Development

NIDA's Office of Translational Initiatives and Program Innovations (OTIPI) takes research discoveries in prevention, detection, and treatment of SUD into candidate health applications for commercialization. OTIPI manages NIDA's Small Business Innovation Research/Small Business Technology Transfer Programs to advance health applications. It also uses novel fit-for-purpose funding authorities, such as Prizes and Open Competitions, and establishes teaching programs that equip scientists with the competence to translate advances in addiction research into products. Many of these efforts take the form of innovative new technology applications, from mobile apps that help patients find open beds in addiction treatment facilities or connect to support communities, to more sophisticated medical devices. (See the Program Portrait "NIDA's Innovative Technology Portfolio.")

<u>Budget Policy</u>: The FY 2022 President's Budget request is \$55.9 million, an increase of \$10.3 million or 22.5 percent compared with the FY 2021 Enacted level.

Intramural Research Program

NIDA conducts research in high priority areas through its Intramural Research Program (IRP). The IRP portfolio includes research to: 1) elucidate the mechanisms underlying the development of SUDs; 2) evaluate potential new therapies for SUDs, including pharmacological and non-pharmacological interventions; and 3) identify and characterize emerging drugs such as synthetic opioids, stimulants, and cannabinoids.

One example of treatment evaluation at the IRP is a bench-to-bedside project in which IRP investigators are testing a novel compound to treat OUD that activates the same receptors as traditional opioids but has only a subset of their cellular actions. IRP investigators are testing whether the compound reduces self-administration of opioids in animal models and people with OUD, and whether it prevents opioid withdrawal with fewer side effects than medications in current use. If successful, this compound could be a new medication for OUD.

The IRP is also working with the National Center for Advancing Translational Sciences on a dopamine D3 receptor antagonist that could be taken together with opioid pain relievers to reduce the chance of developing OUD. Preliminary animal studies suggest that the compound reduces opioid self-administration and drug-seeking behavior without reducing the pain-relieving effects of opioids. This compound holds promise as an adjunct to opioid treatment for pain and potentially for OUD.

Non-pharmacological addiction treatments are also being developed in NIDA's IRP. The on-site treatment-research clinic includes efforts to develop a smartphone app that uses machine learning to detect or predict stress, craving, and drug use within hours—and a parallel project to develop content that the app could deliver "just in time." Because current apps purporting to serve these functions do not meet scientific standards of evidence, IRP is addressing a major gap in mobile health. Using passive measurement and digital phenotyping techniques, the IRP is also

developing interventions and big data methodologies to prevent HIV transmission associated with unprotected sex in the context of substance use.

<u>Budget Policy:</u> The FY 2022 President's Budget request is \$105.2 million, an increase of \$3.1 million or 3.0 percent compared with the FY 2021 Enacted level.

Research Management and Support

Research Management and Support 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. RMS staff at NIDA play leadership roles in helping to coordinate NIDA's involvement in the NIH HEAL InitiativeSM, spearheading NIH's response to the opioid overdose epidemic.

In addition to the infrastructure required to support research and training, NIDA strives to provide evidence-based resources and educational materials about substance use and addiction, including information about timely public health topics such as opioid overdose prevention, marijuana research, use and consequences of vaping, synthetic drug trends, and medications for treatment of SUD, including OUD. To this end, the RMS portfolio incorporates education and outreach activities to inform public health policy and practice with the goal of ensuring that NIDA is the primary trusted source for scientific information on drug use and addiction. Staff supported by NIDA's RMS budget coordinate key activities that help to train the next generation of addiction scientists. In addition, NIDA's RMS portfolio includes the NIDAMED initiative, ²¹ which is aimed at engaging and educating clinicians in training and in practice in the latest science related to drug use and addiction.

<u>Budget Policy:</u> The FY 2022 President's Budget request is \$78.3 million, an increase of \$1.3 million or 1.7 percent compared with the FY 2021 Enacted level.

²¹ www.drugabuse.gov/nidamed-medical-health-professionals

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2013	\$1,054,001,000		\$1,057,196,000	\$1,053,367,366
Rescission				\$2,106,735
Sequestration				(\$52,871,798)
2014	\$1,071,612,000		\$1,064,490,000	\$1,025,435,000
Rescission				\$0
2015	\$1,023,268,000			\$1,028,614,000
Rescission				\$0
2016	\$1,047,397,000	\$1,050,875,000	\$1,069,086,000	\$1,077,488,000
Rescission				\$0
2017 ¹	\$1,050,550,000	\$1,107,700,000	\$1,103,032,000	\$1,090,853,000
Rescission				\$0
2018	\$864,998,000	\$1,107,497,000	\$1,113,442,000	\$1,383,603,000
Rescission				\$0
2019	\$1,137,403,000	\$1,400,126,000	\$1,420,591,000	\$1,419,844,000
Rescission				\$0
2020	\$1,296,379,000	\$1,489,237,000	\$1,490,498,000	\$1,462,016,000
Rescission				\$0
2021	\$1,431,770,000	\$1,476,590,000	\$1,505,192,000	\$1,479,660,000
Rescission				\$0
2022	\$1,852,503,000			

¹ Budget Estimate to Congress includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse

Authorizing Legislation

	PHS Act/	U.S. Code	2021 Amount	FY 2021 Enacted	2022 Amount	2022 Amount FY 2022 President's Budget
	Other Citation	Citation	Authorized		Authorized	
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				\$1,480,309,000	_^	\$1,852,503,000
National Institute on Drug Abuse	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$1,480,309,000		\$1,852,503,000

Amounts Available for Obligation¹

Source of Funding	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation	\$1,462,016	\$1,479,660	\$1,852,503
Secretary's Transfer	0	0	0
OAR HIV/AIDS Transfers	-4,292	649	0
Subtotal, adjusted budget authority	\$1,457,724	\$1,480,309	\$1,852,503
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,457,724	\$1,480,309	\$1,852,503
Unobligated balance lapsing	-41	0	0
Total obligations	\$1,457,683	\$1,480,309	\$1,852,503

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

Budget Authority by Object Class¹

		FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total con	mpensable workyears:			
	Full-time equivalent	388	388	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	\$199	\$204	\$5
	Average GM/GS grade	13.0	13.0	0.0
	Average GM/GS salary	\$128	\$131	\$3
	Average salary, Commissioned Corps (42 U.S.C.	¢122	¢125	¢2
	207)	\$122	\$125	\$3
	Average salary of ungraded positions	\$154	\$158	\$4
	ODJECT CLASSES	EV 2021 E 4 1	FY 2022 President's	FY 2022
	OBJECT CLASSES	FY 2021 Enacted	Budget	+/- FY 2021
	Personnel Compensation			
11.1	Full-Time Permanent	30,606	31,190	584
11.3	Other Than Full-Time Permanent	13,552	13,860	308
11.5	Other Personnel Compensation	1,614	1,651	37
11.7	Military Personnel	836	971	135
11.8	Special Personnel Services Payments	5,840	5,973	133
11.9	Subtotal Personnel Compensation	\$52,448	\$53,645	\$1,197
12.1	Civilian Personnel Benefits	16,528	17,406	878
12.2	Military Personnel Benefits	453	466	13
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	\$69,429	\$71,517	\$2,088
21.0	Travel & Transportation of Persons	433	690	258
22.0	Transportation of Things	235	239	4
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	2,391	2,434	43
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	47,443	46,043	-1,400
25.2	Other Services	18,993	19,234	240
25.3	Purchase of goods and services from government	100,893	107,439	6,547
25.4	accounts	510	500	2
	Operation & Maintenance of Facilities	519	522	3
25.5 25.6	R&D Contracts	23,499	23,922	423
25.6	Medical Care	499	518	18
	Operation & Maintenance of Equipment	6,024 0	6,133 0	108 0
25.8 25.0	Subsistence & Support of Persons Subtotal Other Contractual Services	\$197,870		\$5,940
26.0	Supplies & Materials	4,924	5,038	
31.0	Equipment	4,309	4,386	78
32.0	Land and Structures	4,309	4,380	1
33.0	Investments & Loans) 34 	0	1
41.0	Grants, Subsidies & Contributions	1,200,683	1,564,353	363,669
42.0	Insurance Claims & Indemnities	1,200,003	1,50 - ,555	202,009
43.0	Interest & Dividends	1	1	0
44.0	Refunds	1	1	0
77.0	Subtotal Non-Pay Costs	\$1,410,880	\$1,780,986	\$370,106
	Total Budget Authority by Object Class	\$1,480,309		\$370,100

 $^{^{\}mbox{\scriptsize 1}}$ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

Salaries and Expenses

OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
Full-Time Permanent (11.1)	\$30,606	\$31,190	\$584
Other Than Full-Time Permanent (11.3)	13,552	13,860	308
Other Personnel Compensation (11.5)	1,614	1,651	37
Military Personnel (11.7)	836	971	135
Special Personnel Services Payments (11.8)	5,840	5,973	133
Subtotal Personnel Compensation (11.9)	\$52,448	\$53,645	\$1,197
Civilian Personnel Benefits (12.1)	\$16,528	\$17,406	\$878
Military Personnel Benefits (12.2)	453	466	13
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$69,429	\$71,517	\$2,088
Travel & Transportation of Persons (21.0)	\$433	\$690	\$258
Transportation of Things (22.0)	235	239	4
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	2,391	2,434	43
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	38,408	39,197	790
Other Services (25.2)	18,993	19,234	240
Purchases from government accounts (25.3)	54,686	57,726	3,040
Operation & Maintenance of Facilities (25.4)	519	522	3
Operation & Maintenance of Equipment (25.7)	6,024	6,133	108
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$118,631	\$122,812	\$4,181
Supplies & Materials (26.0)	\$4,924	\$5,038	\$114
Subtotal Non-Pay Costs	\$126,614	\$131,213	\$4,600
Total Administrative Costs	\$196,043	\$202,730	\$6,687

Detail of Full-Time Equivalent Employment (FTE)

]	FY 2020 Final		F	Y 2021 Enacte	ed	FY 202	2 President's	Budget
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for the Clinical Trials Network									
Direct:	13		13	14		14	14		14
Reimbursable:	13		13	14		14	14	_	14
Total:	13		13	14		14	14	_	14
Total.	13		13	14		14	14	-	14
Division of Epidemiology, Services and Prevention Research									
Direct:	24	2	26	26	1	27	26	1	27
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	24	2	26	26	1	27	26	1	27
Division of Extramural Research									
Direct:	44		44	44		44	44		44
Reimbursable:	44	-	44	44	-	44	44	-	44
Total:	44	-	44	44	-	44	44	-	44
Total.	77		77				77	-	44
Division of Neuroscience and Behavior									
Direct:	24	-	24	25	-	25	25	-	25
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	24	-	24	25	-	25	25	-	25
Division of Therapeutics and Medical Consequences	20		20	20		20	20		20
Direct:	28	-	28	29	-	29	29	-	29
Reimbursable:	20	-	28	29	-	20	20	-	- 20
Total:	28	-	28	29	-	29	29	-	29
Intramural Research Program									
Direct:	112	4	116	116	4	120	116	4	120
Reimbursable:	1	_	1	1		1	1	-	1
Total:	113	4	117	117	4	121	117	4	121
Office of Management	2.1			22		22			22
Direct:	21	-	21	23	-	23	23	-	23
Reimbursable:	49	-	49	60		60	60	-	60
Total:	70	-	70	83	-	83	83	-	83
Office of Science Policy and Communication									
Direct:	23	_	23	22	_	22	22	_	22
Reimbursable:	-	_	-	-	_	-	-	_	-
Total:	23	_	23	22	_	22	22	-	22
Office of the Director									
Direct:	18	-	18	23	-	23	23	-	23
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	18	-	18	23	-	23	23	-	23
Total	357	6	363	383	5	388	383	5	388
Includes FTEs whose payroll obligations are supported by the	NIH Common	Fund.			-,				
FTEs supported by funds from Cooperative Research and									
Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR				Av	erage GS Gra	de			
2018					13.0				
2019					13.3				
2020					13.1				
2021					13.0				
2022					13.0				

Detail of Positions¹

GRADE	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	197,300	199,273	203,856
General Schedule			
GM/GS-15	65	61	61
GM/GS-14	66	70	70
GM/GS-13	82	90	90
GS-12	46	44	44
GS-11	11	14	14
GS-10	0	0	0
GS-9	8	9	9
GS-8	5	8	8
GS-7	7	4	4
GS-6	2	2	2
GS-5	0	0	0
GS-4	0	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	292	303	303
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	3	2	2
Senior Grade	2	2	2
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	6	5	5
Ungraded	91	93	93
Total permanent positions	297	309	309
Total positions, end of year	390	402	402
Total full-time equivalent (FTE) employment, end of year	363	388	388
Average ES salary	197,300	199,273	203,856
Average GM/GS grade	13.1	13.0	13.0
Average GM/GS salary	126,642	127,908	130,850

 $^{^{\}mbox{\scriptsize 1}}$ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.