DEPARTMENT OF HEALTH AND HUMAN SERVICES

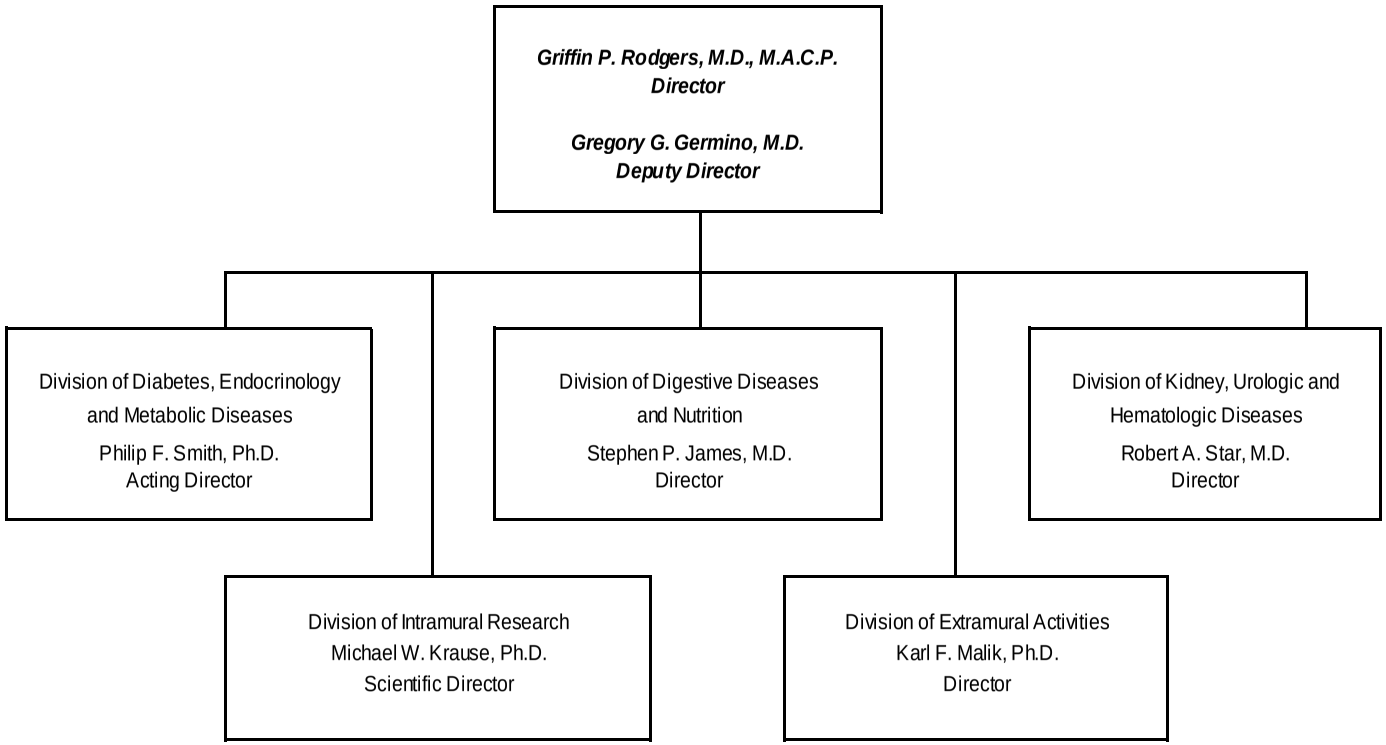
NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases

Organization Structure



NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases

For carrying out section 301 and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, **[**$2,029,823,000**]***$1,746,493,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Amounts Available for Obligation[1,2]
(Dollars in Thousands)

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation	$1,970,797	$2,029,823	$1,746,493
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(150,000)*	*(150,000)*	*(150,000)*
Secretary's Transfer	-4,630	0	0
Subtotal, adjusted appropriation	$1,966,167	$2,029,823	$1,746,493
OAR HIV/AIDS Transfers	-2,714	0	0
Subtotal, adjusted budget authority	$1,963,453	$2,029,823	$1,746,493
Unobligated balance lapsing	-46	0	0
Total obligations	$1,963,407	$2,029,823	$1,746,493

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2018 - $3,746 FY 2019 - $6,000 FY 2020 - $6,000

[2] 3 FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,903	$889,225	1,931	$928,586	1,969	$821,326	38	-$107,260
Administrative Supplements	*(105)*	15,941	*(106)*	16,000	*(91)*	13,760	*(-15)*	-2,240
Competing:								
Renewal	156	77,039	161	79,692	141	59,877	-20	-19,815
New	508	228,216	529	239,073	462	179,627	-67	-59,446
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	664	$305,256	690	$318,765	603	$239,504	-87	-$79,261
Subtotal, RPGs	2,567	$1,210,422	2,621	$1,263,351	2,572	$1,074,590	-49	-$188,761
SBIR/STTR	115	61,166	117	62,400	100	53,490	-17	-8,910
Research Project Grants	2,682	$1,271,588	2,738	$1,325,751	2,672	$1,128,080	-66	-$197,671
Research Centers:								
Specialized/Comprehensive	95	$115,676	95	$116,000	82	$100,600	-13	-$15,400
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	50	0	50	0	43	0	-7
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	95	$115,726	95	$116,050	82	$100,643	-13	-$15,407
Other Research:								
Research Careers	450	$77,056	460	$79,000	400	$68,679	-60	-$10,321
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	544	0	540	0	458	0	-82
Other	112	67,107	114	67,500	99	58,691	-15	-8,809
Other Research	562	$144,706	574	$147,040	499	$127,828	-75	-$19,212
Total Research Grants	3,339	$1,532,020	3,407	$1,588,841	3,253	$1,356,551	-154	-$232,290
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	302	$14,512	310	$14,802	267	$12,730	-43	-$2,072
Institutional Awards	808	48,191	824	49,155	690	41,173	-134	-7,982
Total Research Training	1,110	$62,703	1,134	$63,957	957	$53,903	-177	-$10,054
Research & Develop. Contracts	136	$94,994	103	$95,000	94	$86,509	-9	-$8,491
(SBIR/STTR) (non-add)	*(2)*	*(133)*	*(3)*	*(750)*	*(3)*	*(575)*	*(0)*	*(-175)*
Intramural Research[2]	356	199,877	373	205,874	373	180,989	0	-24,885
Res. Management & Support	274	73,860	287	76,151	287	68,541	0	-7,610
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(50)*	*(0)*	*(50)*	*(0)*	*(0)*
Total, NIDDK	630	$1,963,453	660	$2,029,823	660	$1,746,493	0	-$283,330

[1] All items in italics and brackets are non-add entries; Excludes mandatory funding for Type 1 Diabetes which is shown in a separate mechanism table.

[2] 3 FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.

NATIONAL INSTITUTES OF HEALTH
Type 1 Diabetes

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2018 Final[2]		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	123	$85,738	132	$102,845	219	$128,780	87	$25,935
Administrative Supplements	*(2)*	332	*(0)*	0	*(0)*	0	*(0)*	0
Competing:								
Renewal	11	16,555	12	23,600	5	3,652	-7	-19,948
New	36	19,866	34	20,150	13	7,093	-21	-13,057
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	47	$36,421	46	$43,750	18	$10,745	-28	-$33,005
Subtotal, RPGs	170	$122,491	178	$146,595	237	$139,525	59	-$7,070
SBIR/STTR	19	9,033	3	1,405	11	5,475	8	4,070
Research Project Grants	189	$131,523	181	$148,000	248	$145,000	67	-$3,000
Research Centers:								
Specialized/Comprehensive	0	$0	0	$0	0	$0	0	$0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	0	$0	0	$0	0	$0	0	$0
Other Research:								
Research Careers	44	$16,477	0	$0	8	$3,000	8	$3,000
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	2,000	0	2,000	0	2,000	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Other Research	44	$18,477	0	$2,000	8	$5,000	8	$3,000
Total Research Grants	233	$150,000	181	$150,000	256	$150,000	75	$0
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	0	0	0	0	0	0	0	0
Total Research Training	0	$0	0	$0	0	$0	0	$0
Research & Develop. Contracts	0	$0	0	$0	0	$0	0	$0
(SBIR/STTR) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Intramural Research	0	0	0	0	0	0	0	0
Res. Management & Support	0	0	0	0	0	0	0	0
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Total, T1D	0	$150,000	0	$150,000	0	$150,000	0	$0

[1] All items in italics and brackets are non-add entries.

[2] Includes $123.7 million of Type 1 Diabetes funding not obligated in FY 2018, and carried over into FY 2019.

Major Changes in the Fiscal Year 2020 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 mechanisms and activity detail and these highlights will not sum to the total change for the FY 2020 President's Budget. The FY 2020 President's Budget request for NIDDK, excluding the proposed $150 million of mandatory funding for Type 1 Diabetes, is $1,746.5 million, a decrease of $283.3 million from the FY 2019 Enacted level. The FY 2020 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NIDDK will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (-$197.7 million; total $1,128.1 million): NIDDK will reduce funding for non-competing RPGs by 14.0 percent, which is a $107.3 million decrease from their full funding level. Competing RPGs are expected to decrease by 24.9 percent or 87 grants compared to the FY 2019 Enacted level of 690 awards, and the amount to support competing awards will be reduced by $79.3 million from the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

Other Research (-$19.2 million; total $127.8 million): NIDDK will reduce funding for other research by 13.0 percent compared to the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

R&D Contracts (-$8.5 million; total $86.5 million): NIDDK will reduce funding for R&D Contracts by 9.0 percent compared to the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

Intramural Research (-$24.9 million; total $181.0 million): NIDDK will reduce funding for Intramural Research by 12.1 percent compared to the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

Research Management and Support (-$7.6 million; total $68.5 million): NIDDK will reduce funding for Research, Management, and Support by 10.0 percent compared to the FY 2019 Enacted level. These reductions are distributed across all administrative support areas of basic, translational or clinical research.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Summary of Changes

(Dollars in Thousands)

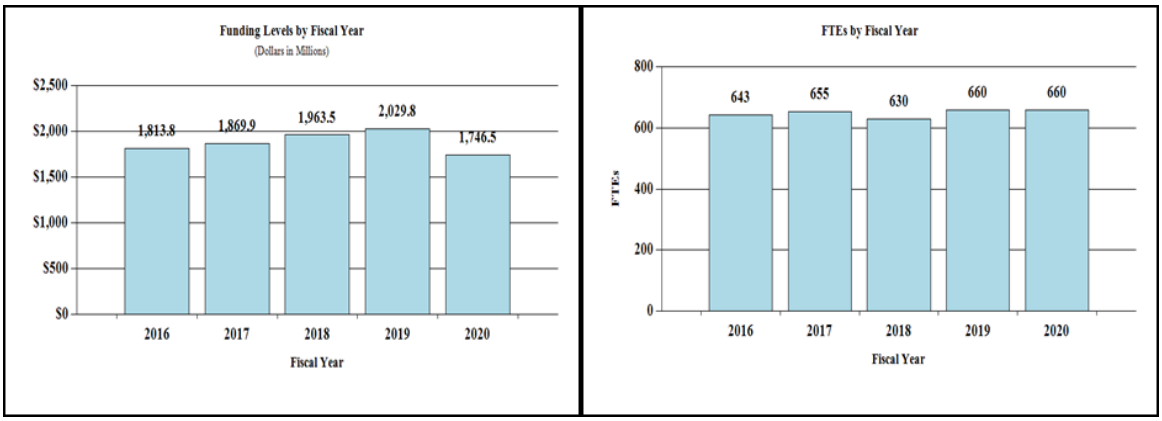
FY 2019 Enacted	$2,029,823
FY 2020 President's Budget	$1,746,493
Net change	-$283,330

CHANGES	FY 2020 President's Budget FTEs	FY 2020 President's Budget Budget Authority	Change from FY 2019 Enacted FTEs	Change from FY 2019 Enacted Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2019 pay increase & benefits		$81,349		$62
b. January FY 2020 pay increase & benefits		81,349		186
c. Paid days adjustment		81,349		313
d. Differences attributable to change in FTE		81,349		0
e. Payment for centrally furnished services		33,422		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		66,218		0
Subtotal				$561
2. Research Management and Support:				
a. Annualization of January 2019 pay increase & benefits		$45,935		$35
b. January FY 2020 pay increase & benefits		45,935		105
c. Paid days adjustment		45,935		208
d. Differences attributable to change in FTE		45,935		0
e. Payment for centrally furnished services		0		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		22,606		0
Subtotal				$348
Subtotal, Built-in				$909

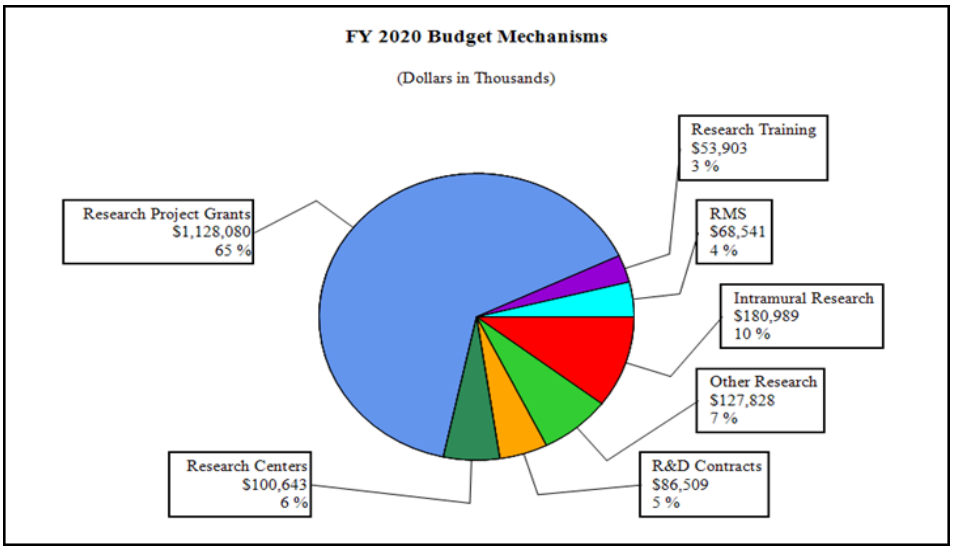
CHANGES	FY 2020 President's Budget No.	FY 2020 President's Budget Amount	Change from FY 2019 Enacted No.	Change from FY 2019 Enacted Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	1,969	$835,086	38	-$109,500
b. Competing	603	239,504	-87	-79,261
c. SBIR/STTR	100	53,490	-17	-8,910
Subtotal, RPGs	2,672	$1,128,080	-66	-$197,671
2. Research Centers	82	$100,643	-13	-$15,407
3. Other Research	499	127,828	-75	-19,212
4. Research Training	957	53,903	-177	-10,054
5. Research and development contracts	94	86,509	-9	-8,491
Subtotal, Extramural		$1,496,963		-$250,835
	FTEs		FTEs	
6. Intramural Research	373	$180,989	0	-$25,446
7. Research Management and Support	287	68,541	0	-7,958
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	660	$1,746,493	0	-$284,239
Total changes				-$283,330

Fiscal Year 2020 Budget Graphs

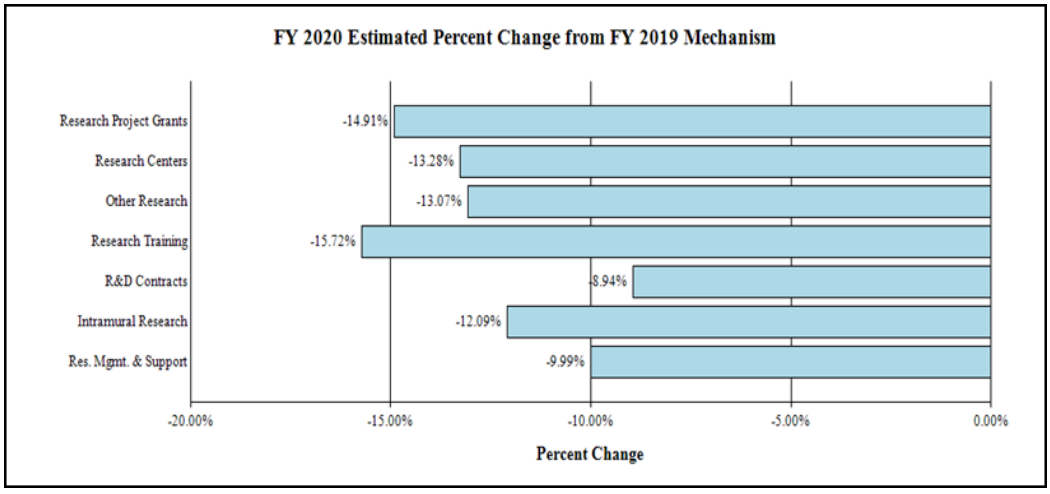
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY2019	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Diabetes, Endocrinology, and Metabolic Diseases		$692,662		$716,473		$613,648		-$102,825
Digestive Diseases and Nutrition		551,023		569,963		488,165		-81,798
Kidney, Urologic, and Hematologic Diseases		446,031		461,362		395,150		-66,212
Type 1 Diabetes (mandatory funding)		*(26,292)*		*(150,000)*		*(150,000)*		*(0)*
Subtotal, Extramural		**$1,689,716**		**$1,747,798**		**$1,496,963**		**-$250,835**
Intramural Research	**356**	**$199,877**	**373**	**$205,874**	**373**	**$180,989**	**0**	**-$24,885**
Research Management & Support	**274**	**$73,860**	**287**	**$76,151**	**287**	**$68,541**	**0**	**-$7,610**
TOTAL	**630**	**$1,963,453**	**660**	**$2,029,823**	**660**	**$1,746,493**	**0**	**-$283,330**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Three FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2019 Amount Authorized	FY 2019 Enacted	2020 Amount Authorized	FY 2020 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,029,823,000	Indefinite	$1,746,493,000
National Institute of Diabetes and Digestive and Kidney Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,029,823,000		$1,746,493,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Appropriations History[1]

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2011	$2,007,589,000		$2,004,674,000	$1,958,100,000
Rescission				($15,876,196)
2012	$1,987,957,000	$1,987,957,000	$1,922,045,000	$1,950,447,000
Rescission				($3,402,845)
2013	$1,942,107,000		$1,947,539,000	$1,797,044,155
Rescission				($3,594,088)
Sequestration				($97,849,260)
2014	$1,961,786,000		$1,949,745,000	$1,894,274,000
Sequestration				($10,800,000)
2015	$1,893,336,000			$1,899,681,000
2016	$1,938,133,000	$1,921,388,000	$1,975,162,000	$1,968,357,000
2017	$1,966,310,000	$1,962,093,000	$2,041,652,000	$2,020,595,000
Sequestration				($10,350,000)
2018	$1,599,534,000	$1,899,733,000	$1,935,597,000	$2,120,797,000
2019	$1,965,434,000	$2,144,333,000	$2,180,892,000	$2,179,823,000
2020	$1,896,493,000			

[1] Includes mandatory financing.

Justification of Budget Request

National Institute of Diabetes and Digestive and Kidney Diseases

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

Budget Authority (BA):

	FY 2018 Actual	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
BA	$2,120,797,000	$2,179,823,000	$1,896,493,000	-$283,330,000
Type 1 Diabetes Mandatory	-$150,000,000	-$150,000,000	-$150,000,000	$0
Labor/HHS:	$1,970,797,000	$2,029,823,000	$1,746,493,000	-$283,330,000
FTEs	630	660	660	0

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

Director's Overview

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to support and conduct research to combat diabetes and other endocrine and metabolic diseases, liver and other digestive diseases, nutritional disorders, obesity, and kidney, urologic, and hematologic diseases. These diseases are chronic, common, costly, and consequential for patients, their families, and the Nation. Diabetes affects an estimated 30.3 million people in the United States, greatly increasing the risk for many serious complications, such as heart disease and kidney failure.[1] Estimates of chronic kidney disease (CKD) show that about 30 million Americans are affected, and over 700,000 have irreversible kidney failure.[2] Many urologic diseases, such as urinary incontinence, urinary tract infections, and benign prostatic hyperplasia, are also highly prevalent.[3] Digestive diseases account for an estimated 72 million ambulatory care visits to doctor's offices, outpatient hospital clinics, and emergency departments, as well as 13.5 million hospitalizations with a primary or secondary diagnosis.[4] Obesity affects nearly 40

[1] Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report, 2017. Atlanta, GA: CDC, Department of Health and Human Services; 2017.
[2] CDC. National Chronic Kidney Disease Fact Sheet, 2017. Atlanta, GA: CDC, Department of Health and Human Services; 2017.U.S. Renal Data System, USRDS 2017 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, NIH, NIDDK, Bethesda, MD, 2017.
[3] Urological Diseases in America. NIDDK/NIH Publication Number 12-7865, 2012.
[4] Everhart JE, et al. Gastroenterology 136: 376-386, 2009.

percent of U.S. adults and over 18 percent of children and adolescents.[5] It is a strong risk factor for type 2 diabetes, nonalcoholic steatohepatitis (NASH), and many other diseases. Cystic fibrosis and other genetic diseases within NIDDK's purview are less widespread, but still devastating in their impact. Building on emerging opportunities from past research investments, NIDDK will continue its vigorous pursuit of research to combat the diseases and disorders within its mission, being guided by the NIDDK Director's priorities: maintain a vigorous investigator-initiated research portfolio, support pivotal clinical studies and trials, preserve a stable pool of talented new investigators, foster exceptional research training and mentoring opportunities, and ensure knowledge dissemination through outreach and communications.

Theme 1: From Inspiration to Innovation

In FY 2020, NIDDK will continue to support research that provides the inspiration for future innovations to combat complex health problems, including research that builds on recent successes. For example, NIDDK-supported research contributed to the development and testing of recently Food and Drug Administration (FDA)-approved next-generation continuous glucose monitors (CGM) for managing diabetes, including the first fully implantable CGM and the first CGM designed to be used as part of an integrated system.[6] These devices are being tested in ongoing NIDDK-supported artificial pancreas clinical trials. Advancements in CGM technologies are also making planned studies of maternal glucose (sugar) levels during pregnancy feasible, toward improving approaches for screening for gestational diabetes (GDM) and informing the development of future GDM clinical trials. NIDDK also supported foundational research that culminated in the recent FDA approval of a drug for the management of moderate to severe pain associated with endometriosis.[7] NIDDK plans to continue its support of basic research that can benefit diseases both within the NIDDK mission and beyond. The support of new and innovative nutrition research will be guided by the first NIH-wide strategic plan on nutrition. The plan was developed by the NIH Nutrition Research Task Force, chaired by the NIDDK Director and co-chaired by the Directors of the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute (NCI), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), with input from across NIH and from external stakeholders. NIDDK will also continue to foster and grow a diverse biomedical research workforce that can meet, with innovation and inspired ideas, the challenges posed by the multiple diseases and conditions within its mission.

Theme 2: Transformational Tools and Technologies

In FY 2020, NIDDK will continue to capitalize on the development and use of transformational tools and technologies to continue its support of multidisciplinary projects studying the development of the genitourinary tract; the gut microbiome; autoimmune diseases such as type 1 diabetes, celiac disease, inflammatory bowel diseases (IBD), autoimmune liver diseases, and some forms of CKD; and metabolic conditions, including obesity, type 2 diabetes, and NASH. Toward a long-term goal of replacing insulin-producing pancreatic beta cells that are destroyed in type 1 diabetes, NIDDK-supported scientists used a gene therapy approach to turn mouse pancreatic alpha cells, which produce the hormone glucagon, into beta-like cells that produced

[5] Hales CM, et al. 2017. CDC. National Center for Health Statistics Data Brief No. 288.
[6] www.fda.gov/newsevents/newsroom/pressannouncements/ucm611454.htm; https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm602870.htm
[7] https://www.fda.gov/Drugs/InformationOnDrugs/ucm616534.htm

insulin and controlled animals' blood glucose levels.[8] Using imaging technology, researchers for the first time visualized the location in mouse brain cells of a protein that transmits appetite-regulating information. They discovered that the protein is located on antenna-like sensory projections called cilia and works with another protein found in primary cilia of brain cells to regulate appetite and body weight, providing new insight into the role of primary cilia in obesity.[9] Researchers have created a mathematical formula to predict which species and strains of bacteria from a donor will successfully colonize the gut in people with recurrent *Clostridium difficile* (*C. difficile*) infections undergoing a fecal microbiota transplant, a procedure in which a sample containing gut bacteria from a healthy donor is introduced into a patient to help reestablish a functional microbiome.[10] These findings could inform the design of future microbe-based therapies for treating gastrointestinal infections and other digestive diseases. New knowledge obtained from studying single-cell gene activity combined with a recently developed analytical tool have enabled the development of models to predict the mature blood cell type of early stage blood cells, providing tools to further the fields of stem cell biology and regenerative medicine.[11]

Theme 3: Building on Basic Science

In FY 2020, NIDDK will continue to build on basic science advances and support research into the causes of and treatments and cures for human diseases. Building on findings from mouse studies and a pilot study in people, results from a clinical trial showed that an immune-suppressing medicine preserves insulin production in people with newly diagnosed type 1 diabetes, paving the way for future studies toward preventing or reversing the disease.[12] Researchers have developed a comprehensive molecular profile of the body's molecular responses to weight fluctuation, illustrating how even short-term periods of modest weight gain can affect metabolism, the gut microbiome, and heart health; data generated by this research could lead to personalized, predictive molecular signatures for type 2 diabetes and other weight-related conditions long before a disease manifests.[13] Studying a racially and ethnically diverse population of people with irritable bowel syndrome (IBS), researchers discovered that some of them have mutations in a gene that codes for an ion channel protein that contributes to gastrointestinal smooth muscle function; understanding genetic underpinnings of IBS could inform new prevention and treatment approaches.[14] Researchers determined that a multicomponent intervention significantly improved medication adherence among young kidney transplant recipients, which could help reduce the risk of rejection or failure of the transplanted kidney.[15] Results from a study showed that in people who do not have CKD, an intensive blood pressure control regimen increased risk of declining kidney function, but this risk is generally outweighed by a reduced risk for cardiovascular events and death. These results could help inform treatment decisions made by patients and their health care providers.[16]

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[8] Xiao X, et al. Cell Stem Cell 22: 78-90, 2018.
[9] Siljee JE, et al. Nat Genet 50: 180-185, 2018.
[10] Smillie CS, et al. Cell Host Microbe 23: 229-240, 2018.
[11] Tusi BK, et al. Nature 555: 54-60, 2018.
[12] Haller MJ, et al. Diabetes Care 41: 1917-1925, 2018.
[13] Piening BD, et al. Cell Systems 6: 157-170, 2018.
[14] Strege PR, et al. Am J Physiol Gastrointest Liver Physiol 314: G494-G503, 2018.
[15] Foster BJ, et al. Am J Kid Dis 72: 30-41, 2018.
[16] Beddhu S, et al. Ann Intern Med 167: 375-383, 2017.

Theme 4: Exploring the Next Frontier

In FY 2020, NIDDK will continue to explore the next frontier of biomedical research through its support of a robust investigator-initiated research portfolio and pivotal clinical studies and trials. The Institute will also continue to foster the growth of a diverse biomedical research workforce by providing special funding consideration and mentoring opportunities for talented young investigators. The training and mentorship opportunities for underrepresented populations offered by the Short-Term Education Programs for Underrepresented Persons and the Network of Minority Health Research Investigators will continue to promote a diverse research pipeline. NIDDK also plans to continue its support of research to combat type 2 diabetes in youth, an emerging health problem. Results from the Restoring Insulin Secretion (RISE) study showed that in young people 10-19 years of age, rapid progression of prediabetes or recent onset type 2 diabetes is not slowed by early combined use of the two approved medications for pediatric type 2 diabetes; analyses of participants' metabolic tests are showing how the disease differs in young people compared to adults, which can inform the development of new therapies.[17] Another NIDDK-supported study found that bariatric surgery to treat severely obese adolescents with type 2 diabetes led to improved outcomes, even remission of diabetes, compared to medical therapies.[18] NIDDK also plans to continue its support of regenerative medicine approaches to improve health and combat disease. Researchers have uncovered a key role for a unique cell type, called a telocyte, in supporting expansion and maturation of the nearby intestinal stem cells that perpetually replenish the inner lining of the gut; the telocytes accomplish this feat by regulating important growth signals sent to the stem cells.[19] Using sophisticated technologies, researchers have provided comprehensive insights into human kidney formation, knowledge that could inform efforts to generate human kidney structures.[20] Future research directions in regenerative medicine are being informed by discussions that NIDDK had with its Advisory Council at three meetings held in 2018.

Overall Budget Policy: The FY 2020 President's Budget request is $1,746.5 million, excluding mandatory Type 1 Diabetes funding, a decrease of $283.3 million or 14.0 percent compared with the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, epidemiology or clinical research.

Program Descriptions and Accomplishments

Diabetes, Endocrinology, and Metabolic Diseases

The objectives of this program are to enhance the understanding of diabetes and other endocrine and metabolic disorders, and to develop and test prevention and treatment strategies. The program supports basic, clinical, and translational research, as well as research training, in areas that include type 1, type 2, and gestational diabetes; cystic fibrosis; obesity; energy balance; and endocrinology. Knowledge from diabetes research is communicated to patients, health professionals, and the public through the National Diabetes Information Clearinghouse and the National Diabetes Education Program.

[17] The RISE Consortium. Diabetes Care 41: 1717-1725, 2018; The RISE Consortium. Diabetes Care 41: 1696-1706, 2018; The RISE Consortium. Diabetes Care 41: 1707-1716, 2018.
[18] Inge TH, et al. JAMA Pediatr 172: 452-460, 2018.
[19] Shoshkes-Carmel M, et al. Nature 557: 242-246, 2018.
[20] Lindström NO, et al. J Am Soc Nephrol. 29: 785-805, 2018.

In FY 2020, NIDDK will continue to support research that makes important contributions to the treatment and prevention of diseases that are associated with the endocrine system and metabolism, such as diabetes and obesity. Researchers have used cutting-edge technologies to examine individual cells from healthy human pancreases to understand how the cells change with age,[21] and have discovered that cells called pericytes play an important role in regulating blood flow through pancreatic islets (clusters of cells containing insulin-producing beta cells and other cell types) and may contribute to islet dysfunction in people with type 2 diabetes.[22] NIDDK plans to use FY 2020 funds to continue its support of an expansion of the Human Pancreas Procurement and Analysis Program to gain additional understanding of the cellular and molecular events in the pancreas that influence development of type 2 diabetes. Scientists have also discovered that a type of immune cell called a macrophage converts into another cell type to become part of healed skin—a process that is crucial for wound closure and that may be impaired in diabetic wound healing.[23] In FY 2020, NIDDK plans to continue support for the Diabetic Foot Consortium to validate biological markers for diabetic foot ulcers that could be used to predict healing outcomes, guide treatment decisions, and monitor healing and response to treatment. Another diabetes-related study has identified novel risk factors that can help predict vulnerability to severe episodes of low blood glucose levels (hypoglycemia) in African American and White individuals with type 2 diabetes, results that could help health care providers predict which people with type 2 diabetes may benefit from additional monitoring to prevent these life-threatening episodes.[24] In research to gain new insights into obesity, scientists found that feeding mice twice a day, with complete food restriction in between, improved metabolism and prevented age- and obesity-associated metabolic defects compared to allowing them 24-hour access to food; [25] and, in another study, scientists used a new genetic tool in mice to map out the cellular brain circuits used by the hormone leptin to control energy balance (calorie intake and calorie burning) and blood glucose levels.[26] These results have implications for future studies of strategies toward combating obesity and other metabolic diseases in people.

Program Portrait: Microphysiological Systems for Modeling Diabetes

FY 2019 Level: $3.0 million
FY 2020 Level: +$5.2 million
Change: +$2.2 million

Diabetes is characterized by the body's inability to produce and/or respond appropriately to insulin, a hormone that is necessary for the body to absorb and use glucose as a cellular fuel. Insulin is produced by beta cells that are found in tiny clusters in the pancreas called islets. While pre-clinical animal models continue to be a key resource for studying diabetes and its complications, including research on islet cell biology, there is a critical need to develop new pre-clinical model systems, such as human tissue chips—also called microphysiological systems (MPS)—that better mimic human physiology. For example, developing an "islet on a chip" has the potential to be transformative in terms of advancing studies in human islet biology, validating diabetes biomarkers, performing drug and toxicity testing of diabetes therapies, and modeling aspects of human diabetes. Based on this need, in 2014, NIDDK created the Consortium on Human Islet Biomimetics (CHIB), as part of the Human Islet Research Network (HIRN), to

[21] Enge M, et al. Cell 171: 321-330.e14, 2017
[22] Almaça J, et al. Cell Metab 27: 630-644.e4, 2018.
[23] Sinha M, et al. Nat Commun 9: 936, 2018.
[24] Lee AK, et al. Diabetes Care 40: 1661-1667, 2017.
[25] Martinez-Lopez N, et al. Cell Metab 26: 856-871.e5, 2017.
[26] Xu J, et al. Nature 556: 505-509, 2018.

create bioengineered human islets. Since then, HIRN-CHIB has made significant progress on recreating an MPS by engineering three-dimensional (3D) "microenvironments" that support survival and function of human islets in the laboratory setting. These laboratory microenvironments incorporate or mimic diverse elements that support islets in the body, such as blood vessels and components of the extracellular matrix. Such systems better represent human islet physiology than conventional two-dimensional islets cultured on plastic dishes, for example.

Building on this and other progress, in 2018, NIDDK announced an initiative to support a new HIRN-CHIB project period beginning in FY 2019. In the next phase, scientists will explore ways to develop an MPS that allows the study of interactions between human islets and immune cells within a 3D microenvironment to mimic aspects of the autoimmune process involved in type 1 diabetes. HIRN-CHIB will work toward an overarching goal of creating a human disease model that could recapitulate some aspects of the complex pathophysiology of type 1 diabetes, by using patient-derived islets (created using induced pluripotent stem cells [iPSCs] generated from adult stem cells) combined with immune components. In FY 2018, NIDDK also began a new research consortium, MPS for Modeling Diabetes (MPS-MOD), to complement the type 1 diabetes research being conducted by HIRN-CHIB and to build on recent progress developing other "tissues-on-a-chip" that have the potential to provide novel insights on diabetes. MPS-MOD, which is also supported by the National Center for Advancing Translational Sciences, will develop human tissue chips mimicking the physiology of diabetes-related metabolic tissues: the islet, liver, skeletal muscle, and white adipose (fat) tissue. MPS-MOD will use iPSC-based modeling, providing an opportunity to study iPSC-derived tissues generated from people with diabetes. The goal of MPS-MOD is to combine the human metabolically active tissue chips with immune system components to develop a fully integrated model of immune-mediated metabolic dysfunction, as a first step towards the generation of reproducible pre-clinical models for human type 2 diabetes and other metabolic diseases. Once developed, it is expected that these multi-dimensional human tissue chips could play a central role in drug development, screening, and testing, thereby speeding the development of new diabetes therapies.

Budget Policy: The FY 2020 President's Budget request for this program is $613.6 million, a decrease of $102.8 million or 14.4 percent compared with the FY 2019 Enacted level.
With FY 2020 resources, NIDDK will continue major diabetes clinical trials. NIDDK will also continue its support of an ancillary study to the Glycemia Reduction Approaches in Diabetes (GRADE) study to examine how the correlation between hemoglobin A1c and average blood glucose differs by racial/ethnic heritage. NIDDK's plans for FY 2020 include continuing research that examines changes in blood glucose levels over the course of pregnancy that could inform future strategies for combating GDM, and research comparing bariatric surgery versus non-surgical approaches for treating type 2 diabetes to inform clinical decision making. In FY 2020, NIDDK will continue funding for research centers to advance research relevant to diabetes and to cystic fibrosis and other genetic metabolic diseases. NIDDK will also continue to fund translational research and support health information dissemination activities to bring scientific discoveries in diabetes and obesity to real-world medical practice and other community settings, along with other efforts as part of an overall balanced research program.

Digestive Diseases and Nutrition

The objectives of this program are to enhance understanding of liver and other digestive diseases, nutrition, and obesity, and to develop and test strategies for disease prevention and treatment. This program supports basic, clinical, and translational research, as well as research training, encompassing fundamental studies of the digestive system; disease-targeted research involving the esophagus, stomach, small intestine, large intestine and anorectum, liver and biliary system, and pancreas; studies relevant to nutrition; and research on obesity. Insights gleaned from scientific efforts are communicated to patients, health professionals, and the public through NIDDK's National Digestive Diseases Information Clearinghouse and Weight-control Information Network.

In FY 2020, NIDDK will continue to support research aimed at improving the prevention and treatment of diseases associated with the digestive system. Recent findings suggested that pancreas divisum, a relatively common birth defect in which parts of the pancreas do not join together, is likely a risk factor for both chronic and acute recurrent pancreatitis in children.[27] In FY 2020, NIDDK plans to continue support for a clinical trial examining whether there is benefit to a surgery currently performed to prevent recurrent pancreatitis in people with pancreas divisum. Researchers in NIDDK's Childhood Liver Disease Research Network (ChiLDReN) identified a protein present at high levels in blood from infants with biliary atresia that may enable early detection of this potentially deadly liver disease that occurs during the first few months of life.[28] NIDDK plans to use FY 2020 funds to continue support of ChiLDReN to pursue research on biliary atresia and other pediatric liver diseases. Toward informing clinical decision making, one clinical trial showed that a low-cost and efficient home-based version of cognitive behavioral therapy, which helps people change thought and behavior patterns, improved symptoms of IBS similarly to a clinic-based version of the therapy,[29] and another trial found that the potentially toxic drug methotrexate is no better than placebo in preventing relapses of ulcerative colitis.[30] New research has shed light on calorie consumption and calorie burning in early pregnancy in women with obesity, which could inform strategies to promote healthy gestational weight gain and reduce racial disparities in pregnancy outcomes.[31] Researchers have used imaging technology to show how a genetic variant can increase obesity risk in people by disrupting the brain's response to food cues, leading to a weakened sense of fullness and subsequent overeating.[32] Studies in mice related to the gut microbiome have shown that nutrient availability can be an important factor determining whether a bacterial strain will successfully colonize the gut,[33] and how changes in diet could bolster the microbiome's ability to keep *C. difficile* infections at bay.[34] These studies provide insight into how future therapies could be designed to treat or prevent disease by shaping the gut microbiome.

Program Portrait: Fatty Liver Disease: The Nonalcoholic Steatohepatitis Clinical Research Network

FY 2019 Level: $5.0 million
FY 2020 Level: $5.0 million
Change: $0.0 million

Nonalcoholic fatty liver disease (NAFLD) is a form of chronic liver disease in which excess fat is stored in the liver. In its more severe form, called nonalcoholic steatohepatitis (NASH), characterized by additional inflammation and fibrosis (scarring), the disease can lead to cirrhosis (a condition in which the liver is scarred and permanently damaged), liver failure, and liver cancer. NAFLD, which is strongly associated with obesity and type 2 diabetes, has historically affected obese, middle-aged adults. However, NAFLD is now frequently observed in young adults and children, and even occurs in the absence of obesity. There are currently no FDA-approved therapies for NAFLD and NASH; the current standard of care is weight loss through diet and exercise, which is challenging to achieve. Additionally, diagnosing these diseases is difficult because an invasive liver biopsy is required. Thus, there is a

[27] Lin TK, et al. J Clin Gastroenterol, 2018 [Epub ahead of print].
[28] Lertudomphonwanit C, et al. Sci Transl Med 9: eaan8462, 2017.
[29] Lackner JM, et al. Gastroenterology 155: 47-57, 2018.
[30] Herfarth H, et al. Gastroenterology. 155: 1098-1108.e9, 2018.
[31] Most J, et al. Obesity 26: 992-999, 2018; Most J, et al. Am J Clin Nutr 107: 957-964, 2018.
[32] Melhorn SJ, et al. Am J Clin Nutr 107: 145-154, 2018.
[33] Shepherd ES, et al. Nature. 557: 434-438, 2018.
[34] Hryckowian AJ, et al. Nat Microbiol 3: 662-669, 2018.

critical need to develop new approaches to prevention and treatment of NAFLD and NASH and to develop non-invasive diagnostics to identify people who could benefit from therapies as they are developed.

To address these needs, in 2002, NIDDK established the NASH Clinical Research Network (CRN) to pursue clinical research on adult and pediatric NAFLD and NASH. The Network aims to gain an understanding of disease causes and progression to develop approaches toward diagnosis, treatment, and clinical management of NAFLD and NASH. Since its inception, the NASH CRN has enrolled over 4,000 adults and children in its databases and has amassed a vast repository of biospecimens. The NASH CRN has completed several clinical trials, including trials showing that a daily dose of the natural form of vitamin E improved NASH in adult study participants overall and in some children.[35] The Network also completed a trial finding that the small molecule drug obeticholic acid (OCA) improved liver health in people with NASH, though the drug was also associated with increases in itching and total cholesterol.[36] This demonstrated efficacy of a small molecule drug in the treatment of NASH fueled an explosion of industry-sponsored NASH clinical trials. The NASH CRN is complementing the industry efforts by testing existing, low-cost agents that industry is unlikely to pursue, as well as conducting early phase studies of agents with novel mechanisms of action. Additionally, the Network is uncovering new knowledge about underlying biology of disease. For example, a recent Network study identified genetic factors associated with responsiveness to vitamin E treatment for NASH.[37] To build on the successes of the Network, as well as to continue to address NASH as a growing public health challenge in the United States, in 2018, NIDDK issued a solicitation to continue the NASH CRN for another project period beginning in FY 2019. The goal of the next phase includes completing ongoing clinical trials and beginning new trials of NASH therapies for children and adults, with an emphasis on low-cost agents that could be implemented in the general population. The Network will also continue to develop and validate non-invasive ways to diagnose NASH, such as by identifying biological markers of the disease and using imaging technologies. Through these approaches, NIDDK expects the NASH CRN to build on its exceptional track record to improve the health of children and adults with NAFLD and NASH.

Budget Policy: The FY 2020 President's Budget request for this program is $488.2 million, a decrease of $81.8 million or 14.4 percent compared with the FY 2019 Enacted level. In FY 2020, NIDDK will continue major clinical research networks to help understand and treat liver diseases. Among its obesity-related efforts in FY 2020, NIDDK will continue to pursue research to understand factors in infancy and early childhood that influence obesity development. NIDDK will also use FY 2020 funds to support an ongoing clinical trial comparing three treatments for fecal incontinence toward informing clinical decision making by patients and their health care providers. Research on intestinal stem cells and the lymphatic system in digestive health and disease, which can benefit a variety of digestive diseases, will continue in FY 2020, along with other efforts as part of an overall balanced research program.

Kidney, Urologic, and Hematologic Diseases

The objectives of this program are to increase the understanding of diseases and disorders of the kidneys, urinary tract, and blood (hematologic), and to develop and test prevention and treatment strategies. Basic, clinical, and translational research, as well as research training, are supported in the areas of chronic kidney disease (CKD), diabetic kidney disease, end-stage renal disease (ESRD or kidney failure), polycystic kidney disease, and many other kidney diseases; urinary incontinence, benign prostatic hyperplasia, interstitial cystitis/painful bladder syndrome, stones, impotence, congenital urologic disorders, and urinary tract infections; and disorders of the blood and blood-forming organs, including sickle cell disease, Cooley's anemia, hemochromatosis, and the anemia of inflammation and chronic disease.

[35] Sanyal AJ, et al. N Engl J Med 362: 1675-1685, 2010; Lavine JE, et al. JAMA 305: 1659-68, 2011.
[36] Neuschwander-Tetri BA, et al. Lancet 385: 956-965, 2015.
[37] Banini BA, et al. J Clin Gastroenterol, 2018 [Epub ahead of print].

In FY 2020, NIDDK will continue to support research aimed at improving the treatment and prevention of kidney, urologic, and hematologic diseases. Scientists established a correlation between the level of a hormone in the blood of people with CKD and the risk of death, a finding that could help identify and personalize care of people with CKD at particularly high risk of death.[38] A recent kidney-related study in mice has shed light on signaling pathways involved in regulating the number of kidney nephrons, the organ's basic functional unit, which opens up therapeutic avenues to promote higher nephron numbers and thus improve kidney function.[39] In another study, scientists have gained new insights into the biological mechanisms underlying the transition from acute kidney injury to CKD, laying the foundation for future studies to prevent this transition.[40] In research to gain new understanding about urinary tract infections (UTIs), scientists have identified two different molecules that can limit growth of microbes that cause UTIs, adding to approaches being pursued to develop new strategies for clinical treatment of these infections.[41] In other research, a large clinical trial studying the use of tamsulosin to treat urinary (kidney) stones in emergency departments discovered that this oral medication was no more effective than placebo to promote stone passage, a finding that could change treatment guidelines.[42]

Researchers discovered that in mice, a non-bladder cell type can migrate to the bladder, take on bladder-cell characteristics, and support bladder regeneration after damage; these findings have implications not only for potential therapies for bladder-related diseases and but also for examining the use of non-organ cell types to promote organ regeneration.[43] Scientists in the Prevention of Lower Urinary Tract Symptoms (PLUS) Consortium published a novel definition of bladder health in women and girls that will inform future research on instrument development for evaluation of bladder health promotion and prevention of lower urinary tract symptoms.[44] In another study, researchers employed a genetic screen using clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (Cas9) to identify a protein in red blood cells that is involved in regulating fetal hemoglobin levels. The discovery provides a potential new therapeutic target for hemoglobinopathies such as sickle cell disease and β-thalassemia—diseases in which increasing levels of fetal hemoglobin provides clinical benefit.[45]

Program Portrait: Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network

[38] Isakova T, et al. J Am Soc Nephrol 29: 579-590, 2018.
[39] Volovelsky O, et al. Proc Natl Acad Sci U S A 115: 5998-6003, 2018.
[40] Liu J, et al. JCI Insight 2: e94716, 2017.
[41] Mike LA, et al. Chem Commun 53:12778-12781, 2017; Ohlemacher SI, et al. J Clin Invest 127:4018-4030, 2017.
[42] Meltzer AC, et al. JAMA Intern Med 178: 1051-1057, 2018.
[43] Joseph DB, et al. Proc Natl Acad Sci U S A 115: 8394-8399, 2018.
[44] Lukacz ES, et al. J Womens Health (Larchmt) 27: 974-981, 2018.
[45] Grevet JD, et al. Science 361: 285-290, 2018.

FY 2019 Level: $3.0 million
FY 2020 Level: $2.5 million
Change: -$0.5 million

The urologic chronic pelvic pain syndrome (UCPPS) interstitial cystitis/painful bladder syndrome (IC/PBS), which predominantly affects women, and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), which affects men, reduce quality of life and productivity and incur significant health care costs for millions of Americans. Symptoms of UCPPS include chronic, often debilitating pain in the pelvic or genital areas, frequently accompanied by urinary symptoms of frequency and urgency. Historically, much of NIDDK-supported research on causes of and treatments for IC/PBS and CP/CPPS focused on the bladder and prostate, respectively. However, research began to reveal that many people with UCPPS frequently have other, overlapping chronic pain conditions, such as IBS and fibromyalgia. These and other insights suggested that, at least in some people, UCPPS might not be a localized pain condition, but may be part of a global pain process involving the central nervous system and potentially other body systems, such as the immune system, and even microbial factors. This suggested the need for a new, multidisciplinary research approach to combat these conditions.

Following intensive consultation with experts from multiple disciplines and with health advocacy groups, NIDDK established the multi-center Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network in 2008 to conduct innovative, collaborative studies of IC/PBS and CP/CPPS. Since its inception, the Network's unique approach has entailed searching "beyond the bladder/prostate" to find the causes of UCPPS, including studying the possible relationships between these conditions and other chronic pain disorders. In its first project period, the Network conducted the central Trans-MAPP Epidemiology and Phenotyping Study to understand how these conditions progress over time and to learn if patients might fall into different subgroups and require different treatments. The Study has yielded valuable knowledge, including new insights into the course of UCPPS, such as symptom variability over time;[46] the importance of self-reported symptom "flares" in assessing these conditions and in patient quality of life in women;[47] brain microstructural differences distinguishing UCPPS from IBS;[48] identification of UCPPS subgroups based on pain and urologic symptom patterns ("profiles") and longitudinal symptom trends;[49] and the detection of future pain trends through noninvasive brain imaging.[50] Many of the findings from the first phase of the Network are now being pursued in its second phase (co-supported by the NIH Office of Research on Women's Health) through the Trans-MAPP Symptoms Patterns Study, to determine their potential role(s) in symptom manifestation, maintenance, and amelioration. In 2018, the NIDDK issued a solicitation to continue the MAPP Research Network for a 3-year project period beginning in FY 2020, so that it may continue collecting data and biological samples from UCPPS participants in the Trans-MAPP Symptoms Patterns Study and conduct its collaborative data analysis. During its next phase, the MAPP Research Network will continue working toward a goal of informing future clinical studies, improving clinical management, and promoting research that leverages Network resources and builds upon its significant progress.

Budget Policy: The FY 2020 President's Budget request for this program is $395.2 million, a decrease of $66.2 million or 14.4 percent compared with the FY 2019 Enacted level. In FY 2020, NIDDK will continue support for ongoing major clinical studies of CKD in adults and children. NIDDK also plans to continue its Kidney Precision Medicine Project to improve the scientific knowledge base of kidney diseases, the clinical utility of kidney biopsies, and the pipeline of new drugs for treatment, toward a long-term goal of personalizing care for people with kidney disease. NIDDK also plans to continue its support of research networks focused on enhancing understanding of glomerular diseases, UCPPS, and lower urinary tract symptoms. Centers focused on kidney, urologic, and hematologic research will receive continued funding.

[46] Stephens-Shields AJ, et al. J Urol 196: 1450-1455, 2016.
[47] Sutcliffe S, et al. Int Urogynecol J 26: 1047-1060, 2015.
[48] Woodworth D, et al. PLoS One 10: e0140250, 2015.
[49] Lai HH, et al. J Urol 198: 622-631, 2017; Naliboff BD, et al. J Urol 198: 848-857, 2017.
[50] Kutch JJ, et al. Pain 158: 1069-1082, 2017.

FY 2020 funds will also be used to support research to understand normal kidney function and disease progression, and research to generate or repair nephrons that can function within the kidney, along with other efforts as part of an overall balanced research program.

Special Statutory Funding Program for Type 1 Diabetes Research
Complementing efforts of the Diabetes, Endocrinology, and Metabolic Disease program, the Special Diabetes Program's goal is to foster improved treatment, prevention, and cure of type 1 diabetes and its complications through basic, clinical, and translational research. The program has six scientific goals: 1) identifying genetic and environmental causes of type 1 diabetes ($5 million); 2) preventing or reversing the disease ($62 million); 3) developing cell replacement therapy ($37.5 million; 4) improving management and care ($23 million); 5) preventing or reducing diabetes complications ($17 million); and 6) attracting new talent and applying new technologies to research ($5.5 million) (FY 2020 estimate dollars). Although focused on type 1 diabetes, aspects of this research are relevant to type 2 diabetes and other autoimmune disorders. For example, people with type 2 diabetes could benefit from research developing novel artificial pancreas technologies and other diabetes management technologies. A finding in which scientists used a CRISPR-Cas9 gene editing approach to reprogram a type of human immune cell (T cell) without using viruses to insert DNA has the potential to be applied toward the development of new therapies for autoimmune diseases, cancer, and other diseases.[51] In FY 2018, NIDDK launched new research in several areas, including: a new clinical trial testing the ability of the drug hydroxychloroquine to prevent or delay type 1 diabetes; studies to increase understanding of how human insulin-producing beta cells are lost in type 1 diabetes and identifying strategies to protect or replace them; development of new technologies and bioengineering approaches to advance cell replacement therapies for type 1 diabetes; and development of new diabetes management technologies, including artificial pancreas devices. NIDDK also continued support for other research, such as a large-scale study of children at high-risk of developing type 1 diabetes to identify factors in the environment that trigger or protect against the disease.

Budget Policy: The FY 2020 President's Budget request for the Special Statutory Funding Program for Type 1 Diabetes Research proposes a two-year reauthorization of the program at $150.0 million each year.

Intramural Research
The objective of the Institute's Intramural Research Program (IRP) is to conduct basic, translational, and clinical biomedical research related to diabetes and other endocrine and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; obesity; kidney diseases; and hematologic diseases. Intramural research is conducted in the Institute's laboratories and clinical facilities in Bethesda, Maryland, as well as in Phoenix, Arizona, where a long-standing research relationship with American Indian communities in the region has led to important scientific advances in diagnosing and treating type 2 diabetes and obesity. Recently, IRP scientists found that the diabetes drug canagliflozin reduces vitamin D levels and calcium uptake, which may explain why this drug can increase the risk of bone fractures.[52] IRP research enabled imaging of a member of the G-protein-coupled receptor family in real time in a living

[51] Roth TL, et al. Nature 559: 405–409, 2018.
[52] Blau JE, et al. JCI Insight 3: e99123, 2018.

animal,[53] determined the three-dimensional structures of proteins that are involved in the maturation of the immune system,[54] and shed new light on cellular pathways involved in the immune response to a bacterium that lives on the skin.[55] Research training is also an integral component of the IRP. This training occurs in both clinical and basic laboratory research at the high school, post baccalaureate, masters, doctoral, postdoctoral, and clinical fellow level, including summer programs specifically benefitting under-served and under-represented groups.

Budget Policy: The FY 2020 President's Budget request for this program is $181.0 million, a decrease of $24.9 million or 12.1 percent compared with the FY 2019 Enacted level.

Research Management and Support (RMS)

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. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute's programs; regulatory compliance; international coordination; and liaison with other Federal agencies, Congress, and the public. Through RMS activities, NIDDK continues its administrative support of meritorious basic, clinical, and translational research and research training efforts, and also continues its health information dissemination and education/outreach activities.

Budget Policy: The FY 2020 President's Budget request for this program is $68.5 million, a decrease of $7.6 million or 10.0 percent compared with the FY 2019 Enacted level.

[53] Kono M, et al. Nat Commun 8: 1163, 2017.
[54] Kim M-S, et al. Mol Cell 70: 358-370, 2018.
[55] Linehan JL, et al. Cell 172: 784-796.e18, 2018.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Budget Authority by Object Class[1, 2]
(Dollars in Thousands)

	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total compensable workyears:			
Full-time equivalent	660	660	0
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary	$191	$192	$1
Average GM/GS grade	12.0	12.0	0.0
Average GM/GS salary	$110	$111	$0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$108	$111	$3
Average salary of ungraded positions	$118	$118	$0

	OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
	Personnel Compensation			
11.1	Full-Time Permanent	41,833	41,993	160
11.3	Other Than Full-Time Permanent	38,810	38,958	148
11.5	Other Personnel Compensation	2,712	2,722	10
11.7	Military Personnel	1,150	1,184	34
11.8	Special Personnel Services Payments	13,695	13,001	-694
11.9	**Subtotal Personnel Compensation**	**$98,200**	**$97,858**	**-$342**
12.1	Civilian Personnel Benefits	28,093	28,627	534
12.2	Military Personnel Benefits	776	799	23
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$127,069**	**$127,284**	**$215**
21.0	Travel & Transportation of Persons	1,893	1,645	-248
22.0	Transportation of Things	165	140	-25
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	910	770	-140
24.0	Printing & Reproduction	4	1	-3
25.1	Consulting Services	771	672	-99
25.2	Other Services	30,797	20,574	-10,223
25.3	Purchase of goods and services from government accounts	187,247	169,149	-18,098
25.4	Operation & Maintenance of Facilities	900	600	-300
25.5	R&D Contracts	14,674	11,521	-3,153
25.6	Medical Care	1,520	1,000	-520
25.7	Operation & Maintenance of Equipment	4,208	2,100	-2,108
25.8	Subsistence & Support of Persons	59	41	-18
25.0	**Subtotal Other Contractual Services**	**$240,176**	**$205,657**	**-$34,519**
26.0	Supplies & Materials	13,592	10,166	-3,426
31.0	Equipment	9,215	6,355	-2,860
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,636,798	1,394,474	-242,324
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$1,902,754**	**$1,619,209**	**-$283,545**
	Total Budget Authority by Object Class	**$2,029,823**	**$1,746,493**	**-$283,330**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Three FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$41,833	$41,993	$160
Other Than Full-Time Permanent (11.3)	38,810	38,958	148
Other Personnel Compensation (11.5)	2,712	2,722	10
Military Personnel (11.7)	1,150	1,184	34
Special Personnel Services Payments (11.8)	13,695	13,001	-694
Subtotal Personnel Compensation (11.9)	**$98,200**	**$97,858**	**-$342**
Civilian Personnel Benefits (12.1)	$28,093	$28,627	$534
Military Personnel Benefits (12.2)	776	799	23
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$127,069**	**$127,284**	**$215**
Travel & Transportation of Persons (21.0)	$1,893	$1,645	-$248
Transportation of Things (22.0)	165	140	-25
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	910	770	-140
Printing & Reproduction (24.0)	4	1	-3
Other Contractual Services:			
Consultant Services (25.1)	746	650	-96
Other Services (25.2)	30,797	20,574	-10,223
Purchases from government accounts (25.3)	125,902	109,363	-16,539
Operation & Maintenance of Facilities (25.4)	900	600	-300
Operation & Maintenance of Equipment (25.7)	4,208	2,100	-2,108
Subsistence & Support of Persons (25.8)	59	41	-18
Subtotal Other Contractual Services	**$162,612**	**$133,328**	**-$29,284**
Supplies & Materials (26.0)	$13,592	$10,166	-$3,426
Subtotal Non-Pay Costs	**$179,176**	**$146,050**	**-$33,126**
Total Administrative Costs	**$306,245**	**$273,334**	**-$32,911**

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2018 Final			FY 2019 Enacted			FY 2020 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Diabetes, Endocrinology, and Metabolic Diseases									
Direct:	29	-	29	30	-	30	30	-	30
Reimbursable:	3	-	3	3	-	3	3	-	3
Total:	32	-	32	33	-	33	33	-	33
Division of Digestive Diseases and Nutrition									
Direct:	23	2	25	24	2	26	24	2	26
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	23	2	25	24	2	26	24	2	26
Division of Extramural Activities									
Direct:	65	-	65	67	-	67	67	-	67
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	65	-	65	67	-	67	67	-	67
Division of Intramural Research Programs									
Direct:	348	8	356	365	8	373	365	8	373
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	348	8	356	365	8	373	365	8	373
Division of Kidney, Urologic, and Hematologic Diseases									
Direct:	22	-	22	23	-	23	23	-	23
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	22	-	22	23	-	23	23	-	23
Office of the Director									
Direct:	130	-	130	138	-	138	138	-	138
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	130	-	130	138	-	138	138	-	138
Total	620	10	630	650	10	660	650	10	660

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

3 FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.

FISCAL YEAR	Average GS Grade
2016	12.0
2017	12.0
2018	12.0
2019	12.0
2020	12.0

NATIONAL INSTITUTES OF HEALTH
National Institute of Diabetes and Digestive and Kidney Diseases

Detail of Positions[1]

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	189,600	191,231	191,958
GM/GS-15	63	63	63
GM/GS-14	64	64	64
GM/GS-13	97	98	99
GS-12	65	69	70
GS-11	36	39	40
GS-10	0	0	0
GS-9	20	26	23
GS-8	14	16	16
GS-7	21	24	24
GS-6	0	0	0
GS-5	3	4	4
GS-4	2	2	2
GS-3	1	1	1
GS-2	1	1	1
GS-1	0	0	0
Subtotal	387	407	407
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	7	6	6
Senior Grade	0	0	0
Full Grade	2	2	2
Senior Assistant Grade	2	2	2
Assistant Grade	0	0	0
Subtotal	11	10	10
Ungraded	246	259	258
Total permanent positions	383	402	401
Total positions, end of year	645	676	676
Total full-time equivalent (FTE) employment, end of year[2]	630	660	660
Average ES salary	189,600	191,231	191,958
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	109,450	110,391	110,810

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

[2] 3 FTEs transferred from NIDDK to NICHD as of FY 2019 for the administration of NIBIB's Director's laboratory.