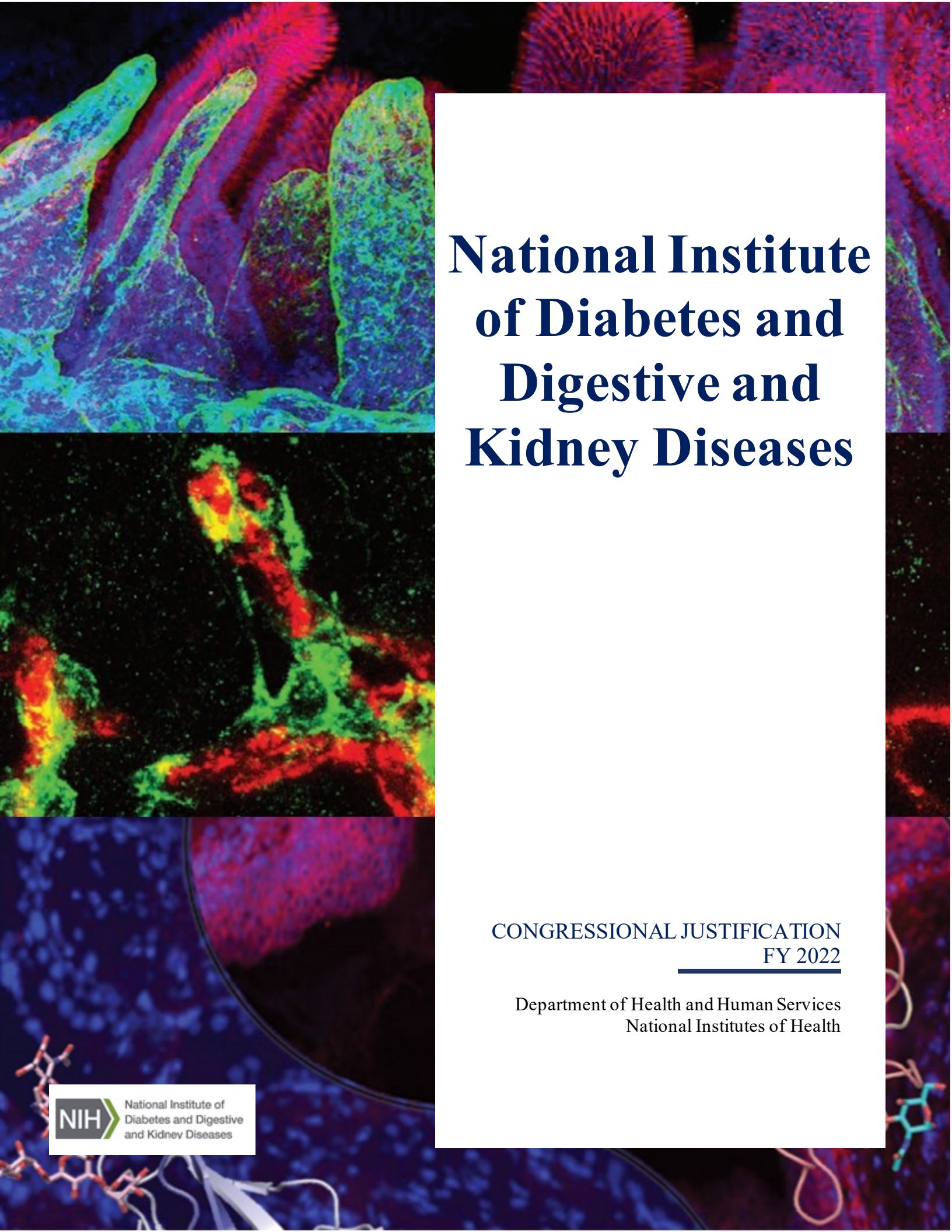

National Institute of Diabetes and Digestive and Kidney Diseases

CONGRESSIONAL JUSTIFICATION
FY 2022

Department of Health and Human Services
National Institutes of Health

NIH National Institute of Diabetes and Digestive and Kidney Diseases

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

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

FY 2022 Budget Table of Contents Page No.

Cover page images from NIDDK-supported research: **Top**: Reprinted by permission from Springer Nature: Nature, Subepithelial telocytes are an important source of Wnts that supports intestinal crypts, Shoshkes-Carmel M, Wang YJ, Wangensteen KJ, Toth B, Kondo A, Massasa EE, Itzkiovitz S, Kaestner KH. 557: 242-246, Copyright 2018; **Middle:** Reprinted from Cell Metabolism, 27:3, Almaça J, Weitz J, Rodriguez-Diaz R, Pereira E, and Caicedo A, The pericyte of the pancreatic islet regulates capillary diameter and local blood flow, 630-644, Copyright 2018, with permission from Elsevier; **Bottom:** Reprinted from Cell Host Microbe, 20:4, Conover MS, Ruer S, Taganna J, Kalas V, De Greve H, Pinkner JS, Dodson KW, Remaut H, Hultgren SJ, Inflammation-Induced Adhesin-Receptor Interaction Provides a Fitness Advantage to Uropathogenic E. coli during Chronic Infection, 482-492, Copyright 2016, with permission from Elsevier.

Director's Overview

Dr. Griffin P. Rodgers, Director

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. Our Institute's mission includes some of the most chronic, common, and costly diseases and conditions affecting the U.S. population, as well as other conditions that are less widespread but still devastating. Diabetes affects an estimated 34.2 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 37 million Americans are affected, and over 783,000 people were treated for irreversible kidney failure in the Nation in 2018.[2,3] Many urologic diseases, such as urinary incontinence, urinary tract infections, and benign prostatic hyperplasia, are also highly prevalent.[4] Digestive diseases accounted for an estimated 66.4 million ambulatory care visits to doctor's offices, outpatient hospital clinics, and emergency departments in 2016, as well as 15.9 million hospitalizations with digestive diseases as a primary or secondary diagnosis.[5,6] Obesity affects more than 40 percent of U.S. adults and over 18 percent of children and adolescents.[7] It is a strong risk factor for type 2 diabetes; fatty liver disease, including nonalcoholic steatohepatitis; and many other diseases. Cystic fibrosis and other genetic diseases within NIDDK's purview are less common, but still severe in their impacts. Building on emerging opportunities from past research investments, our Institute will continue its vigorous pursuit of research to combat the diseases and disorders within its mission, being guided by the following priorities: maintain a vigorous investigator-initiated research portfolio, support pivotal clinical studies and trials, promote a steady and diverse pool of talented new investigators, foster exceptional research training and mentoring opportunities, and ensure knowledge dissemination through outreach and communications.

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[1] Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report. Atlanta, GA: HHS, 2020. www.cdc.gov/diabetes/data/statistics-report/index.html

[2] CDC. Chronic Kidney Disease in the United States, 2019. Atlanta, GA: HHS, 2019. www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

[3] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States. NIH, NIDDK, Bethesda, Maryland, 2020. adr.usrds.org/2020

[4] Urological Diseases in America. NIDDK/NIH Publication Number 12-7865, 2012. www.niddk.nih.gov/-/media/Files/Strategic-Plans/urologic/Urologic_Diseases_in_America41312.pdf

[5] National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey, CDC. www.cdc.gov/nchs/ahcd/index.htm

[6] Healthcare Cost and Utilization Project, National Inpatient Sample, Agency for Healthcare Research and Quality. www.hcup-us.ahrq.gov/nisoverview.jsp

[7] Hales CM, et al. 2020. CDC. National Center for Health Statistics Data Brief No. 360. www.cdc.gov/nchs/products/databriefs/db360.htm; Hales CM, et al. 2017. CDC. National Center for Health Statistics Data Brief No. 288. www.cdc.gov/nchs/products/databriefs/db288.htm

Responding to Urgent Public Health Needs

NIDDK, together with all of NIH, has responded to the urgent public health challenge of the COVID-19 pandemic. For example, NIDDK provided funding supplements to grantees for research on the relationship between COVID-19 and diabetes and other metabolic diseases, as well as diseases of the kidney and digestive system. NIDDK also solicited studies of mechanisms underlying poor outcomes from SARS-CoV-2 infection in people with diseases in its mission, including variable susceptibility, altered course of disease, and morbidity and mortality, as well as studies of how SARS-CoV-2 and COVID-19 cause acute or chronic damage to organs and biological systems of interest to the Institute. Work by scientists in NIDDK's Intramural Research Program broadened our understanding of how the virus is transmitted by demonstrating how speech might promote viral spread, even from people without apparent symptoms, underscoring the vital importance of mask-wearing to stem the pandemic.[8] NIDDK-supported scientists contributed to efforts to understand diabetes and obesity as risk factors that can increase COVID-19 disease severity.[9] NIDDK seeks to further accelerate research progress on COVID-19 and diseases in its mission by funding studies, including on HIV-related comorbidities, and by participating in efforts across the NIH to study COVID-19 and associated health disparities.[10]

Several other pieces of NIDDK's mission touch on pressing needs for improving human health, and we continue our commitment to advance this research. Rising rates of type 2 diabetes prompted a research response in the form of the NIDDK's Diabetes Prevention Program (DPP), ongoing DPP Outcomes Study, and related translational studies, which identified effective means of prevention now used in programs across the country and world; recent efforts focused on possible connections between taking the diabetes drug metformin and lower rates of cardiovascular disease and cancer.[11] To address the highly prevalent, but often hidden condition of fecal incontinence, an ongoing NIDDK clinical trial is comparing the effectiveness of three treatments to improve symptoms, mental wellbeing, and quality of life.[12] In response to the public health crisis of chronic pain and related opioid overuse, NIDDK-supported research has provided key insights into prevalent, but poorly understood chronic urologic pelvic pain syndromes in women and men, and is working toward developing interventions to reduce opioid use in patients on hemodialysis.[13]

Addressing Health Disparities and Scientific Workforce Diversity

Many NIDDK mission diseases place disparate burdens on minority groups and people with

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[8] Anfinrud P, et al. N Engl J Med 382: 2061-2063, 2020; Stadnytskyi V, et al. Proc Natl Acad Sci USA 117:11875-11877, 2020.

[9] Kruglikov IL, et al. Obesity (Silver Spring). 2020 Jul;28(7):1187-1190; Korytkowski M, et al. J Clin Endocrinol Metab. 2020 Sep 1;105(9):dgaa342.

[10] grants.nih.gov/grants/guide/notice-files/NOT-DK-20-018.html, grants.nih.gov/grants/guide/notice-files/NOT-DK-20-020.html, https://grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-021.html, grants.nih.gov/grants/guide/notice-files/NOT-OD-20-119.html, grants.nih.gov/grants/guide/notice-files/NOT-OD-20-120.html, grants.nih.gov/grants/guide/notice-files/NOT-OD-20-121.html, grants.nih.gov/grants/guide/notice-files/NOT-MD-20-022.html, grants.nih.gov/grants/guide/notice-files/NOT-MH-20-053.html, grants.nih.gov/grants/guide/notice-files/NOT-OD-20-097.html, grants.nih.gov/grants/guide/pa-files/PAR-20-237.html, ncats.nih.gov/n3c

[11] www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp

[12] clinicaltrials.gov/ct2/show/NCT03811821

[13] www.mappnetwork.org/, www.niddk.nih.gov/research-funding/research-programs/hemodialysis-opioid-prescription-effort-consortium

limited resources. These disparities have been exacerbated by the ongoing novel coronavirus pandemic, with increased rates of COVID-19 and worse outcomes in people with obesity, diabetes, and/or other diseases. NIDDK remains firmly committed to addressing mounting health disparities associated with many of the diseases and conditions within its mission and to enhancing diverse representation among its biomedical research workforce. For example, the Institute is taking a number of innovative steps to encourage research projects on understanding and mitigating disparities in the development, diagnosis, and treatment of NIDDK-mission diseases.[14] Major advances resulting from the Institute's support for health disparities-related research include a recent study that found community barbershops served as promising venues for screening Black men for type 2 diabetes and identifying those with undiagnosed disease, so treatment could begin earlier.[15] NIDDK's clinical studies focus on health outcomes for racial/ethnic populations at higher risk, such as the Nonalcoholic Steatohepatitis Clinical Research Network's adult and pediatric studies in individuals of Hispanic and South Asian descent that have uncovered genetic risk factors and tested potential therapies.[16] Past research progress identifying variants in the *APOL1* gene that increase kidney disease risk in African Americans, now the basis for the APOL1 Long-term Kidney Transplantation Outcomes Network, and ongoing work developing new, blood stem-cell transplant-based treatments for sickle cell disease, which also disproportionately affects African Americans, further demonstrate the NIDDK's long-standing commitment to health disparities research.[17]

Complementing efforts to reflect the diversity of affected populations in its studies, NIDDK actively engages in efforts to enhance diversity and inclusivity within its scientific workforce to ensure that our research benefits from the best scientific minds and diverse insights to advance progress. NIDDK supports research training programs and early career opportunities for individuals from diverse backgrounds, such as underrepresented minorities, disadvantaged groups, or those from rural areas.[18]

Investing in Foundational Research and Beyond

The steady advancement of foundational knowledge in NIDDK mission areas has reshaped our understanding of diseases and, in many cases, led to dramatic improvements in prevention and treatment. In 2021, the 100th anniversary of the discovery of insulin, the NIDDK is continuing to build on progress in new insulin formulations and delivery devices.[19] For example, the approval by the U.S. Food and Drug Administration (FDA) of a new artificial pancreas technology was based on a clinical trial supported by the Special Diabetes Program (SDP, see section below), and the technology was developed with support from the NIDDK and SDP.[20] Basic research

[14] grants.nih.gov/grants/guide/notice-files/not-dk-20-003.html, grants.nih.gov/grants/guide/notice-files/NOT-DK-20-012.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-015.html

[15] Osorio M, et al. JAMA Intern Med 180: 596-597, 2020.

[16] jhuccs1.us/nash/

[17] Genovese G, et al. Science. 329(5993):841-5, 2010; theapollonetwork.org/; Hsieh MM, et al. JAMA. 312(1):48-56, 2014; clinicaltrials.gov/ct2/show/NCT00061568.

[18] www.niddk.nih.gov/research-funding/research-programs/diversity-programs/research-training-opportunities-students/short-term-research-experience-underrepresented-persons-step-up, aspirnaut.org/undergraduateinternships/, www.niddk.nih.gov/research-funding/research-programs/diversity-programs/network-minority-health-research-investigators-nmri

[19] Maikawa CL, et al. Nat Biomed Eng. 2020 May;4(5):507-517.

[20] www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-automated-insulin-dosing-controller-designed-allow-more-choices, Brown SA, et al. N Engl J Med. 381(18):1707-1717, 2019.

advances have also played an essential role in moving therapeutics towards more targeted, personalized approaches, including the NIDDK IBD Genetics Consortium's cataloguing of genetic risk factors that can inform new treatments and studies by NIDDK-supported investigators to develop therapeutic foods directed at the unique gut microbes of malnourished children.[21] Improving measures of patient experiences is another area of investment now yielding benefits, such as in the Symptoms of Lower Urinary Tract Dysfunction Research Network, which developed comprehensive questionnaires to improve measures that are now being used in non-NIH clinical trials.[22]

As we look to the future, advances stemming from research efforts supported currently by the NIDDK have the potential to transform understanding of human disease and its management. The Accelerating Medicines Partnership in Type 2 Diabetes Program is building on the long-term investment of NIDDK in studying type 2 diabetes genetics to identify new targets for therapy by finding rare mutations that markedly affect disease risk.[23] NIDDK's Intestinal Stem Cell Consortium is characterizing the niche supporting intestinal stem cells in health and disease, as a basis for developing novel therapies to regenerate the human intestine.[24] NIDDK's Kidney Precision Medicine Project (KPMP) is stimulating development of personalized therapeutics for acute kidney injury and chronic kidney disease.[25]

NIDDK has invested resources in recent fiscal years by supporting research programs with the potential to yield transformative results in understanding, preventing, and treating disease. For example, since its establishment in 2017, the KPMP has engaged in the ambitious task of analyzing kidney biopsies from people with kidney disease using cutting-edge technologies to identify new therapeutic targets.[26] The NIDDK-supported Human Pancreas Analysis Program, launched in 2016 and continued in recent years, aims to unravel basic mechanisms of the disease processes at work in both type 1 and type 2 diabetes that are key to designing future prevention trials.[27] Continuations of NIDDK's Childhood Liver Disease Research Network, including new studies of pediatric primary sclerosing cholangitis, and of the Prevention of Lower Urinary Tract Symptoms Consortium (PLUS) will support important ongoing work in these clinical studies.[28]

Overall Budget Policy: The FY 2022 President's Budget request is $2,219.3 million, excluding mandatory Type 1 Diabetes funding, an increase of $87.4 million or 4.1 percent compared with the FY 2021 Enacted level. This increase includes additional funding for opioids and pain

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[21] ibdgc.uchicago.edu/, Gehrig JL, et al. Science. 365(6449):eaau4732. 2019.
[22] nih-lurn.org/questionnaires.aspx, www.frontiersin.org/articles/10.3389/fdgth.2020.00007/full
[23] www.nih.gov/research-training/accelerating-medicines-partnership-amp/type-2-diabetes
[24] iscconsortium.org/
[25] www.kpmp.org/
[26] grants.nih.gov/grants/guide/rfa-files/RFA-DK-16-026.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-16-027.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-16-028.html, grants.nih.gov/grants/guide/pa-files/PA-16-451.html
[27] grants.nih.gov/grants/guide/rfa-files/rfa-dk-15-027.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-18-015.html, grants.nih.gov/grants/guide/rfa-files/rfa-dk-18-016.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-016.html
[28] grants.nih.gov/grants/guide/rfa-files/rfa-dk-18-501.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-18-502.html, grants.nih.gov/grants/guide/rfa-files/rfa-dk-19-015.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-19-016.html.

management research. The remaining portion of the increase is distributed across all programmatic areas and basic, epidemiologic, clinical, or translational research.

National Institute of Diabetes and Digestive and Kidney Diseases

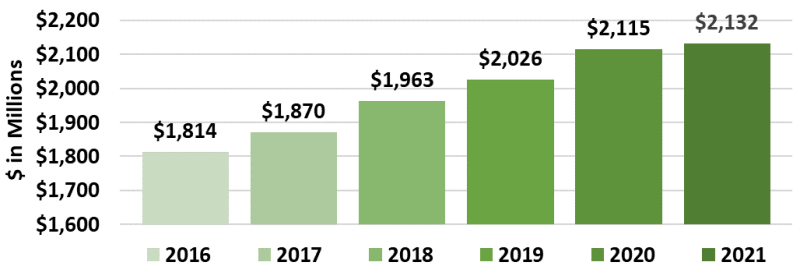
Introduction to NIDDK Research

Established in 1950, the NIDDK supports and conducts research on some of the most chronic, common, and costly conditions, including diabetes and other endocrine and metabolic diseases, liver and other digestive diseases, obesity, kidney diseases, urologic diseases, and hematologic (blood) diseases. The Diabetes, Endocrinology, and Metabolic Diseases program; the Digestive Diseases and Nutrition program; the Kidney, Urologic, and Hematologic Diseases program; and the NIDDK Intramural Research Program support basic, clinical, and translational research across the United States. The NIDDK also supports research training and career development, as well as outreach efforts to patients, healthcare providers, and the public.

Griffin P. Rodgers, M.D., M.A.C.P.

Dr. Rodgers has been Director of NIDDK since 2007 and had served as Deputy Director since 2001. As a leading hematology investigator, he is widely recognized for his contributions to development of the first effective—and FDA-approved—therapy for sickle cell anemia.

NIDDK Appropriations History (FY 2016-2021)

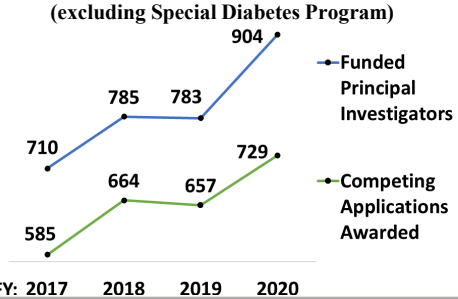


President's Budget Request ($ in Millions): $2,219 (FY 2022)

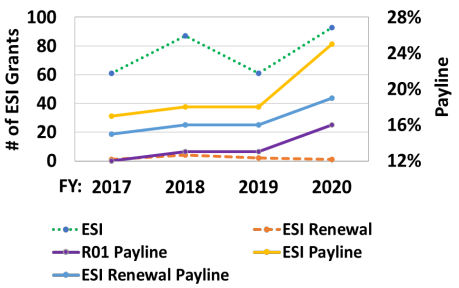
Facts and Figures

- 635 Full-time Equivalent Employees (4-year average, FYs 2017-2020)

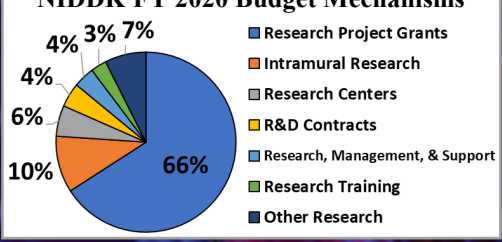
NIDDK Research Project Grants
(excluding Special Diabetes Program)



NIDDK Paylines and Early Stage Investigators (ESIs)



NIDDK FY 2020 Budget Mechanisms



Recent NIDDK Research Highlights

- An immune-targeting drug delayed **type 1 diabetes** progression in high-risk individuals for at least 2 years.
- Research defining subgroups of people with **chronic kidney disease** has paved the way for kidney precision medicine.
- Research advances showed how **inflammatory bowel disease** varies from person to person, moving toward more personalized therapies.
- **Type 2 diabetes** drug classes made possible by NIDDK research provided cardiovascular health benefits in people with diabetes.
- **Bariatric surgery** in adolescents with severe obesity resulted in substantial improvements in type 2 diabetes and blood pressure along with weight loss.
- Studies detailed how the **gut microbiome** interacts with diet and nutrition, affecting inflammatory bowel disease, diabetes, urinary tract infections, obesity, and undernutrition.

National Institute of Diabetes and Digestive and Kidney Diseases

Selected Current Activities

- **Kidney Precision Medicine Project** is analyzing kidney biopsies from a broad range of people, using cutting-edge technologies to identify new therapeutic targets and stimulate development of personalized therapies.
- **Type 1 Diabetes Special Statutory Funding Program** is funding research to improve blood glucose management technologies such as continuous glucose monitors and artificial pancreas devices.
- **NASH Clinical Research Network**'s adult and pediatric studies are testing potential therapies and uncovering genetic and racial/ethnic risk factors for nonalcoholic fatty liver disease and nonalcoholic steatohepatitis.
- **Accelerating Medicine Project-T2D** is working to identify diabetes drug targets by finding rare mutations that affect risk of type 2 diabetes.
- **Intestinal Stem Cell Consortium** studies intestinal stem cells' roles in intestinal health and disease, aiming to identify and develop novel therapies to regenerate the human intestine.
- **Center for Identification and Study of Individuals with Atypical Diabetes Mellitus** has begun to study atypical cases of diabetes, with the goal of understanding how best to classify diabetes subtypes in the future.

Selected Recent Accomplishments

- Studies of speech-generated droplets showed their potential importance in **SARS-CoV-2** transmission.
- **Restoring Insulin Secretion Consortium** demonstrated important differences between type 2 diabetes in adolescents and adults.
- New drugs based on NIDDK-supported research can dramatically reduce disease burden for many with **cystic fibrosis**.
- Research advances increased understanding and treatment of **inflammatory bowel diseases** such as **Crohn's disease** and **ulcerative colitis**.
- NIDDK-sponsored research has paved the way for **microbiome-directed therapeutic foods** and increased understanding of how the brain receives information from the gut.
- Findings from the **Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research** and **Symptoms of Lower Urinary Tract Dysfunction Research Networks** improved how these common, burdensome conditions are understood and treated.

Selected Future Research Initiatives

- NIDDK will continue to **address the increasing burden of chronic diseases** and to **reduce health disparities** in diseases within NIDDK's mission.
- **Type 1 Diabetes in Acute Pancreatitis Consortium** will study interplay between different pancreatic functions to better understand type 1 diabetes and pancreatitis.
- NIDDK will support developing new technologies to sample and monitor the **gut and gut microbiome,** as well as **wearable smart devices** to monitor how nutrients, metabolites, and hormones fluctuate in the body over time.
- **Caring for Outpatients after Acute Kidney Injury Consortium** will work to develop and test treatments to help acute kidney injury survivors.

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 mechanisms 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 request for NIDDK, excluding $141.4 million of mandatory funding for Type 1 Diabetes[29], is $2,219.3 million, an increase of $87.4 million from the FY 2021 Enacted level. Within this request level, NIDDK will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (+$66.1 million; total $1,479.2 million): NIDDK will increase funding for non-competing RPGs by $34.1 million, a 3.4 percent increase compared to the FY 2021 Enacted level, including funding individual non-competing awards at their full commitment level. Competing RPGs are expected to increase by 8.8 percent or 59 grants compared to the FY 2021 Enacted level of 664 awards, and the amount to support competing awards will be increased by $29.2 million from the FY 2021 Enacted level. These increases are distributed across all programmatic areas and basic, translational or clinical research.

Research Centers (+$2.3 million; total $119.4 million): NIDDK will increase funding for Research Centers by 2.0 percent compared to the FY 2021 Enacted level. This increase is distributed across all programmatic areas and basic, translational or clinical research.

Other Research (+$4.8 million; total $155.5 million): NIDDK will increase funding for Other Research by 3.2 percent compared to the FY 2021 Enacted level. This increase is distributed across all programmatic areas and basic, translational or clinical research.

R&D Contracts (+$2.3 million; total $95.2 million): NIDDK will increase funding for R&D Contracts by 2.5 percent compared to the FY 2021 Enacted level. This increase is distributed across all programmatic areas and basic, translational or clinical research.

Intramural Research (+$5.4 million; total $222.2 million): NIDDK will increase funding for Intramural Research by 2.5 percent compared to the FY 2021 Enacted level. This increase is distributed across all programmatic areas and basic, translational or clinical research.

Research Management and Support (+$2.0 million; total $82.8 million): NIDDK will increase funding for Research, Management, and Support by 2.5 percent compared to the FY 2021 Enacted level. This increase is distributed across all administrative support areas of basic, translational or clinical research.

[29] Type 1 Diabetes amount reflects budget authority of $150.0 million reduced by $8.6 million for Budget Control Act sequestration.

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

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,956	$941,215	1,987	$1,000,357	2,006	$1,034,466	19	$34,109
Administrative Supplements	*(126)*	27,634	*(90)*	15,000	*(90)*	15,000	*(0)*	0
Competing:								
Renewal	145	76,433	152	82,980	166	90,947	14	7,967
New	581	281,587	511	248,681	554	269,515	43	20,834
Supplements	3	1,652	1	257	3	701	2	444
Subtotal, Competing	729	$359,672	664	$331,918	723	$361,163	59	$29,245
Subtotal, RPGs	2,685	$1,328,520	2,651	$1,347,275	2,729	$1,410,629	78	$63,354
SBIR/STTR	103	65,199	104	65,764	108	68,527	4	2,763
Research Project Grants	2,788	$1,393,720	2,755	$1,413,039	2,837	$1,479,156	82	$66,117
Research Centers:								
Specialized/Comprehensive	96	$116,987	96	$117,000	98	$119,340	2	$2,340
Clinical Research	0	149	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	50	0	50	0	50	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	96	$117,186	96	$117,050	98	$119,390	2	$2,340
Other Research:								
Research Careers	452	$81,592	450	$84,000	461	$87,100	11	$3,100
Minority Biomedical Research Support	0	532	0	532	0	532	0	0
Other	112	74,653	99	66,199	101	67,854	2	1,655
Other Research	564	$156,778	549	$150,731	562	$155,486	13	$4,755
Total Research Grants	3,448	$1,667,683	3,400	$1,680,820	3,497	$1,754,032	97	$73,212
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	296	$13,982	293	$14,094	297	$14,994	4	$900
Institutional Awards	781	46,252	775	46,622	766	50,118	-9	3,496
Total Research Training	1,077	$60,235	1,068	$60,716	1,063	$65,112	-5	$4,396
Research & Develop. Contracts	120	$92,100	120	$92,894	122	$95,216	2	$2,322
(SBIR/STTR) (non-add)	*(2)*	*(725)*	*(2)*	*(725)*	*(2)*	*(810)*	*(0)*	*(85)*
Intramural Research	347	215,016	366	216,736	366	222,154	0	5,418
Res. Management & Support	285	80,112	300	80,765	300	82,784	0	2,019
SBIR Admin. (non-add)	*(2)*	*(43)*	*(2)*	*(25)*	*(2)*	*(10)*	*(0)*	*(-15)*
Total, NIDDK	632	$2,115,146	666	$2,131,931	666	$2,219,298	0	$87,367

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

NATIONAL INSTITUTES OF HEALTH
Type 1 Diabetes

Budget Mechanism - Total[1,2]

(Dollars in Thousands)

MECHANISM	FY 2020 Final[3]		FY 2021 Enacted		FY 2022 President's Budget[4]		FY 2022 +/- FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	79	$103,142	22	$76,000	18	$63,000	-4	-$13,000
Administrative Supplements	*(0)*	0	*(26)*	10,490	*(28)*	12,287	*(2)*	1,797
Competing:								
Renewal	0	0	0	0	0	0	0	0
New	50	39,500	20	23,500	25	30,000	5	6,500
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	50	$39,500	20	$23,500	25	$30,000	5	$6,500
Subtotal, RPGs	129	$142,642	42	$109,990	43	$105,287	1	-$4,703
SBIR/STTR	10	5,061	12	5,475	11	5,163	-1	-312
Research Project Grants	139	$147,704	54	$115,465	54	$110,450	0	-$5,015
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	0	$0	0	$0	0	$0	0	$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	2,000	0	6,000	0	6,000	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	296	18	28,535	16	25,000	-2	-3,535
Other Research	0	$2,296	18	$34,535	16	$31,000	-2	-$3,535
Total Research Grants	139	$150,000	72	$150,000	70	$141,450	-2	-$8,550
Total, T1D	0	$150,000	0	$150,000	0	$141,450	0	-$8,550

[1] All items in italics and brackets are non-add entries.
[2] Figures reflect budget authority provided in each year. A portion of this budget authority will be carried over and obligated in later years.
[3] Includes mandatory Type 1 Diabetes funding not obligated in FY 2020 and carried over into FY 2021.
[4] FY 2022 total reflects budget authority (in thousands) of $150,000 reduced by $8,550 for Budget Control Act sequestration.

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 diseases, [$2,131,975,000] *$2,219,298,000*.

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

Summary of Changes

(Dollars in Thousands)

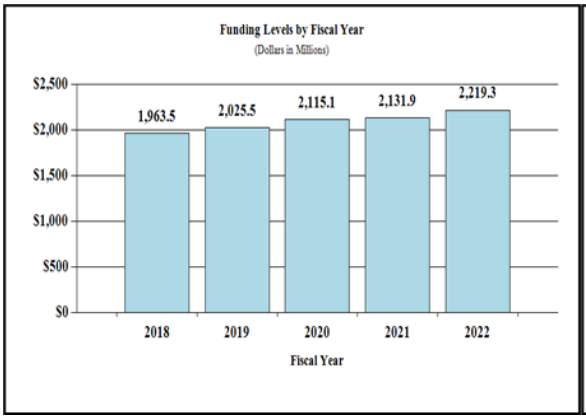
FY 2021 Enacted	$2,131,931
FY 2022 President's Budget	$2,219,298
Net change	$87,367

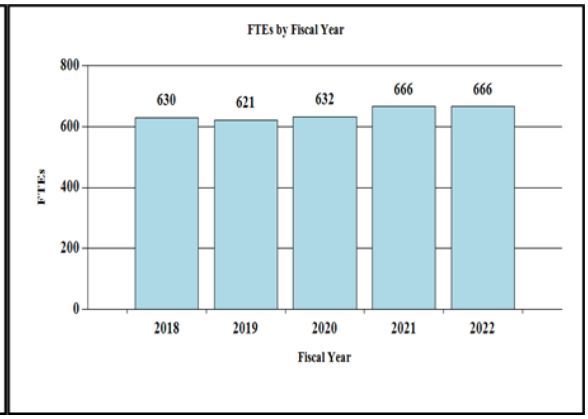
CHANGES	FY2021 Enacted FTEs	FY2021 Enacted Budget Authority	FY 2022 President's Budget FTEs	FY 2022 President's Budget Budget Authority	Built-In Change from FY 2021 Enacted FTEs	Built-In Change from FY 2021 Enacted Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2021 pay increase & benefits		$86,572		$88,654		$570
b. January FY 2022 pay increase & benefits		86,572		88,654		1,712
c. Payment for centrally furnished services		39,400		41,370		1,970
d. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		90,764		92,130		1,166
Subtotal						$5,418
2. Research Management and Support:						
a. Annualization of January 2021 pay increase & benefits		$51,086		$52,643		$389
b. January FY 2022 pay increase & benefits		51,086		52,643		1,168
c. Payment for centrally furnished services		2,308		2,423		115
d. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		27,371		27,718		347
Subtotal						$2,019
Subtotal, Built-in						$7,437

CHANGES	FY2021 Enacted No.	FY2021 Enacted Amount	FY 2022 President's Budget No.	FY 2022 President's Budget Amount	Program Change from FY 2021 Enacted No.	Program Change from FY 2021 Enacted Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	1,987	$1,015,357	2,006	$1,049,466	19	$34,109
b. Competing	664	331,918	723	361,163	59	29,245
c. SBIR/STTR	104	65,764	108	68,527	4	2,763
Subtotal, RPGs	2,755	$1,413,039	2,837	$1,479,156	82	$66,117
2. Research Centers	96	$117,050	98	$119,390	2	$2,340
3. Other Research	549	150,731	562	155,486	13	4,755
4. Research Training	1,068	60,716	1,063	65,112	-5	4,396
5. Research and development contracts	120	92,894	122	95,216	2	2,322
Subtotal, Extramural		$1,834,430		$1,914,360		$79,930
	FTEs		FTEs		FTEs	
6. Intramural Research	366	$216,736	366	$222,154	0	$0
7. Research Management and Support	300	80,765	300	82,784	0	0
Subtotal, Program	666	$2,131,931	666	$2,219,298	0	$79,930
Total built-in and program changes						$87,367

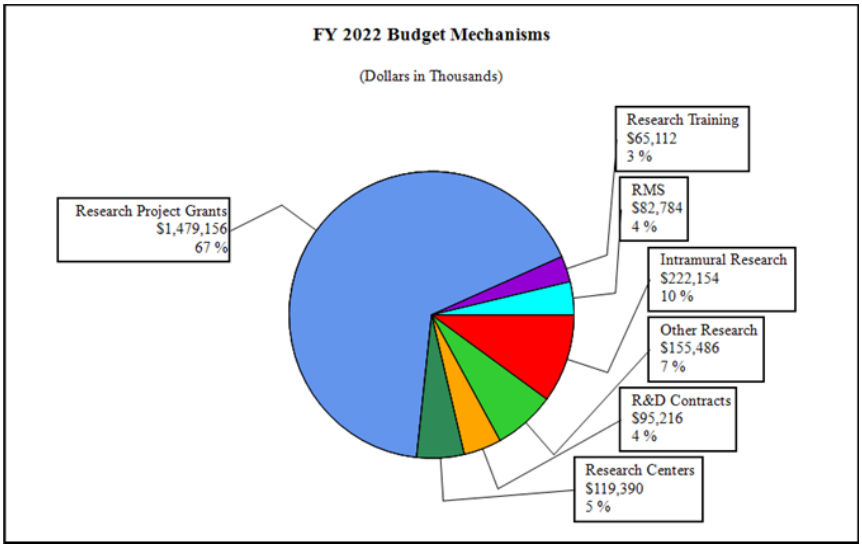
Fiscal Year 2022 Budget Graphs

History of Budget Authority and FTEs:

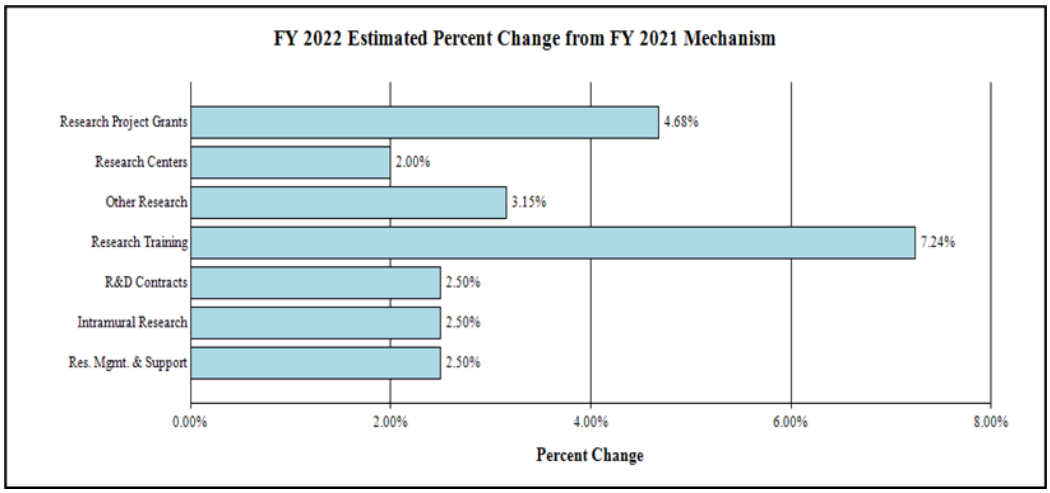




Distribution by Mechanism:



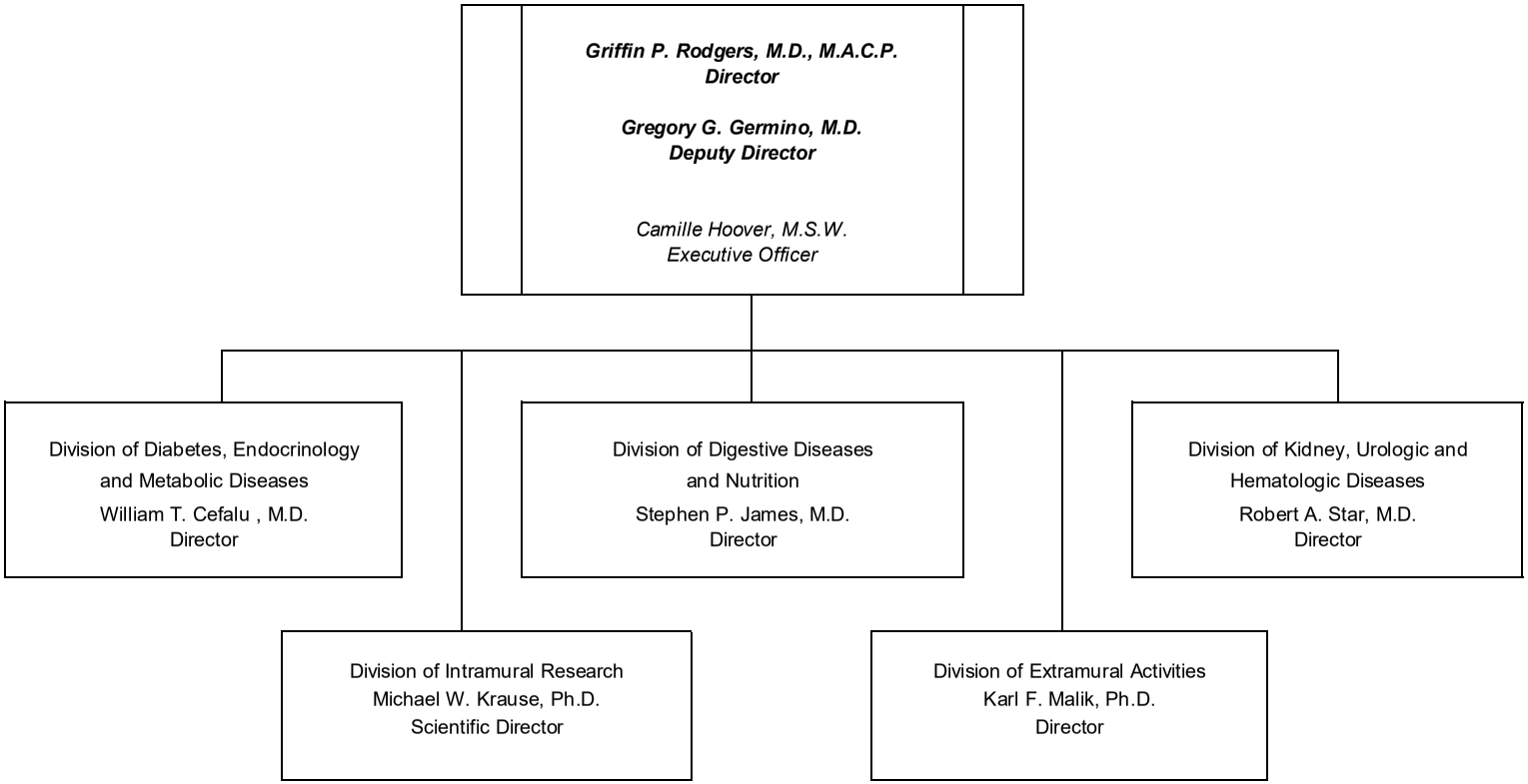
Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases

Organization Structure



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

Budget Authority by Activity[1]

(Dollars in Thousands)

	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget[2]		FY 2022 +/- FY 2021 Enacted	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Diabetes, Endocrinology, and Metabolic Diseases		$686,673		$692,111		$722,268		$30,157
Digestive Diseases and Nutrition		641,464		646,543		674,714		28,171
Kidney, Urologic, and Hematologic Diseases		491,881		495,776		517,378		21,602
Type 1 Diabetes (mandatory funding)		*(150,000)*		*(150,000)*		*(141,450)*		*(-8,550)*
Subtotal, Extramural		**$1,820,018**		**$1,834,430**		**$1,914,360**		**$79,930**
Intramural Research	**347**	**$215,016**	**366**	**$216,736**	**366**	**$222,154**	**0**	**$5,418**
Research Management & Support	**285**	**$80,112**	**300**	**$80,765**	**300**	**$82,784**	**0**	**$2,019**
TOTAL	**632**	**$2,115,146**	**666**	**$2,131,931**	**666**	**$2,219,298**	**0**	**$87,367**

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

[2] Type 1 Diabetes FY 2022 amount reflects budget authority (in thousands) of $150,000 reduced by $8,550 for Budget Control Act sequestration.

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 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
BA	$2,265,146,000	$2,281,931,000	$2,360,748,000	$78,817,000
Type 1 Diabetes Mandatory:				
Current Law[30]	-$150,000,000	-$150,000,000	-$141,450,000	$8,550,000
Labor/HHS	$2,115,146,000	$2,131,931,000	$2,219,298,000	$87,367,000
	632	666	666	0

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

Program Descriptions

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.

In FY 2022, NIDDK will continue to support foundational research that may lead to better ways to treat and prevent diseases that are associated with the endocrine system and metabolism, such as diabetes and obesity. Recent discoveries from such efforts include new insights into the basic mechanisms underlying diabetes. Studies of a protein called adipsin secreted by fat cells, which is involved in maintaining fat tissue and regulating metabolism, have led to new discoveries about beta cell health in mice, with possible implications for treating diabetes.[31] Another study, using both human beta cells and a mouse model, found that rare variations in the *SLC30A8* gene, which were previously found to protect against type 2 diabetes, promote insulin release in response to rising blood glucose, potentially by increasing the

[30] Type 1 Diabetes FY 2022 amount reflects budget authority of $150,000,000 reduced by $8,550,000 for Budget Control Act sequestration.
[31] Gómez-Banoy N, et al. Nat Med 25: 1739-1747, 2019.

proportion of insulin that is ready for release.[32] With FY 2022 resources, NIDDK will continue major clinical and translational research studies in diabetes, endocrinology, and metabolic diseases. In a recent study based on 29 years of following participants in the NIDDK's landmark Diabetes Control and Complications Trial and its follow up, the Epidemiology of Diabetes Interventions and Complications study, researchers determined that blood glucose levels and age are the strongest risk factors for total cardiovascular disease (heart disease and stroke) burden in people with type 1 diabetes.[33] For type 2 diabetes, an analysis combining information from multiple genetic studies in people of East Asian descent yielded a wealth of new information that may help improve treatment and prevention, in this population and others.[34] NIDDK seeks to accelerate progress in obesity research by funding clinical trials focused on elucidating physiological mechanisms underlying individual variability in maintaining reduced weight over time.[35]

The Rare and Atypical Diabetes Network

FY 2021 Level:	$5.0 million
FY 2022 Level:	$5.0 million
Change:	$0

In diabetes mellitus, blood glucose levels become elevated due to the body's inability to produce and/or respond appropriately to insulin. In most cases, diabetes is classified as being type 1, characterized by destruction of insulin producing beta cells, usually via autoimmunity; type 2, generally associated with obesity and characterized by insulin resistance and relative insulin deficiency; or gestational diabetes, which manifests during pregnancy. However, in some people with diabetes, the disease does not seem to fall neatly into one of these categories or does not respond to treatment in the normally expected ways. NIDDK established the Rare and Atypical Diabetes Network (RADIANT) to obtain the data needed to understand these unusual forms of diabetes for the first time. The Network will therefore screen about 2,000 people with unknown or atypical forms of diabetes and utilize questionnaires, physical exams, genetic sequencing, blood samples, and other tests to build a comprehensive resource of genetic, clinical, and descriptive data for the scientific and healthcare communities. People found to have unknown forms of diabetes may receive additional testing. Some participant family members may also be invited to take part in the study. RADIANT will provide information on how and why diabetes can vary so greatly and may one day help to establish new diagnostic criteria for diabetes, find new markers for screening, or identify drug targets for new therapies that could ultimately bring more precision to diabetes treatment. Insights gained from this research may also help advance the understanding and treatment of more common forms of diabetes.

[1] www.atypicaldiabetesnetwork.org/

Budget Policy: The FY 2022 President's Budget request for this program is $722.3 million, an increase of $30.2 million or 4.4 percent compared with the FY 2021 Enacted level. With FY 2022 resources, NIDDK will continue major diabetes clinical trials. NIDDK's plans for FY 2022 include continuing research that examines changes in blood glucose levels, both early in pregnancy and over its course, which could provide information on prediction of gestational diabetes mellitus and fetal outcomes, as well as future strategies for combatting this form of diabetes. NIDDK is also conducting research comparing bariatric surgery versus non-surgical approaches for treating type 2 diabetes to inform clinical decision making. In FY 2022, NIDDK will continue funding for research centers to advance basic and clinical 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-

[32] Dwivedi OP, et al. Nat Genet 51: 1596-1606, 2019.
[33] Bebu I, et al. Diabetes Care 43: 867-874, 2020.
[34] Spracklen CN, et al. Nature 582: 240-245, 2020.
[35] grants.nih.gov/grants/guide/rfa-files/rfa-dk-19-017.html

Gastroparesis Clinical Research Consortium

FY 2021 Level: $6.4 million
FY 2022 Level: $6.7 million
Change: $0.3 million

In people with gastroparesis, stomach muscles that grind food into pieces for digestion in the adjoining small intestine work poorly, and the stomach takes too long to empty its contents. This "delayed gastric emptying" can cause chronic nausea, vomiting, and abdominal pain, often leading to malnutrition, dehydration, and other serious complications. Diabetes, surgery, and other conditions are known to cause gastroparesis in some people, but often the causes are unknown, which makes the development of treatments more challenging. In 2006, NIDDK established the multi-center Gastroparesis Clinical Research Consortium to accelerate research on the causes and progression of this disorder and to explore new treatment approaches. The Consortium includes a Gastroparesis Registry—the largest clinical and physiologic data repository on adult gastroparesis in the world. Women make up the majority of participants, reflecting the higher incidence of gastroparesis in this group. Over the years, the Consortium has undertaken several trials to characterize gastroparesis and test new approaches to diagnosis and treatment. For example, a recent study of people in the Registry with both diabetes and symptoms of gastroparesis found that those with delayed gastric emptying had a higher number of diabetic complications than those with normal gastric emptying.[2] Consortium researchers found that the balance of parasympathetic (active during rest) and sympathetic (active during stress) nervous system functioning is disrupted in many people with gastroparesis.[3] Using information from the Registry, Consortium researchers studied people who underwent treatment with gastric electrical stimulation and determined that this procedure was effective for treating nausea in people with more severe gastroparesis.[4] The Consortium was recently continued for an additional five years, including support for the first U.S.-based registry of children and adolescents with gastroparesis, ancillary studies, and a repository of samples to allow further studies of disease processes and biomarker identification.[5]

[1] jhuccs1.us/gpcrc/
[2] Parkman HP, et al. Am J Gastroenterol. 114:1778-179, 2019.
[3] Nguyen L, et al. Neurogastroenterol Motil. Feb 15:e13810, 2020.
[4] Abell TL, et al. Neurogasteroenterol Motil. 31(12):e13714, 2019.
[5] grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-504.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-505.html

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 eating disorders, and research on obesity.

In FY 2022, NIDDK will continue to support research aimed at improving the prevention and treatment of diseases associated with the digestive system. For example, recent NIDDK-supported research on therapeutic approaches to inflammatory bowel disease have found a tell-tale combination of cells in people with Crohn's disease who do not respond to one of its most effective treatments, targeting a component of the inflammatory response called tumor necrosis factor.[36] Another study showed that high levels of a common fungus in the gut could signal whether a microbe-based treatment called fecal microbiota transplantation would be successful for people with ulcerative colitis.[37] Other NIDDK-supported digestive disease researchers have developed a new mouse model that mimics the immune system features and gluten-dependent intestinal damage seen in people with celiac disease, providing a new research tool for

[36] Martin JC, et al. Cell 178: 1493-1508.e20, 2019
[37] Leonardi I, et al. Cell Host Microbe 27: 823-829.e3, 2020.

discovering and testing therapies.[38] A number of recent advances by investigators in the NIDDK's International Study Group of Pediatric Pancreatitis: In Search for a Cure study, part of the Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer, have enhanced understanding of pancreatitis development and management in children.[39] Among advances in research on liver diseases, scientists working on biliary atresia, a severe and potentially deadly childhood liver disease, found that a newborn screening approach could identify those with the disease and enable earlier diagnosis and treatment, and another group identified a unique gene activity signature for this disease that predicts survival and could inform new treatment approaches.[40] NIDDK has supported research to discover that consuming high amounts of fructose, such as in foods containing the additive high-fructose corn syrup, may promote nonalcoholic fatty liver disease through damaging the intestinal barrier.[41] In research on obesity, scientists have found that people with severe obesity who underwent bariatric surgery had significantly more short- and long-term weight loss compared to those who did not have surgery.[42] Guided by the recently released Strategic Plan for NIH Nutrition Research, NIDDK seeks to accelerate progress in research on nutrition by funding studies on new technologies to sample and monitor nutrients, metabolites, hormones, and the gut, including its resident microbes.[43] Advances in these areas will pave the way for improvements in the prevention, diagnosis, and treatment of digestive diseases in FY 2022 and beyond.

Budget Policy: The FY 2022 President's Budget request for this program is $674.7 million, an increase of $28.2 million or 4.4 percent compared with the FY 2021 Enacted level. In FY 2022, NIDDK will continue major clinical research networks to help understand and treat liver diseases, and will support a new Liver Cirrhosis Network to conduct research on cirrhosis resulting from various forms of chronic liver disease.[44] Among its obesity-related efforts in FY 2022, NIDDK will continue to pursue research to understand factors in infancy and early childhood that influence body composition and obesity development, and to determine how policies influence obesity-related behaviors and weight outcomes in adults.[45] 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 2022, along with other efforts, such as support for centers focused on digestive diseases research, as part of an overall balanced research program.

[38] Abadie V, et al. Nature 578: 600-604, 2020.
[39] Bellin MD, et al. J Pediatr Gastroenterol Nutr 69: 599-606, 2019; Dike CR, et al. J Pediatr Gastroenterol Nutr 71: 112-118, 2020; Lin TK, et al. J Pediatr Gastroenterol Nutr 69: 704-709, 2019; Palermo TM, et al. Contemp Clin Trials 88: 105898, 2020; Perito ER, et al. J Pediatr Gastroenterol Nutr 70: 106-114, 2020.
[40] Harpavat S, et al. JAMA 323: 1141-1150, 2020; Luo Z, et al. Gastroenterology 157: 1138-1152.e14, 2019.
[41] Todoric J, et al. Nat Metab 2: 1034-1045, 2020.
[42] Arterburn DE, et al. Ann Surg March 2020, Online ahead of print.
[43] dpcpsi.nih.gov/onr/strategic-plan, grants.nih.gov/grants/guide/pa-files/PAR-20-133.html, grants.nih.gov/grants/guide/pa-files/PAR-20-134.html
[44] grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-003.html, grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-004.html
[45] grants.nih.gov/grants/guide/notice-files/NOT-DK-19-007.html, grants.nih.gov/grants/guide/notice-files/NOT-DK-20-036.html, grants.nih.gov/grants/guide/pa-files/PAR-18-854.html

The Hemodialysis Opioid Prescription Effort (HOPE) Consortium

FY 2021 Level: $5.1 million
FY 2022 Level: $5.1 million
Change: $0

Pain is a common problem in End-Stage Renal Disease (ESRD) Hemodialysis (HD) patients, but its prevalence varies widely by geography, dialysis unit, and possibly ethnicity. Pain has been linked to decreased quality of life, lack of social support, depressed mood, and other mental health disorders. Chronic opioid prescription has been identified in approximately 20 percent of U.S. ESRD HD patients, far higher than in Medicare comparison populations. Opioid doses prescribed to HD patients exceed Centers for Disease Control and Prevention (CDC) recommendations. Prescription and dose level have been associated with higher rates of hospitalizations, withdrawal from dialysis, and mortality.

In conjunction with the NIH's Helping to End Addiction Long-term (HEAL) Initiative, the NIDDK in 2019 launched the Hemodialysis Opioid Prescription Effort (HOPE) consortium, which will recruit HD patients receiving chronic opioid prescriptions and develop interventions that may reduce opioid prescriptions in the hemodialysis population, while maintaining pain control and enhancing quality of life for the participants. The study will initiate multipronged (behavioral, cognitive, and medical) pain treatments tailored individually to each patient and use novel strategies to reduce dependence on opioids in affected patients. The consortium, comprised of eight Clinical Centers and a Scientific and Data Research Center, will evaluate chronic opioid prescription rate, prescription drug dose, pain control, patient satisfaction with care, perception of quality of life, hospitalization rates, and mortality. HOPE researchers will also examine comorbid illnesses and social determinants of health to identify novel risk factors for pain and opioid use in this population. The HOPE consortium has embraced patient participation and patient-centric evaluations and incorporated these into its plans. The study developed its research protocol in FY 2020, and patient recruitment will begin in FY 2021.

[1] www.niddk.nih.gov/research-funding/research-programs/hemodialysis-opioid-prescription-effort-consortium; heal.nih.gov/research/clinical-research/hemodialysis

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.

In recent research, NIDDK-supported scientists developed a noninvasive technology using ultrasound beams to lift and reposition an object in a living body—an advance that could potentially be used to treat people with disease associated with urinary stones (also referred to as kidney stones), which are one of the most common disorders of the urinary tract.[46] Investigators in the Prevention of Lower Urinary Tract Symptoms Consortium conducted foundational studies on women's bladder health experiences, and researchers in the Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network provided key insights into highly prevalent yet poorly understood urologic chronic pelvic pain syndromes in women and men.[47] New

[46] Ghanem MA, et al. PNAS 117: 16848-16855, 2020.
[47] Lowder JL, et al. Neurourol Urodyn. 38(5):1339-1352, 2019; Low LK, et al. J Adv Nurs. 2019 Jul 9. doi: 10.1111/jan.14148; Camenga DR, et al. Int J Environ Res Public Health. 16(18): 3338, 2019; Sutcliffe S, et al. J Womens Health (Larchmt). 28(6):827-841, 2019; Sutcliffe S, et al. BJU Int. 124(3):522-531, 2019; Clemens JQ, et al. Neurourol Urodyn. 2020 Jun 23. doi: 10.1002/nau.24423.

findings in mice about immune response to urinary tract infections (UTIs) could help explain the high rates of UTI recurrence, particularly in women, and results from the Symptoms of Lower Urinary Tract Dysfunction Research Network identified subgroups of men with different lower urinary tract symptoms; both studies could help treat these urinary symptoms in the future.[48] In hematology research, efforts by investigators in NIDDK's Porphyrias Consortium continued to make progress toward understanding and managing these disorders.[49] NIDDK also supported a live animal imaging study in mice of hematopoietic stem and progenitor cells in the bone marrow, which revealed new insights into the variety of niches where these cells reside.[50] Such robust progress in the kidney, urologic, and hematologic diseases will continue in FY 2022.

Activities in this portfolio will support the continued focus on advancing kidney health in patients with CKD and kidney failure. The HHS initiative to transform kidney health is focused on reducing the risk of kidney failure through research and prevention, improving access to quality treatment options, and increasing access to kidney transplantation. NIH aims to support these goals through research activities, including an NIDDK notice of special interest, active through 2023, to encourage small business grant applications to develop innovative approaches to treating ESRD and address critical accompanying challenges such as vascular access and fluid management during dialysis.[51] Two scientific workshops are being planned for 2021: one focused on improving home dialysis opportunities, and the other on improving access to kidney transplantation for people with kidney failure. Ongoing research efforts, including the APOL1 Long-term Kidney Transplantation Outcomes Network and the Kidney Precision Medicine Program, also support the HHS initiative to transform prevention and treatment of kidney diseases.

Budget Policy: The FY 2022 President's Budget request for this program is $517.4 million, an increase of $21.6 million or 4.4 percent compared with the FY 2021 Enacted level. In FY 2022, NIDDK plans to build on a 2019 workshop on strategies to improve clinical outcomes among patients surviving an episode of acute kidney injury by establishing the Caring for OutPatiEnts after Acute Kidney Injury Consortium.[52] NIDDK also plans to continue support for research and training opportunities for young investigators in pediatric nephrology through training opportunities associated with some of its clinical trials on pediatric CKD, regular data workshops for the Chronic Kidney Disease in Children study aimed at junior faculty, and supporting pilot and feasibility studies through its Pediatric Centers of Excellence in Nephrology.[53] Centers focused on kidney, urologic, and hematologic research will receive continued funding. FY 2022 funds will also be used to support clinical studies on hemodialysis, such as a clinical trial

[48] Wu J, et al. Nat Immunol 21: 671–683, 2020; Liu G, et al. J Urol 202: 1230-1239, 2019.
[49] Langendonk JG, et al. N Engl J Med. 373(1):48-59, 2015; www.rarediseasesnetwork.org/cms/porphyrias; www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-increase-pain-free-light-exposure-patients-rare-disorder
[50] Christodoulou D, et al. Nature. 578(7794):278-283, 2020.
[51] grants.nih.gov/grants/guide/notice-files/NOT-DK-19-027.html
[52] www.niddk.nih.gov/news/meetings-workshops/2019/improving-care-patients-hospitalization-aki, grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-011.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-012.html
[53] projectreporter.nih.gov/project_info_description.cfm?aid=9805607&icde=50886064&ddparam=&ddvalue=&ddsub=&cr=2&csb=default&cs=ASC&pball=, ckidworkshop.org/, grants.nih.gov/grants/guide/rfa-files/rfa-dk-16-032.html

comparing the effects of using higher and lower serum phosphate targets, and the Hemodialysis Opioid Prescription Effort consortium described above, along with other efforts as part of an overall balanced research program.[54]

Special Statutory Funding Program for Type 1 Diabetes Research

Complementing efforts of the Diabetes, Endocrinology, and Metabolic Disease program, the overarching goal of the Special Diabetes Program (SDP) is to foster a deeper understanding of type 1 diabetes, toward improved treatment, prevention, and cure of the disease 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; 2) preventing or reversing the disease; 3) developing cell replacement therapy; 4) improving management and care; 5) preventing or reducing diabetes complications; and 6) attracting new talent and applying new technologies to research. Although focused on type 1 diabetes, aspects of this research are relevant to type 2 diabetes and other autoimmune disorders. For example, the Human Pancreas Analysis Program will provide information about cellular mechanisms of disease that will also help to better define mechanisms underlying type 2 diabetes.[55] In addition, people with type 2 diabetes could benefit from research developing novel artificial pancreas technologies and other diabetes management technologies.

Recent efforts supported by the SDP are greatly expanding understanding of autoimmunity in type 1 diabetes. Using a systematic approach in a mouse model of type 1 diabetes, researchers identified and characterized the protein fragments (peptides) associated with beta cell autoimmunity.[56] Scientists, for the first time, developed functional human islet-like organoids that are shielded from immune system attack, an advance that allowed these organoids to treat a mouse model of diabetes for weeks without immunosuppressive drugs.[57] Clinical research found that a new artificial pancreas system is more effective than sensor-augmented pump therapy at increasing the time people with type 1 diabetes spend with blood glucose levels in a healthy range, knowledge that led to FDA approval of the new system in 2019.[58] These efforts will help people to improve their blood glucose management over time, which, as shown by other NIDDK-supported research advances, will result in reduced risk of complications from diabetes. Researchers in the SEARCH for Diabetes in Youth study group demonstrated that rates of both type 1 and type 2 diabetes continue to increase in people under the age of 20 in the United States, with higher rates of increase among racial/ethnic minority youth.[59] NIDDK seeks to accelerate progress by funding clinical trials to test artificial pancreas device systems in populations that have been understudied, such as those with difficult to manage type 1 diabetes. In addition, by establishing a clinical consortium to study type 1 diabetes occurring after acute pancreatitis,

[54] clinicaltrials.gov/ct2/show/NCT04095039, www.niddk.nih.gov/research-funding/research-programs/hemodialysis-opioid-prescription-effort-consortium
[55] hirnetwork.org/hpap-overview
[56] Wan X, et al. Nat Immunol 21: 455-463, 2020.
[57] Yoshihara E, et al. Nature 2020 Aug 19. doi: 10.1038/s41586-020-2631-z.
[58] Brown SA, et al. N Engl J Med 381: 1707-1717, 2019.
[59] Divers J, et al. MMWR Morb Mortal Wkly Rep 69: 161-165, 2020.

NIDDK aims to further the understanding of how associated diseases can contribute to diabetes.[60]

Budget Policy: The FY 2022 President's Budget request for the Special Statutory Funding Program for Type 1 Diabetes Research is $141.4 million, a reduction of $8.6 million from the FY 2021 enacted level. This reduction is due to the application of mandatory sequestration to this program in FY 2022.

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 conducted a series of experiments showing how speech might promote the spread of the virus that causes COVID-19, even from people who have no apparent symptoms of the disease—results that underscore the importance of mask-wearing to stem the pandemic.[61] Other intramural studies, in partnership with scientists at academic institutions in the United States and Germany, demonstrated how changes in people's gut microbiomes, due to diet or antibiotic use, directly altered the amount of nutrients extracted from a given amount of food, backing up results from animal models and indirect associations in prior human studies.[62] In FY 2022, the Intramural Research Program will continue to advance research in these and other areas.

Budget Policy: The FY 2022 President's Budget request for intramural research is $222.2 million, an increase of $5.4 million or 2.5 percent compared with the FY 2021 Enacted level.

Research Management and Support

Research Management and Support (RMS) activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, research 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 continues its communication of research-based health information to patients, health professionals, and the public.[63]

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[60] grants.nih.gov/grants/guide/rfa-files/RFA-DK-19-036.html, grants.nih.gov/grants/guide/rfa-files/RFA-DK-19-022.html

[61] Anfinrud P, et al. N Engl J Med 382: 2061-2063, 2020; Stadnytskyi V, et al. Proc Natl Acad Sci USA 117:11875-11877, 2020.

[62] Basolo A, et al. Nat Med 26: 589-598, 2020.

[63] www.niddk.nih.gov/health-information

Budget Policy: The FY 2022 President's Budget request for RMS is $82.8 million, an increase of $2.0 million or 2.5 percent compared with the FY 2021 Enacted level.

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Appropriations History

Fiscal Year	Budget Estimate to Congress[1]	House Allowance	Senate Allowance	Appropriation[1]
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	$2,129,027,000	$2,155,327,000	$2,264,314,000
2021	$2,074,211,000	$2,132,498,000	$2,169,021,000	$2,281,975,000
2022	$2,360,748,000			

[1] Includes mandatory funding for Type 1 Diabetes.

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2021 Amount Authorized	FY 2021 Enacted	2022 Amount Authorized	FY 2022 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,131,931,000	Indefinite	$2,219,298,000
National Institute of Diabetes and Digestive and Kidney Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,131,931,000		$2,219,298,000

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National Institute of Diabetes and Digestive and Kidney Diseases

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation	$2,114,314	$2,131,975	$2,219,298
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(150,000)*	*(150,000)*	*(150,000)*
Type 1 Diabetes Sequestration	*(0)*	*(0)*	*(-8,550)*
Subtotal, adjusted appropriation	$2,114,314	$2,131,975	$2,219,298
OAR HIV/AIDS Transfers	832	-44	0
Subtotal, adjusted budget authority	$2,115,146	$2,131,931	$2,219,298
Subtotal, adjusted budget authority	$2,115,146	$2,131,931	$2,219,298
Unobligated balance lapsing	-62	0	0
Total obligations	$2,115,084	$2,131,931	$2,219,298

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2020 - $4,037 FY 2021 - $6,000 FY 2022 - $6,000

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Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total compensable workyears:				
	Full-time equivalent	666	666	0
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	$200	$204	$5
	Average GM/GS grade	12.0	12.0	0.0
	Average GM/GS salary	$117	$120	$3
	Average salary, Commissioned Corps (42 U.S.C. 207)	$105	$107	$3
	Average salary of ungraded positions	$164	$167	$3
	OBJECT CLASSES	**FY 2021 Enacted**	**FY 2022 President's Budget**	**FY 2022 +/- FY 2021**
	Personnel Compensation			
11.1	Full-Time Permanent	45,246	46,276	1,030
11.3	Other Than Full-Time Permanent	41,647	42,594	947
11.5	Other Personnel Compensation	3,465	3,544	79
11.7	Military Personnel	842	866	24
11.8	Special Personnel Services Payments	13,503	13,303	-200
11.9	**Subtotal Personnel Compensation**	**$104,703**	**$106,583**	**$1,880**
12.1	Civilian Personnel Benefits	32,437	34,181	1,744
12.2	Military Personnel Benefits	518	533	15
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$137,658**	**$141,297**	**$3,639**
21.0	Travel & Transportation of Persons	930	922	-8
22.0	Transportation of Things	195	196	1
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	270	273	3
24.0	Printing & Reproduction	20	19	-1
25.1	Consulting Services	58,674	60,955	2,281
25.2	Other Services	21,652	20,608	-1,044
25.3	Purchase of goods and services from government accounts	141,416	146,386	4,970
25.4	Operation & Maintenance of Facilities	165	168	3
25.5	R&D Contracts	19,994	19,956	-38
25.6	Medical Care	1,824	1,818	-6
25.7	Operation & Maintenance of Equipment	5,000	4,936	-64
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$248,725**	**$254,827**	**$6,102**
26.0	Supplies & Materials	12,100	12,220	120
31.0	Equipment	12,997	12,900	-97
32.0	Land and Structures	500	500	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,718,536	1,796,144	77,608
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$1,994,273**	**$2,078,001**	**$83,728**
	Total Budget Authority by Object Class	**$2,131,931**	**$2,219,298**	**$87,367**

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

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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
Full-Time Permanent (11.1)	$45,246	$46,276	$1,030
Other Than Full-Time Permanent (11.3)	41,647	42,594	947
Other Personnel Compensation (11.5)	3,465	3,544	79
Military Personnel (11.7)	842	866	24
Special Personnel Services Payments (11.8)	13,503	13,303	-200
Subtotal Personnel Compensation (11.9)	**$104,703**	**$106,583**	**$1,880**
Civilian Personnel Benefits (12.1)	$32,437	$34,181	$1,744
Military Personnel Benefits (12.2)	518	533	15
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$137,658**	**$141,297**	**$3,639**
Travel & Transportation of Persons (21.0)	$930	$922	-$8
Transportation of Things (22.0)	195	196	1
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	270	273	3
Printing & Reproduction (24.0)	20	19	-1
Other Contractual Services:			
Consultant Services (25.1)	58,624	60,905	2,281
Other Services (25.2)	21,652	20,608	-1,044
Purchases from government accounts (25.3)	77,875	81,004	3,129
Operation & Maintenance of Facilities (25.4)	165	168	3
Operation & Maintenance of Equipment (25.7)	5,000	4,936	-64
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$163,316**	**$167,621**	**$4,305**
Supplies & Materials (26.0)	$12,100	$12,220	$120
Subtotal Non-Pay Costs	**$176,831**	**$181,251**	**$4,420**
Total Administrative Costs	**$314,489**	**$322,548**	**$8,059**

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

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2020 Final			FY 2021 Enacted			FY 2022 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Diabetes, Endocrinology, and Metabolic Diseases									
Direct:	27	-	27	30	-	30	30	-	30
Reimbursable:	3	-	3	3	-	3	3	-	3
Total:	30	-	30	33	-	33	33	-	33
Division of Digestive Diseases and Nutrition									
Direct:	24	1	25	27	1	28	27	1	28
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	24	1	25	27	1	28	27	1	28
Division of Extramural Activities									
Direct:	66	1	67	66	1	67	66	1	67
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	66	1	67	66	1	67	66	1	67
Division of Intramural Research Programs									
Direct:	342	5	347	361	5	366	361	5	366
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	342	5	347	361	5	366	361	5	366
Division of Kidney, Urologic, and Hematologic Diseases									
Direct:	25	-	25	27	-	27	27	-	27
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	25	-	25	27	-	27	27	-	27
Office of the Director									
Direct:	138	-	138	145	-	145	145	-	145
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	138	-	138	145	-	145	145	-	145
Total	625	7	632	659	7	666	659	7	666
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									

FISCAL YEAR	Average GS Grade
2018	12.0
2019	12.0
2020	12.0
2021	12.0
2022	12.0

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

Detail of Positions[1]

GRADE	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	197,300	199,549	204,099
General Schedule			
GM/GS-15	68	68	68
GM/GS-14	68	70	70
GM/GS-13	108	106	106
GS-12	69	72	72
GS-11	30	35	35
GS-10	0	0	0
GS-9	28	30	30
GS-8	12	12	12
GS-7	16	14	14
GS-6	5	4	4
GS-5	2	3	3
GS-4	2	2	2
GS-3	0	0	0
GS-2	2	2	2
GS-1	0	0	0
Subtotal	410	418	418
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	2	3	3
Senior Grade	1	0	0
Full Grade	3	2	2
Senior Assistant Grade	1	2	2
Assistant Grade	0	0	0
Subtotal	7	7	7
Ungraded	244	249	249
Total permanent positions	408	415	415
Total positions, end of year	662	675	675
Total full-time equivalent (FTE) employment, end of year	632	666	666
Average ES salary	197,300	199,549	204,099
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	115,635	116,953	119,620

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