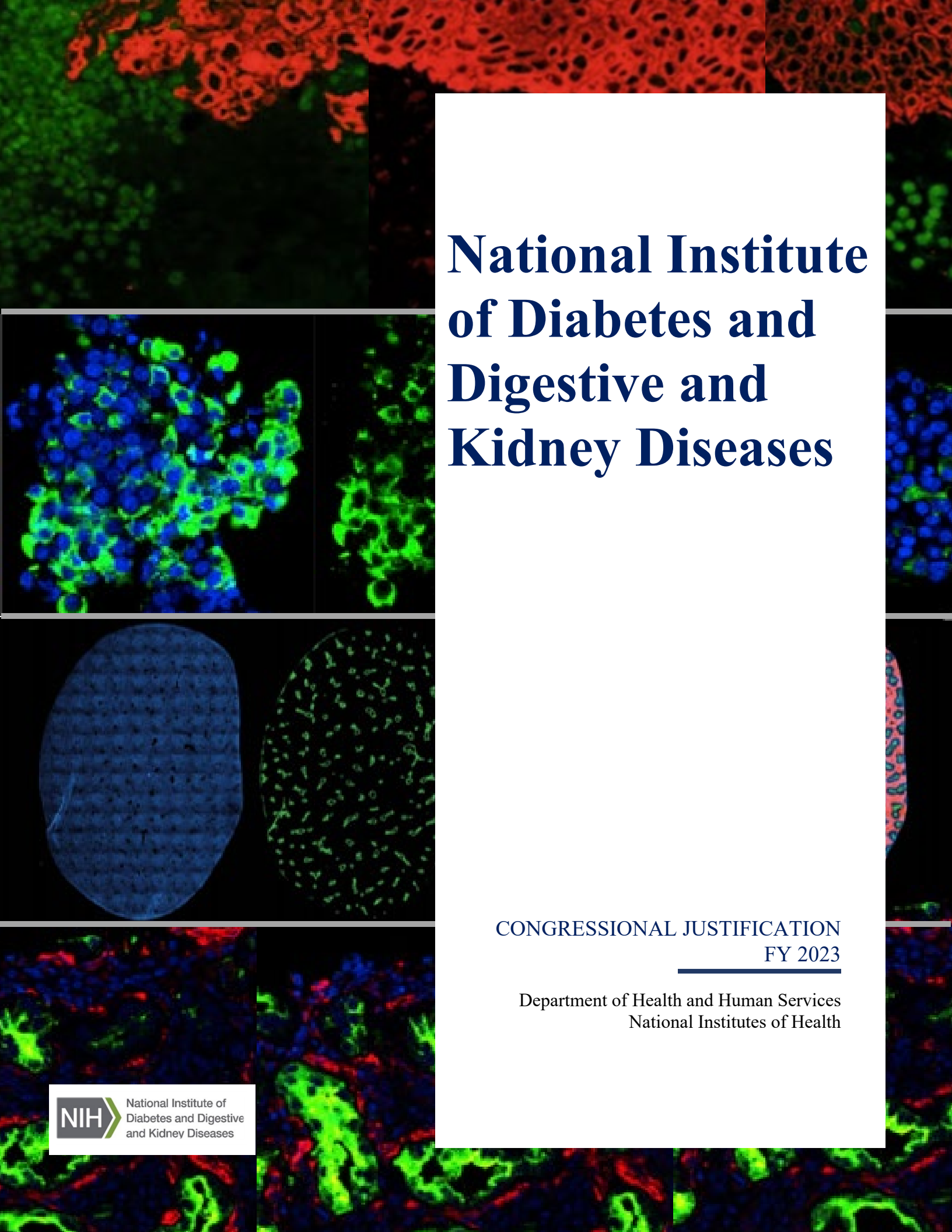

National Institute of Diabetes and Digestive and Kidney Diseases

CONGRESSIONAL JUSTIFICATION
FY 2023

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 2023 Budget Table of Contents

Cover page images from NIDDK-supported research, from top to bottom: **1**. Sawaya AP, Stone RC, Brooks SR,…Tomic-Canic M. Deregulated immune cell recruitment orchestrated by FOXM1 impairs human diabetic wound healing. Nat Commun 11: 4678, 2020. DOI: 10.1038/s41467-020-18276-0 and reprinted under the terms of the Creative Commons CC-BY license;[1] **2.** Tang X, Uhl S, Zhang T,…Chen S. SARS-CoV-2 infection induces beta cell transdifferentiation. Cell Metab 33: 1557-1591.e7, 2021. DOI: 10.1016/j.cmet.2021.05.015 and reprinted under the terms of the Creative Commons CC-BY license;[2] **3.** From Wei Y, Wang YG, Jia Y,...Zhu H. Liver homeostasis is maintained by midlobular zone 2 hepatocytes. Science 371: eabb1625, 2021. Reprinted with permission from AAAS; **4.** Reprinted from Cell Metab, Vol 33, Mori Y, Ajay AK, Chang J-H,…Bonventre JV; KIM-1 mediates fatty acid uptake by renal tubular cells to promote progressive diabetic kidney disease, 1042-1061, Copyright 2021, with permission from Elsevier.

[1] www.nature.com/articles/s41467-020-18276-0; creativecommons.org/licenses/by/4.0/

[2] www.sciencedirect.com/science/article/pii/S1550413121002321; creativecommons.org/licenses/by/4.0/

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. 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. Many of these diseases and conditions also place a disproportionate burden on ethnic and racial minority groups, underscoring the importance of pursuing research toward health equity. 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.[3] Estimates of chronic kidney disease show that about 37 million Americans are affected, and over 783,000 people were treated for irreversible kidney failure in the Nation in 2018.[4,5] Many urologic diseases, such as urinary incontinence, urinary tract infections, and benign prostatic hyperplasia, are also highly prevalent.[6] Digestive diseases accounted for an estimated 66.4 million ambulatory care visits to doctor's offices, outpatient hospital clinics, and emergency departments, as well as 16.5 million hospitalizations with digestive diseases as a primary or secondary diagnosis.[7,8] Obesity affects more than 40 percent of U.S. adults and over 19 percent of children and adolescents.[9] It is a strong risk factor for type 2 diabetes; fatty liver disease, including nonalcoholic steatohepatitis (NASH); 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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[3] Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report. Atlanta, GA: HHS, 2020. www.cdc.gov/diabetes/data/statistics-report/index.html

[4] CDC. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: HHS, 2021. www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html

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

[6] 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

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

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

[9] Hales CM, et al. 2020. CDC. National Center for Health Statistics Data Brief No. 360. www.cdc.gov/nchs/products/databriefs/db360.htm; Fryar CD, et al. 2020. CDC. National Center for Health Statistics Health E-Stats. www.cdc.gov/nchs/data/hestat/obesity-child-17-18/obesity-child.htm

Responding to Urgent Public Health Needs

NIDDK has continued to respond to the urgent public health challenge posed by the COVID-19 pandemic, including supporting research that is shedding new light on the disease. For example, NIDDK-supported researchers demonstrated in laboratory models how SARS-CoV-2 infects certain human cells and tissues—including liver cells and insulin-producing pancreatic beta cells—and also discovered that SARS-CoV-2 infection directly induces changes in beta cells that could affect the course or onset of diabetes.[10] Other researchers contributed knowledge about COVID-19 vaccination in immunocompromised individuals, such as in solid organ transplant recipients.[11] To propel additional progress, NIDDK made new awards to study the impact of COVID-19 on organs and diseases of interest to our Institute.[12] We also spearheaded a statutory Diabetes Mellitus Interagency Coordinating Committee meeting to discuss progress and opportunities related to COVID-19 and diabetes toward facilitating collaboration and coordination across the government. Another key aspect of NIDDK's response has been to alleviate the burden imposed by the pandemic on the biomedical research enterprise. For example, the Institute provided funding for award extensions to early career scientists, such as recipients of training and career development awards, whose career trajectories were significantly impacted by COVID-19.[13] Additionally, NIDDK provided supplemental funding to several early-stage investigators and clinical researchers in their final grant year whose research progress was significantly impacted by COVID-19.[14]

While responding to the COVID-19 pandemic, NIDDK remains mindful that many diseases and disorders within its mission place an urgent personal and financial toll on the United States. As such, we plan to continue our vigorous support of research to combat them, while regularly assessing scientific progress and opportunities to ensure that research is addressing timely public health needs. For example, we recently expanded our successful Accelerating Medicines Partnership (AMP®) for Type 2 Diabetes program to include five additional metabolic diseases under a new program called AMP® Common Metabolic Diseases (CMD).[15] AMP® CMD will add substantial amounts of new data in the quest to understand the genes and pathways that underlie metabolic diseases toward identifying new therapeutic targets. To address the increasing prevalence of NASH, NIDDK is supporting a new network to conduct research on cirrhosis resulting from various forms of chronic liver disease.[16] In this endeavor, we are partnering with the National Institute on Alcohol Abuse and Alcoholism to address alcoholic steatohepatitis and the National Cancer Institute to address liver cirrhosis as a major risk factor for liver cancer. The Institute also began a new research consortium to address the significant increase in the global burden of chronic kidney diseases of uncertain or non-traditional

[10] Yang L, et al. Cell Stem Cell 27: 125–136, 2020; Tang X, et al. Cell Metab 33: 1577-1591.e7, 2021.
[11] Werbel WA, et al. Ann Intern Med 174: 1330-1332, 2021.
[12] grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-021.html
[13] grants.nih.gov/grants/guide/notice-files/NOT-OD-21-052.html; grants.nih.gov/grants/guide/pa-files/PA-20-272.html
[14] grants.nih.gov/grants/guide/pa-files/PA-20-272.html
[15] www.niddk.nih.gov/research-funding/research-programs/accelerating-medicines-partnership-common-metabolic-diseases; ACCELERATING MEDICINES PARTNERSHIP and AMP are registered service marks of the U.S. Department of Health and Human Services.
[16] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-003.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-004.html

etiologies, and supports research to develop interventions to reduce opioid use in people on hemodialysis in response to the public health crisis of chronic pain and related opioid overuse.[17]

Addressing Health Disparities and Scientific Workforce Diversity in Pursuit of Health Equity

Many NIDDK mission diseases place disparate burdens on racial and ethnic minority groups and people with limited resources, and these disparities have been exacerbated by the COVID-19 pandemic. NIDDK remains committed to addressing health disparities and working to achieve health equity using multiple approaches. Advances stemming from the Institute's support for health disparities-related research include findings from the Chronic Renal Insufficiency Cohort (CRIC) Study. Based on detailed analysis of CRIC data, researchers proposed changing a key measure in kidney disease diagnosis and treatment to eliminate the use of race as a variable, providing a non-biased kidney function test that does not compromise accuracy and represents an important step toward eliminating health disparities in estimating kidney function.[18] Another study that included racial and ethnic minority groups and individuals who are underserved showed that type 2 diabetes self-care may be improved by addressing the role of family and friends.[19] Other NIDDK clinical studies also include racial and ethnic populations at greater risk, such as the NASH Clinical Research Network's adult and pediatric studies in individuals of Hispanic and South Asian descent.[20]

NIDDK also actively engages in efforts to enhance diversity and inclusivity within its scientific workforce to ensure that research benefits from the best scientific minds and diverse insights. NIDDK supports research training and early career development opportunities for individuals from diverse backgrounds, such as racial and ethnic minority groups, groups experiencing disadvantage, or those from rural areas. For example, the Institute is continuing a program to support educational activities to encourage undergraduate and high school students from diverse backgrounds to pursue research careers.[21] Other initiatives focus on enhancing the diversity of the research workforce who could successfully compete for independent research funding, and supporting new investigators from diverse backgrounds.[22] While spearheading efforts related to racial and ethnic diversity, NIDDK also supports initiatives to attract new expertise to tackle our disease areas, such as emerging clinician scientists and bioinformatics experts.[23] To inform these and other health equity activities, NIDDK held a series of forums with its Advisory Council to obtain input on topics such as disparities in the scientific workforce and how NIDDK research can improve health equity and disease outcomes.[24]

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[17] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-017.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-018.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-019.html; heal.nih.gov/research/clinical-research/hemodialysis

[18] Hsu C-Y, et al. N Engl J Med doi: 10.1056/NEJMoa2103753, 2021.

[19] Mayberry LS, et al. Ann Behav Med 55: 165-178, 2021.

[20] jhuccs1.us/nash/

[21] www.niddk.nih.gov/research-funding/research-programs/diversity-programs/research-training-opportunities-students/step-up; grants.nih.gov/grants/guide/rfa-files/rfa-dk-21-023.html

[22] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-034.html; grants.nih.gov/grants/guide/pa-files/PAR-19-222.html

[23] grants.nih.gov/grants/guide/pa-files/par-19-378.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-21-019.html; grants.nih.gov/grants/guide/notice-files/not-dk-21-022.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-024.html; dknet.org/about/new-investigator-pilot

[24] www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council

Promoting Stakeholder Engagement

By engaging its stakeholder community, NIDDK can ensure that biomedical research benefits all populations, including those who are underserved and marginalized. With input from its Advisory Council, NIDDK has enhanced efforts to promote stakeholder engagement in recent years. For example, the APOL1 Long-term Kidney Transplantation Outcomes (APOLLO) Network, which is determining the impact of *APOL1* genetic variants on kidney transplant outcomes for both living African American donors and recipients, is pioneering the Institute's approach to participant engagement via its Community Advisory Council (CAC).[25] Composed of African American transplant recipients, kidney donors, and individuals on dialysis, the CAC provides input and guidance on study design, including recruitment, retention, implementation of protocols, and return of results. People with kidney diseases have also been instrumental in shaping the Kidney Precision Medicine Project, the Hemodialysis Opioid Prescription Effort (HOPE) Consortium, and a new program called Caring for OutPatiEnts after Acute Kidney Injury (COPE-AKI).[26] NIDDK is planning to support a new Stakeholder Engagement Innovation Center to provide research resources to educate investigators in partner- and community-engaged research and to develop a community of diverse, multidisciplinary researchers with expertise in critically needed methods to improve diabetes prevention and treatment interventions in populations with health disparities.[27]

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, NIDDK launched the Diabetic Foot Consortium in 2020 as the first-ever multicenter network to study diabetic foot ulcers, a common and burdensome complication of diabetes and the leading cause of lower limb amputations in the United States.[28] NIDDK also expanded and renewed the Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer to continue conducting key studies on chronic pancreatitis and factors that increase the risk of pancreatic cancer in children and adults with chronic pancreatitis, pancreatogenic diabetes, and newly diagnosed diabetes.[29] Additionally, NIDDK recently began the Chronic Kidney Diseases of UnceRtain Etiology in Agricultural Communities Research Consortium to address the increase in the global burden of chronic kidney diseases of uncertain or non-traditional etiologies, particularly in agricultural communities; this research may also address health impacts potentially linked to climate change.[30] As we look to the future, NIDDK research will be guided by a new Strategic Plan, which complements the Institute's disease-specific planning efforts.[31] The Plan, with the overarching theme of "Multidisciplinary Researchers, Diverse Stakeholders, Pathways to Health for All," was developed with broad external input and will help to accelerate research into the causes, treatment, and prevention of diseases and conditions within NIDDK's mission.

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[25] theapollonetwork.org/info.cfm

[26] Tuttle KR, et al. Clin J Am Soc Nephrol 16: 660-668, 2021; heal.nih.gov/research/clinical-research/hemodialysis; grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-011.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-012.html

[27] www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/concept-clearances/ddemd-stakeholder-engagement-innovation-center

[28] diabeticfootconsortium.org/

[29] cpdpc.mdanderson.org/about-cpdpc.html

[30] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-017.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-018.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-019.html

[31] www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

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.

Recent NIDDK Research Highlights

- Type 2 diabetes medications made possible by NIDDK research provided cardiovascular health benefits in people with diabetes, and one of these drugs was also recently approved as a treatment for obesity.
- Recent studies have given important insights into how the liver repairs itself after injury, which could lead to new therapeutic strategies for liver diseases.
- Research has provided the foundation for the first approved treatment for primary hyperoxaluria type 1 (PH1), a serious disease that could lead to kidney failure.
- Scientists are developing 3D chips that replicate the function of human organs or tissues, such as the liver, kidney, and pancreatic islet, to speed progress toward new therapies.
- Researchers are analyzing characteristics of individual cells to provide unprecedented scientific insights into how cellular differences can play a role in diseases within NIDDK's mission.

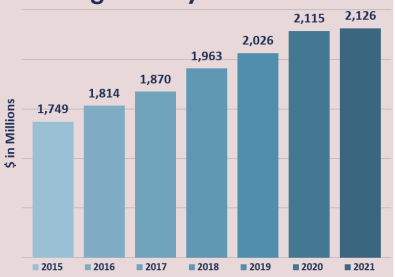
Introduction to NIDDK Research

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.

Facts and Figures

637: Number of Full-Time Equivalent Employees (4-year average, FYs 2018-2021)

Funding History*

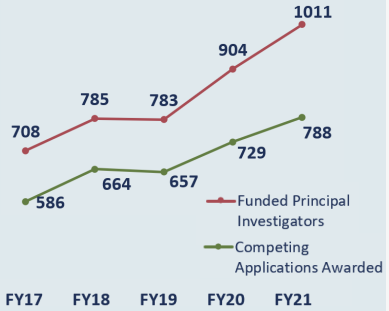


FY 2022 CR (in millions): $2,132

FY 2023 President's Budget Request (in millions): $2,206

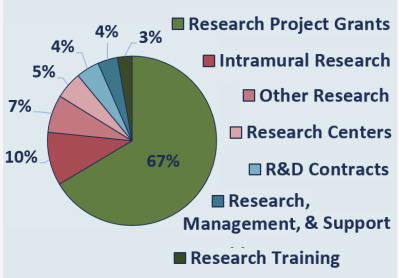
*excludes mandatory T1D funding

Research Project Grants*

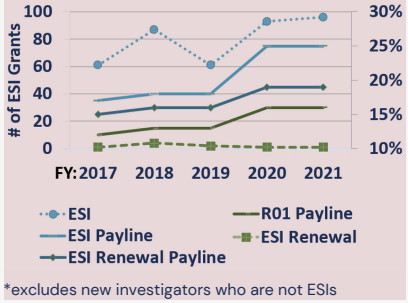


*excludes mandatory T1D funding

FY 2021 Mechanisms



Paylines and Early Stage Investigators (ESIs*)



*excludes new investigators who are not ESIs

Selected Current Activities

- The Glycemic Observation and Metabolic Outcomes in Mothers and Offspring study (GO MOMs) aims to improve gestational diabetes screening and diagnosis by better understanding blood glucose levels throughout pregnancy.
- The Accelerating Medicines Partnership (AMP®) Common Metabolic Diseases initiative is gaining knowledge about genes and pathways underlying metabolic diseases, which will help identify new therapeutic targets.
- The Liver Cirrhosis Network is conducting research on cirrhosis resulting from chronic liver diseases such as alcoholic steatohepatitis, a major risk factor for liver cancer.
- The Hemodialysis Opioid Prescription Effort (HOPE) Consortium supports research on interventions to reduce opioid use in people on hemodialysis in response to the public health crisis of chronic pain and related opioid overuse.
- NIDDK supports efforts to address health disparities and scientific workforce diversity, such as the Program to Advance the Career Development of Scientists from Diverse Backgrounds Conducting Nutrition, Obesity, Diabetes, and Related Research.

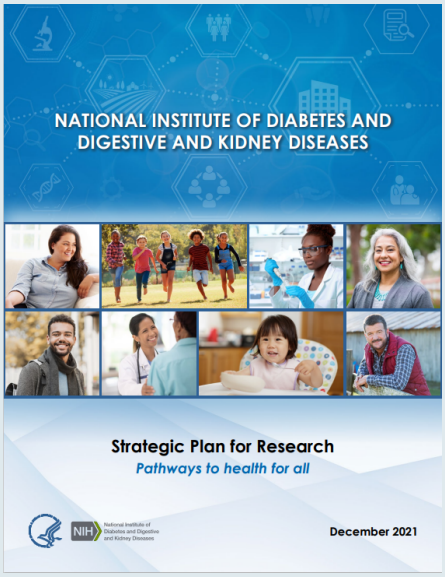
NIDDK Recent Advances and Emerging Opportunities is an annual compendium that highlights examples of the many research advances published by NIDDK-funded scientists and their colleagues, along with personal stories of people who have given time and effort to participate in NIDDK-sponsored clinical research.

Selected Recent Accomplishments

- Researchers found that SARS-CoV-2 infection directly causes changes in beta cells that could affect the course or onset of diabetes, helping to understand the devastating relationship between COVID-19 and chronic disease.
- Recent studies explored the impacts of foods designed to shape the gut microbial landscape in children with malnutrition and in adults with obesity, showing the promise of this approach for helping to address these disparate public health challenges.
- New research has shed light on how known genetic risk factors can contribute to Crohn's disease and treatment response, opening the door to new treatment approaches.
- A new study has revealed a potential blood-based biomarker of human kidney function and disease.
- Researchers have demonstrated the efficacy of a new, more easily implemented, and more natural approach to studying bladder function in people.

Selected Future Research Initiatives

- A new Stakeholder Engagement Innovation Center will help to develop a community of diverse, multidisciplinary researchers to improve diabetes prevention and treatment interventions in populations with health disparities.
- A new initiative will stimulate innovative research to better understand the underlying causes of obesity during infancy and early childhood.
- Building upon discoveries that identified over 250 regions of the genome that are linked to inflammatory bowel disease (IBD), a new initiative will use an animal model to identify specific genes that play a role in IBD.
- Building upon its successes, the Kidney Precision Medicine Project will be expanded, including increasing the number and diversity of study participants and enhancing the depth of clinical and molecular analyses.



Released in December 2021, *NIDDK Strategic Plan for Research: Pathways to Health for All* presents a broad vision for the future of the Institute, complementing and informing NIDDK's disease-specific planning efforts.

Major Changes in the Fiscal Year 2023 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 2023 President's Budget. The FY 2023 President's Budget request for NIDDK, excluding the proposed $141.5 million of mandatory funding for Type 1 Diabetes, is $2,206.1 million, an increase of $74.1 million from the FY 2022 CR level. The FY 2023 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) (+$65.2 million; total $1,479.6 million): NIDDK will increase funding for non-competing RPGs by $79.1 million, including funding individual non-competing awards at their full commitment level. Funding for competing RPGs is expected to decrease by $16.5 million, or 4.9 percent, relative to the FY 2022 CR level, resulting in 63 fewer grants compared to the FY 2022 CR level of 724 awards. These changes in funding are distributed across all programmatic areas and basic, translational or clinical research.

Research Centers (-$0.1 million; total $110.0 million): NIDDK will decrease funding for Research Centers by 0.05 percent compared to the FY 2022 CR level. These decreases are distributed across all programmatic areas and basic, translational or clinical research.

Other Research (-$0.6 million; total $151.2 million): NIDDK will decrease funding for Other Research by 0.4 percent compared to the FY 2022 CR level. These decreases are distributed across all programmatic areas and basic, translational or clinical research.

R&D Contracts (+$1.0 million; total $97.0 million): NIDDK will increase funding for R&D Contracts by 1.0 percent compared to the FY 2022 CR level. These increases are distributed across all programmatic areas and basic, translational or clinical research.

Intramural Research (+$5.5 million; total $223.8 million): NIDDK will increase funding for Intramural Research by 2.5 percent compared to the FY 2022 CR level. These increases will cover pay raises for intramural researchers and other inflationary costs, and are distributed across all programmatic areas and basic, translational or clinical research.

Research Management and Support (+$2.1 million; total $84.1 million): NIDDK will increase funding for Research, Management, and Support by 2.5 percent compared to the FY 2022 CR level. These increases will cover pay raises for RMS staff and other inflationary costs, and 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

Budget Mechanism *

(Dollars in Thousands)

Mechanism	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Projects:								
Noncompeting	1,947	$968,118	2,011	$999,801	2,128	$1,078,909	117	$79,108
Administrative Supplements	*(93)*	$11,725	*(87)*	$11,000	*(90)*	$11,200	3	$200
Competing:								
Renewal	166	$74,484	145	$65,650	142	$63,258	-3	-$2,392
New	621	$291,583	578	$271,515	518	$257,383	-60	-$14,132
Supplements	1	$223	1	$200	1	$250	0	$50
Subtotal, Competing	**788**	**$366,290**	**724**	**$337,365**	**661**	**$320,891**	**-63**	**-$16,474**
Subtotal, RPGs	2,735	$1,346,134	2,735	$1,348,166	2,789	$1,411,000	54	$62,834
SBIR/STTR	109	$66,311	108	$66,250	113	$68,569	5	$2,319
Research Project Grants	2,844	$1,412,445	2,843	$1,414,416	2,902	$1,479,569	59	$65,153
Research Centers								
Specialized/Comprehensive	89	$109,807	90	$110,000	90	$109,950	0	-$50
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	$50	0	$0
Research Centers in Minority Institutions	0	$0	0	$0	0	$0	0	$0
Research Centers	**89**	**$109,857**	**90**	**$110,050**	**90**	**$110,000**	**0**	**-$50**
Other Research:								
Research Careers	463	$87,037	460	$87,100	459	$87,000	-1	-$100
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	$532	0	$532	0	$532	0	$0
Other	112	$65,212	114	$64,212	113	$63,678	-1	-$534
Other Research	**575**	**$152,781**	**574**	**$151,844**	**572**	**$151,210**	**-2**	**-$634**
Total Research Grants	3,508	$1,675,083	3,507	$1,676,310	3,564	$1,740,779	57	$64,469
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	309	$15,115	308	$15,268	304	$15,558	-4	$290
Institutional Awards	742	$43,654	738	$44,000	735	$44,836	-3	$836
Total Research Training	**1,051**	**$58,769**	**1,046**	**$59,268**	**1,039**	**$60,394**	**-7**	**$1,126**
Research & Develop. Contracts	124	$94,420	126	$96,000	128	$97,000	2	$1,000
SBIR/STTR (non-add)	*(2)*	*($749)*	*(2)*	*($750)*	*(2)*	*($750)*	*(0)*	*($0)*
Intramural Research	368	$216,339	380	$218,329	388	$223,787	8	$5,458
Res. Management & Support	298	$80,919	311	$82,068	318	$84,120	7	$2,052
SBIR Admin. (non-add)	*(0)*	*($0)*	*(0)*	*($0)*	*(0)*	*($5)*	*(0)*	*($5)*
Total, NIDDK	**666**	**$2,125,530**	**691**	**$2,131,975**	**706**	**$2,206,080**	**15**	**$74,105**

* All items in italics and brackets are non-add entries.

NATIONAL INSTITUTES OF HEALTH

Type 1 Diabetes

Budget Mechanism [*, 1]

(Dollars in Thousands)

Mechanism	FY 2021 Final[2]		FY 2022 CR[3]		FY 2023 President's Budget[3]		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Projects:								
Noncompeting	131	$112,134	100	$83,287	88	$73,287	-12	-$10,000
Administrative Supplements	*(3)*	$587	*(4)*	$3,500	*(5)*	$5,000	1	$1,500
Competing:								
Renewal	1	$9,884	0	$0	0	$0	0	$0
New	6	$904	25	$32,000	31	$40,000	6	$8,000
Supplements	0	$0	0	$0	0	$0	0	$0
Subtotal, Competing	**7**	**$10,788**	**25**	**$32,000**	**31**	**$40,000**	**6**	**$8,000**
Subtotal, RPGs	138	$123,508	125	$118,787	119	$118,287	-6	-$500
SBIR/STTR	16	$5,492	14	$5,163	14	$5,163	0	$0
Research Project Grants	154	$129,000	139	$123,950	133	$123,450	-6	-$500
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	5	$10,000	5	$10,000	0	$0
Cancer Education	0	$0	0	$0	0	$0	0	$0
Cooperative Clinical Research	0	$6,000	0	$0	0	$0	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	5	$15,000	5	$7,500	6	$8,000	1	$500
Other Research	**5**	**$21,000**	**10**	**$17,500**	**11**	**$18,000**	**1**	**$500**
Total Research Grants	159	$150,000	149	$141,450	144	$141,450	-5	$0
Total, T1D	**0**	**$150,000**	**0**	**$141,450**	**0**	**$141,450**	**0**	**$0**

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

[1] Figures reflect budget authority provided in each year. A portion of this budget authority will be carried over and obligated in later years.

[2] Includes mandatory Type 1 Diabetes funding not obligated in FY 2021 and carried over into FY 2022.

[3] FY 2022 and FY 2023 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 disease, $2,206,080,000.

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

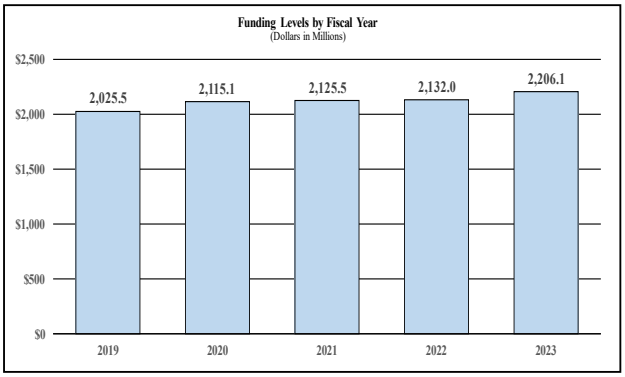
Summary of Changes
(Dollars in Thousands)

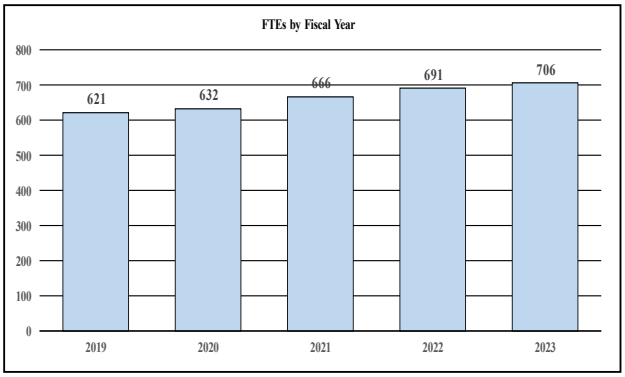
FY 2022 CR	$2,131,975
FY 2023 President's Budget	$2,206,080
Net change	$74,105

CHANGES	FY 2022 CR FTEs	FY 2022 CR Budget Authority	FY 2023 President's Budget FTEs	FY 2023 President's Budget Budget Authority	Built-In Change from FY 2022 CR FTEs	Built-In Change from FY 2022 CR Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2022 pay increase & benefits		$90,437		$95,775		$1,018
b. January FY 2023 pay increase & benefits		$90,437		$95,775		$3,055
c. Paid days adjustment		$90,437		$95,775		-$317
d. Differences attributable to change in FTE		$90,437		$95,775		$1,582
e. Payment for centrally furnished services		$38,857		$39,634		$777
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$89,035		$88,378		$1,833
Subtotal						$7,948
2. Research Management and Support:						
a. Annualization of January 2022 pay increase & benefits		$55,029		$58,726		$710
b. January FY 2023 pay increase & benefits		$55,029		$58,726		$2,129
c. Paid days adjustment		$55,029		$58,726		-$225
d. Differences attributable to change in FTE		$55,029		$58,726		$1,083
e. Payment for centrally furnished services		$1,439		$1,467		$28
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$25,600		$23,927		$983
Subtotal						$4,708
Subtotal, Built-in						$12,656

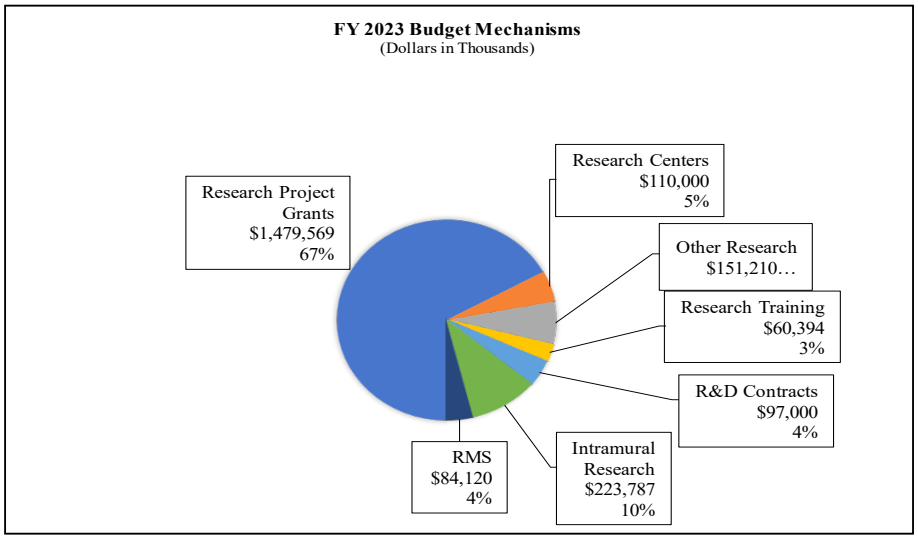
CHANGES	FY 2022 CR No.	FY 2022 CR Amount	FY 2023 President's Budget No.	FY 2023 President's Budget Amount	Program Change from FY 2022 CR No.	Program Change from FY 2022 CR Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	2,011	$1,010,801	2,128	$1,090,109	117	$79,308
b. Competing	724	$337,365	661	$320,891	-63	-$16,474
c. SBIR/STTR	108	$66,250	113	$68,569	5	$2,319
Subtotal, RPGs	2,843	$1,414,416	2,902	$1,479,569	59	$65,153
2. Research Centers	90	$110,050	90	$110,000	0	-$50
3. Other Research	574	$151,844	572	$151,210	-2	-$634
4. Research Training	1,046	$59,268	1,039	$60,394	-7	$1,126
5. Research and development contracts	126	$96,000	128	$97,000	2	$1,000
Subtotal, Extramural		$1,831,578		$1,898,173		$66,595
6. Intramural Research	380	$218,329	388	$223,787	8	-$2,490
7. Research Management and Support	311	$82,068	318	$84,120	7	-$2,656
8. Construction		$0		$0		$0
9. Buildings and Facilities		$0		$0		$0
Subtotal, Program	691	$2,131,975	706	$2,206,080	15	$61,449
Total built-in and program changes						$74,105

History of Budget Authority and FTEs:

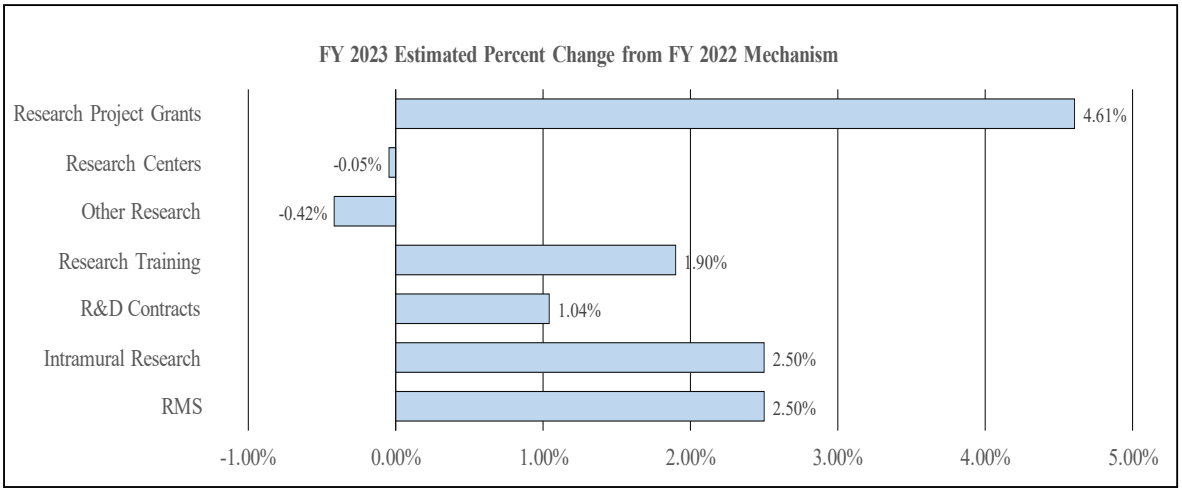




Distribution by Mechanism:



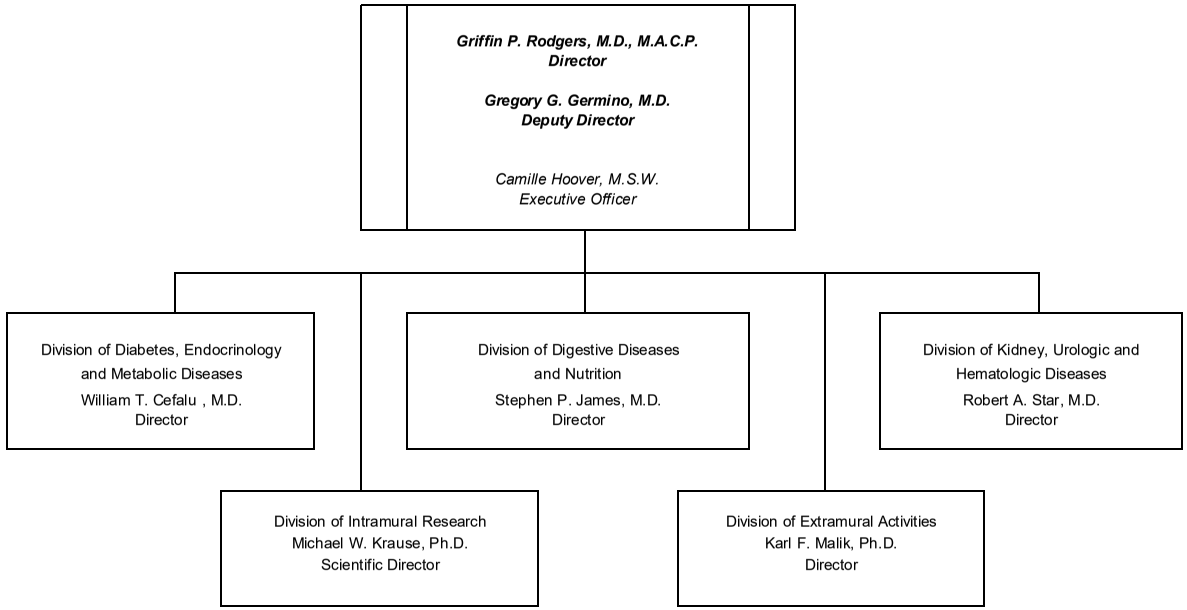
Change by Selected Mechanisms:



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 *
(Dollars in Thousands)

	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022 CR	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Diabetes, Endocrinology, and Metabolic Diseases		$662,772		$663,970		$688,112		$24,142
Digestive Diseases and Nutrition		$647,062		$648,232		$671,801		$23,569
Kidney, Urologic, and Hematologic Diseases		$518,439		$519,376		$538,260		$18,884
(Type 1 Diabetes (mandatory funding)) [1]		*($150,000)*		*($141,450)*		*($141,450)*		*($0)*
Subtotal, Extramural		**$1,828,272**		**$1,831,578**		**$1,898,173**		**$66,595**
Intramural Research	**368**	**$216,339**	**380**	**$218,329**	**388**	**$223,787**	**8**	**$5,458**
Research Management & Support	**298**	**$80,919**	**311**	**$82,068**	**318**	**$84,120**	**7**	**$2,052**
TOTAL	**666**	**$2,125,530**	**691**	**$2,131,975**	**706**	**$2,206,080**	**15**	**$74,105**

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

[1] Type 1 Diabetes FY 2022 and FY 2023 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 2021 Final	FY 2022 Continuing Resolution	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	$2,275,530,000	$2,273,425,000	$2,347,530,000	$74,105,000
Type 1 Diabetes Mandatory:[32]	-$150,000,000	-$141,450,000	-$141,450,000	$0
Labor/HHS	$2,125,530,000	$2,131,975,000	$2,206,080,000	$74,105,000
FTE	666	691	706	15

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

Overall Budget Policy: The FY 2023 President's Budget request is $2,206.1 million, excluding mandatory Type 1 Diabetes funding, an increase of $74.1 million or 3.5 percent compared with the FY 2022 CR level. This increase includes $20.0 million targeted to enhance pain research across the NIDDK portfolio, as part of an NIH-wide initiative to increase research into opioids and pain management. Other NIDDK increases are distributed across all programmatic areas and basic, epidemiologic, clinical, or translational research.

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.

[32] Type 1 Diabetes FY 2022 and FY 2023 amounts reflect budget authority of $150,000,000 reduced by $8,550,000 for Budget Control Act sequestration.

In FY 2023, 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 research revealing how diabetic foot ulcers may "stall" in their healing due to a blunted immune response at the wound.[33] State-of-the-art genetics studies have provided important new knowledge about the complex genetic landscape of both type 1 and type 2 diabetes.[34] Insights gained from these and other studies may open new avenues to preventing or treating diabetes and its complications. In other research, scientists discovered that, in response to exercise, mouse placentas produced high levels of a protein called superoxide dismutase 3 that was critical for conferring metabolic health benefits to offspring.[35] These findings may inform future strategies to prevent risk for metabolic diseases, like obesity and type 2 diabetes, from being passed from mothers to their children.

Glycemic Observation and Metabolic Outcomes in Mothers and Offspring Study

Gestational diabetes (GDM) is a form of diabetes that develops during pregnancy, but usually resolves after pregnancy. GDM is known to confer short- and long-term health risks to mothers and children, including high birth weight babies and delivery complications. However, GDM is usually diagnosed between the 24th and 28th week of pregnancy, which may be too late to counteract some long-lasting harm to the mother and child. NIDDK established the Glycemic Observation and Metabolic Outcomes in Mothers and Offspring study, or GO MOMs, to improve gestational diabetes screening and diagnosis by better understanding blood glucose levels throughout pregnancy.[1] The study aims to enroll about 2,150 women without diabetes in their first trimester of pregnancy, and is using continuous glucose monitoring technology to map blood glucose levels throughout pregnancy. GO MOMs builds on a previous NIH-funded landmark study of hyperglycemia and adverse pregnancy outcomes and its follow-up, which found that women with elevated blood glucose during pregnancy—even if not high enough to meet the definition of GDM—are significantly more likely to develop type 2 diabetes or prediabetes years after pregnancy than their counterparts without elevated blood glucose.[2] The research also demonstrated that children born to women with elevated blood glucose during pregnancy were more likely to have obesity and impaired glucose metabolism a decade later. The effects in children are thought to occur much earlier during pregnancy than when GDM is currently screened. Thus, GO MOMs will build on these key findings by providing critical information to determine the timing and approach for future clinical trials to understand when and how to screen for and treat elevated blood glucose in pregnancy, and if this treatment will have any effect on children years later. This research is expected to set the stage for healthier generations to come.

[1] www.gomomsstudy.org/
[2] www.hapo.northwestern.edu/index.html

With FY 2023 resources, NIDDK will continue major clinical and translational research studies in diabetes, endocrinology, and metabolic diseases. In a landmark study based on 30 years of following participants in NIDDK's Diabetes Control and Complications Trial and its follow up, the Epidemiology of Diabetes Interventions and Complications study, researchers discovered that blood glucose control and blood pressure management were associated with improved cognitive function in people with type 1 diabetes as they age, informing strategies to preserve cognitive function over the lifespan.[36] Another study suggested the need for a better test to identify future type 2 diabetes risk in people over age 70, so that proven prevention strategies could be targeted to those who would benefit from them.[37] On the opposite end of the age spectrum, results from the Treatment Options for Type 2 Diabetes in Adolescents and Youth

[33] Sawaya AP, et al. Nat Commun 11: 4678, 2020.
[34] Robertson CC, et al. Nat Genet 53: 962-971, 2021; Chen J, et al. Nat Genet 53: 840-860, 2021.
[35] Kusuyama J, et al. Cell Metab 33: 939-956.e8, 2021.
[36] Jacobson AM, et al. Lancet Diabetes Endocrinol 9: 436-445, 2021.
[37] Rooney MR, et al. JAMA Intern Med 181: 511-519, 2021.

(TODAY) follow-up study showed that people with type 2 diabetes diagnosed during youth have a high risk of developing complications at early ages and have a greater chance of multiple complications within 15 years after diagnosis; complications were also more common among participants of racial and ethnic minority groups.[38] Other clinical research found that continuing treatment for teenagers with type 2 diabetes helped to keep the disease from getting worse, but the treatment must be continued.[39] Together, these results underscore the importance of continuing research toward preventing and treating youth-onset type 2 diabetes.

Budget Policy: The FY 2023 President's Budget request for this program is $688.1 million, an increase of $24.1 million or 3.6 percent compared with the FY 2022 CR level. With FY 2023 resources, NIDDK will continue major diabetes clinical trials. NIDDK will also continue pilot and feasibility studies to foster innovative strategies to address barriers for use of diabetes self-management education and support; continue the Rare and Atypical Diabetes Network that could yield insight not only into rare forms of diabetes, but also into the heterogeneity of type 2 diabetes; and support new research on type 2 diabetes and youth that could inform novel prevention and treatment approaches.[40] In FY 2023, 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-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, 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 2023, NIDDK will continue to support research aimed at improving the prevention and treatment of diseases associated with the digestive system. For example, NIDDK-supported researchers have solved the mystery of how variants in the *NOD2* gene contribute to intestinal inflammation in Crohn's disease, finding an important role for a protein called gp130 and thus offering new possible therapeutic approaches to treat this disease.[41] A study of signals passed between intestinal cells during rotavirus infection has uncovered a potential therapeutic target for this common cause of diarrhea, dehydration, and death in children around the world.[42] Two other recent studies explored the impacts of foods designed to shape the gut microbial landscape

[38] TODAY Study Group; Bjornstad P, et al. N Engl J Med 385: 416-426, 2021.
[39] Hannon TS, et al. Pediatr Diabetes 21: 1437-1446, 2020.
[40] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-032.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-21-002.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-21-003.html; https://www.atypicaldiabetesnetwork.org/
[41] Nayar S, et al. Nature 593: 275-281, 2021.
[42] Chang-Graham AL, et al. Science 370: eabc3621, 2020.

in children with malnutrition and in adults with obesity.[43] This research demonstrated the promise of this approach for helping to address these disparate public health challenges.

Related to research on liver diseases, scientists are testing the use of a protective coating called a lipid nanoparticle (LNP) to deliver treatments for multiple forms of liver disease, including liver fibrosis, nonalcoholic fatty liver disease, and drug-induced liver injury. For example, a study in mice showcased the ability of LNP-encapsulated messenger RNA (mRNA) to deliver controlled bursts of growth factors to safely boost liver regeneration.[44] Other research related to liver regeneration in mice has identified which cells of the liver contribute in large part toward maintaining the organ or regenerating it after injury.[45] These findings serve as a foundation to inform new therapeutic strategies for liver diseases. In research on obesity, a small, short-term clinical trial in women with overweight or obesity, who were also post-menopause and had prediabetes, found that dietary supplementation with nicotinamide mononucleotide improved insulin sensitivity in muscle; additional research could help to determine if this nutritional supplement is therapeutically valuable for this or other populations.[46] A large-scale study identified genes that increase risk of obesity while protecting against disease, results that help to clarify the complex genetic underpinnings of obesity and may represent new therapeutic targets to reduce cardiometabolic risk associated with excess body fat.[47] Advances such as these will pave the way for improvements in the prevention, diagnosis, and treatment of digestive diseases in FY 2023 and beyond.

Inflammatory Bowel Disease Genetics Consortium

Inflammatory bowel disease (IBD) is the collective term for a group of debilitating digestive disorders, including Crohn's disease and ulcerative colitis, characterized by chronic inflammation in the gastrointestinal tract. IBD affects millions of people in the United States. Not only can the disease be very painful, but it is also usually accompanied by diarrhea, bleeding, and loss of appetite. Despite the high burden of IBD, it has been extremely difficult to pinpoint the precise causes of the inflammation, although it appears to result from complicated interactions between multiple genetic and environmental factors. NIDDK's IBD Genetics Consortium (IBDGC) was established in 2002 to identify genes that are involved in IBD susceptibility.[1] In collaboration with the International IBD Genetics Consortium, the IBDGC has identified over 250 regions of the human genome that are associated with risk of IBD. The IBDGC and its collaborators have also illuminated profound differences in the genetic architecture of IBD among people of different ancestries, such as a finding that the genetic risk landscape for IBD in African Americans is very different from that of people with European ancestry.[2] These and other results have provided important new insights into the nature of the disease, and have also informed classification of IBD clinical subtypes. However, many of the specific genes involved in IBD, along with their respective genetic variants that contribute to IBD susceptibility, have yet to be identified. To continue these critical investigations, NIDDK plans to renew the Consortium in 2022. Goals of the next phase include continuing to identify genetic risk regions, particularly in populations currently underrepresented in IBD genomic studies; identify specific genes and genetic variants involved in IBD susceptibility; and elucidate the biological mechanisms by which genetic variants influence disease. The overall goal remains the same—to improve people's health and quality of life by enhancing the ability to detect and treat IBD.

[1] ibdgc.uchicago.edu/
[2] Somineni, et al. Am J Hum Genet 108: 431-445, 2021.

[43] Chen RY, et al. N Engl J Med 384: 1517-1528, 2021; Delannoy-Bruno O, et al. Nature 595: 91-95, 2021.
[44] Rizvi F, et al. Nat Commun 12: 613, 2021.
[45] Wei Y, et al. Science 371: eabb1625, 2021.
[46] Yoshino M, et al. Science 372: 1224-1229, 2021.
[47] Huang LO, et al. Nat Metab 3: 228-243, 2021.

Budget Policy: The FY 2023 President's Budget request for this program is $671.8 million, an increase of $23.6 million or 3.6 percent compared with the FY 2022 CR level. In FY 2023, NIDDK will continue major clinical research networks to help understand and treat liver diseases, including a new Liver Cirrhosis Network conducting research on cirrhosis resulting from various forms of chronic liver disease.[48] Among its obesity-related efforts in FY 2023, NIDDK will continue to support the Physiology Of the WEight-Reduced State (POWERS) clinical trial consortium, which seeks to characterize the physiological mechanisms underlying individual variability in maintenance of reduced weight over time, as preventing regain of lost weight is a difficult challenge in the treatment of obesity. NIDDK will also use FY 2023 funds to continue the IBD Genetics Consortium to shed light on the underlying causes of IBD. 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 2023, along with other efforts, such as support for centers focused on digestive diseases research, 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.

[48] grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-003.html, grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-004.html

Symptoms of Lower Urinary Tract Dysfunction Research Network

Lower urinary tract symptoms (LUTS) are common in both men and women, and the incidence and prevalence increase as people age. People with LUTS face a number of social, mental, and physical health effects as a result of their symptoms, and treatments for LUTS are not very effective, have significant side-effects, and are costly. To address the gaps in understanding and treating LUTS, NIDDK established the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) in 2012.[1] LURN is an interdisciplinary, cooperative research network with several long-term goals: to identify and explain the important subtypes of LUTS in women and men; to improve the measurement of patient experiences of LUTS; to disseminate novel findings to researchers, clinicians, and patients; and to generate data, research tools, and biological samples for future studies. To help attain these intertwined goals, LURN enrolled nearly 2,000 women and men from among individuals presenting with LUTS to a health care provider at a LURN research site. Working with these participants, LURN collected clinical data, health-related quality of life assessments, and self-reported symptom measurements at baseline, and characterized these and changes in LUTS over a 12-month period, yielding a wealth of data and enabling numerous informative studies. For example, a critical goal for LURN has been to develop improved means for finding clinically important subtypes among people with LUTS. Their approach was to pursue an intensive questionnaire development process, which culminated in a comprehensive urinary symptom questionnaire for in-depth studies as well as two shorter ones for research and clinical use, respectively. Much remains to be learned about LUTS—their causes, development, and how best to manage and treat people with these symptoms. For example, "LURN II" is currently working on measure(s) to evaluate the effects of therapeutic interventions in people with LUTS. Because of LURN and other NIDDK-supported programs, more comprehensive subgrouping of people with LUTS is now possible, with important implications for future trial design and clinical management.

[1]nih-lurn.org

In FY 2023, NIDDK will continue to support research aimed at improving the treatment and prevention of kidney, urologic, and hematologic diseases. For example, long-term NIDDK-supported research provided the foundation for the first U.S. Food and Drug Administration (FDA)-approved treatment for primary hyperoxaluria type 1 (PH1)—a rare and serious genetic disease that primarily affects the kidneys and that could lead to kidney failure.[49] Other research related to PH1 suggests that kidney failure may be reversible in some people with the disease, challenging the conventional belief that kidney failure in PH1 is always irreversible and paving the way for further investigation.[50] In other recent research, Kidney Precision Medicine Project scientists developed a robust research pipeline for rigorous and reproducible analysis of human kidney biopsies—a foundation for future research toward personalized care for people with kidney diseases.[51] In another study, scientists leveraged advanced protein profiling techniques, existing clinical cohorts, and cellular studies to identify a potential new blood-based biomarker of human kidney function and disease prognosis, called testican-2.[52] These findings could inform future research, such as developing targeted blood tests for testican-2 and conducting studies of its association with kidney disease outcomes. Future research could also build on results showing that the protein KIM-1 plays a key role in progression of diabetic kidney disease and may serve as a promising target for small-drug therapy.[53]

Research has also shed new light on why hematopoietic (blood) stem cells' (HSCs) capacity to develop into different types of blood and immune cells diminishes as people age. Researchers discovered that aging of HSCs in mouse bone marrow may be linked to low levels of the

[49] www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-rare-metabolic-disorder
[50] Lorenz EC, et al. Am J Kidney Dis 77: 816-819, 2021.
[51] El-Achkar TM, et al. Physiol Genomics 53: 1-11, 2021.
[52] Ngo D, et al. Proc Natl Acad Sci U S A 117: 25026-25035, 2020.
[53] Mori Y, et al. Cell Metab 33:1042-1061.e7, 2021.

hormone insulin-like growth factor 1, suggesting that therapeutic strategies aimed at increasing levels of this hormone may halt HSC aging toward preserving health.[54] A new study in healthy people conducted by researchers in the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network showed that a more easily implemented and more natural approach to bladder filling can form the basis for future studies of the neurobiological contributions of urologic conditions, such as bladder pain or sudden urinary urgency.[55] Such robust research in the kidney, urologic, and hematologic diseases will continue in FY 2023.

Budget Policy: The FY 2023 President's Budget request for this program is $538.3 million, an increase of $18.9 million or 3.6 percent compared with the FY 2022 CR level. In FY 2023, NIDDK plans to continue supporting new research programs related to kidney diseases, such as the Chronic Kidney Diseases of UnceRtain Etiology in Agricultural Communities Research Consortium described above.[56] Another new program, COPE-AKI, is developing and testing interventions that aim to improve clinical outcomes among people surviving an episode of acute kidney injury.[57] NIDDK also plans to continue its Kidney Precision Medicine Project, which is analyzing kidney biopsies from a broad range of people using cutting-edge technologies to understand kidney diseases and injury, identify new therapeutic targets, and stimulate development of personalized therapies. NIDDK also plans to continue its support of research networks focused on enhancing understanding of glomerular diseases, urologic chronic pelvic pain syndrome, and lower urinary tract symptoms. Centers focused on kidney, urologic, and hematologic research will receive continued funding in FY 2023, 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 Diseases 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, other autoimmune disorders, and other diseases. For example, people with type 2 diabetes could benefit from research developing novel artificial pancreas technologies and other diabetes management technologies. In a study with even broader applicability, researchers contributed important new knowledge related to the link between SARS-CoV-2 infection and diabetes.[58]

[54] Young K, et al. Cell Stem Cell 28: 1473-1482.e7, 2021.
[55] Mawla I, et al. Sci Rep 10: 19901, 2020.
[56] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-017.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-018.html; grants.nih.gov/grants/guide/rfa-files/RFA-DK-20-019.html
[57] grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-011.html; grants.nih.gov/grants/guide/rfa-files/rfa-dk-20-012.html
[58] Tang X, et al. Cell Metab 33: 1577-1591.e7, 2021.

Recent efforts supported by the SDP are greatly expanding our understanding of autoimmunity in type 1 diabetes. For example, clinical research is showing that people with type 1 diabetes may benefit from therapies that interfere with autoimmunity: follow-up data from a clinical trial found that treatment with an anti-CD3 monoclonal antibody (teplizumab) that targets the immune system slowed the progression to clinical type 1 diabetes by 3 or more years in high-risk individuals.[59] Other clinical trial results showed that a next-generation artificial pancreas device outperformed a commercially available device in helping adolescents and young adults with type 1 diabetes keep their blood glucose levels in a healthy range.[60] Developing new and improved diabetes management technologies could help people improve their blood glucose management over time, which, as shown by other NIDDK-supported research advances, will result in reduced risk of disease complications. Future plans include the support of research to identify mechanisms that promote earlier development of cardiovascular disease in people with type 1 diabetes compared to individuals without diabetes, which could shed light on the development of interventions to prevent and treat cardiovascular disease in this population.[61] To promote health equity, NIDDK plans to support pilot and feasibility trials of interventions designed to improve technology adoption in individuals from underrepresented backgrounds with type 1 diabetes.[62] NIDDK also plans to continue a program to ensure that a robust pipeline of talented new investigators continue to embark on successful careers in type 1 diabetes research.[63]

Budget Policy: The FY 2023 President's Budget request for the Special Statutory Funding Program for Type 1 Diabetes Research proposes to fund this program at $141.5 million in FY 2023. A reduction of $8.5 million is applied to the program due to the mandatory Budget Control Act sequestration in FY 2023.

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 researchers studying beta cells in a mouse model found that the protein beta-arrestin-1 is involved in increasing beta cell numbers during obesity—results that have implications for future efforts to treat or prevent diabetes.[64] Also related to obesity, IRP researchers compared a plant-based, low-fat diet to an animal-based, low-carbohydrate diet, finding that while each diet had benefits in the short-term, the low-fat diet led to less caloric intake and a significant loss of body fat.[65] This study provides important new knowledge about competing models of obesity related to the roles of dietary fats and carbohydrates. Another study showed that animal models infected

[59] Sims EK, et al. Sci Transl Med 13: eabc8980, 2021.
[60] Bergenstal RM, et al. Lancet 397: 208-219, 2021.
[61] grants.nih.gov/grants/guide/rfa-files/RFA-HL-21-014.html
[62] grants.nih.gov/grants/guide/rfa-files/rfa-dk-21-018.html
[63] grants.nih.gov/grants/guide/rfa-files/RFA-DK-19-026.html
[64] Barella LF, et al. Nat Commun 12: 3385, 2021.
[65] Hall K, et al. Nat Med 27: 344-353, 2021.

with different hepatitis C viral subtypes, including a drug-resistant one, responded well to a combination treatment of a new drug (fluoxazolevir) with approved hepatitis C drugs—potentially representing the next generation of hepatitis C treatments.[66] In FY 2023, the Intramural Research Program will continue to advance research in these and other areas.

Budget Policy: The FY 2023 President's Budget request for this program is $223.8 million, an increase of $5.5 million or 2.5 percent compared with the FY 2022 CR 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.[67]

Budget Policy: The FY 2023 President's Budget request for this program is $84.1 million, an increase of $2.1 million or 2.5 percent compared with the FY 2022 CR level.

[66] Ma CD, et al. Nat Microbiol 5: 1532-1541, 2020.
[67] www.niddk.nih.gov/health-information

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Appropriations History

Fiscal Year	Budget Estimate to Congress [1]	House Allowance	Senate Allowance	Appropriation[1]
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	$2,238,625,000	$2,217,136,000	$2,273,425,000
Sequestration				(-$8,550,000)
2023	$2,347,530,000			

[1] Includes mandatory funding for Type 1 Diabetes

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2022 Amount Authorized	FY 2022 CR	2023 Amount Authorized	FY 2023 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,131,975,000	Indefinite	$2,206,080,000
National Institute of Diabetes and Digestive and Kidney Diseases	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,131,975,000		$2,206,080,000

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Amounts Available for Obligation [1]

(Dollars in Thousands)

Source of Funding	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation	$2,131,975	$2,131,975	$2,206,080
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*($150,000)*	*($150,000)*	*($150,000)*
Type 1 Diabetes Sequestration	*($0)*	*-($8,550)*	*-($8,550)*
Secretary's Transfer	-$6,401	$0	$0
Subtotal, adjusted appropriation	$2,125,574	$2,131,975	$2,206,080
OAR HIV/AIDS Transfers	-$44	$0	$0
Subtotal, adjusted budget authority	**$2,125,530**	**$2,131,975**	**$2,206,080**
Unobligated balance lapsing	-$160	$0	$0
Total obligations	$2,125,370	$2,131,975	$2,206,080

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2021 - $4,215 FY 2022 - $6,000 FY 2023 - $6,000

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

		FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Total compensable workyears:				
	Full-time equivalent	691	706	15
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	$204	$211	$8
	Average GM/GS grade	12.0	12.0	0.0
	Average GM/GS salary	$120	$125	$5
	Average salary, Commissioned Corps (42 U.S.C. 207)	$102	$106	$4
	Average salary of ungraded positions	$127	$131	$5
	OBJECT CLASSES	**FY 2022 CR**	**FY 2023 President's Budget**	**FY 2023 +/- FY 2022**
	Personnel Compensation			
11.1	Full-Time Permanent	$48,358	$51,177	$2,819
11.3	Other Than Full-Time Permanent	$42,312	$44,794	$2,482
11.5	Other Personnel Compensation	$4,227	$4,472	$245
11.7	Military Personnel	$732	$761	$29
11.8	Special Personnel Services Payments	$13,003	$13,003	$0
11.9	**Subtotal Personnel Compensation**	**$108,632**	**$114,207**	**$5,575**
12.1	Civilian Personnel Benefits	$36,366	$39,809	$3,443
12.2	Military Personnel Benefits	$468	$485	$17
13.0	Benefits to Former Personnel	$0	$0	$0
	Subtotal Pay Costs	**$145,466**	**$154,501**	**$9,035**
21.0	Travel & Transportation of Persons	$61	$150	$89
22.0	Transportation of Things	$212	$110	-$102
23.1	Rental Payments to GSA	$0	$0	$0
23.2	Rental Payments to Others	$0	$0	$0
23.3	Communications, Utilities & Misc. Charges	$336	$336	$0
24.0	Printing & Reproduction	$24	$24	$0
25.1	Consulting Services	$57,056	$57,781	$725
25.2	Other Services	$25,389	$20,460	-$4,928
25.3	Purchase of Goods and Services from Government Accounts	$145,211	$151,074	$5,863
25.4	Operation & Maintenance of Facilities	$375	$375	$0
25.5	R&D Contracts	$21,036	$19,408	-$1,628
25.6	Medical Care	$1,340	$1,340	$0
25.7	Operation & Maintenance of Equipment	$4,620	$4,585	-$35
25.8	Subsistence & Support of Persons	$0	$0	$0
25.0	**Subtotal Other Contractual Services**	**$255,027**	**$255,023**	**-$3**
26.0	Supplies & Materials	$13,057	$13,050	-$7
31.0	Equipment	$5,015	$4,712	-$303
32.0	Land and Structures	$699	$500	-$199
33.0	Investments & Loans	$0	$0	$0
41.0	Grants, Subsidies & Contributions	$1,712,078	$1,777,673	$65,595
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	**$1,986,509**	**$2,051,579**	**$65,070**
	Total Budget Authority by Object Class	**$2,131,975**	**$2,206,080**	**$74,105**

[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 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel Compensation			
Full-Time Permanent (11.1)	$48,358	$51,177	$2,819
Other Than Full-Time Permanent (11.3)	$42,312	$44,794	$2,482
Other Personnel Compensation (11.5)	$4,227	$4,472	$245
Military Personnel (11.7)	$732	$761	$29
Special Personnel Services Payments (11.8)	$13,003	$13,003	$0
Subtotal, Personnel Compensation (11.9)	**$108,632**	**$114,207**	**$5,575**
Civilian Personnel Benefits (12.1)	$36,366	$39,809	$3,443
Military Personnel Benefits (12.2)	$468	$485	$17
Benefits to Former Personnel (13.0)	$0	$0	$0
Subtotal Pay Costs	**$145,466**	**$154,501**	**$9,035**
Travel & Transportation of Persons (21.0)	$61	$150	$89
Transportation of Things (22.0)	$212	$110	-$102
Rental Payments to Others (23.2)	$0	$0	$0
Communications, Utilities & Misc. Charges (23.3)	$336	$336	$0
Printing & Reproduction (24.0)	$24	$24	$0
Other Contractual Services			
Consultant Services (25.1)	$55,012	$55,781	$769
Other Services (25.2)	$25,389	$20,460	-$4,928
Purchase of Goods and Services from Government Accounts (25.3)	$82,922	$88,422	$5,500
Operation & Maintenance of Facilities (25.4)	$375	$375	$0
Operation & Maintenance of Equipment (25.7)	$4,620	$4,585	-$35
Subsistence & Support of Persons (25.8)	$0	$0	$0
Subtotal Other Contractual Services	**$168,318**	**$169,623**	**$1,306**
Supplies & Materials (26.0)	$13,057	$13,050	-$7
Subtotal Non-Pay Costs	**$182,008**	**$183,293**	**$1,286**
Total Administrative Costs	**$327,474**	**$337,794**	**$10,321**

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Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2021 Final			FY 2022 CR			FY 2023 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Activities									
Direct:	65	1	66	67	1	68	69	1	70
Total:	65	1	66	67	1	68	69	1	70
Office of the Director									
Direct:	145	1	146	147	1	148	149	1	150
Total:	145	1	146	147	1	148	149	1	150
Division of Diabetes, Endocrinology, and Metabolic Diseases									
Direct:	29	-	29	32	-	32	33	-	33
Reimbursable:	3	-	3	3	-	3	3	-	3
Total:	32	-	32	35	-	35	36	-	36
Division of Digestive Diseases and Nutrition									
Direct:	26	1	27	29	1	30	30	1	31
Total:	26	1	27	29	1	30	30	1	31
Division of Kidney, Urologic, and Hematologic Diseases									
Direct:	27	-	27	30	-	30	31	-	31
Total:	27	-	27	30	-	30	31	-	31
Division of Intramural Research Programs									
Direct:	363	5	368	375	5	380	383	5	388
Total:	363	5	368	375	5	380	383	5	388
Total	658	8	666	683	8	691	698	8	706

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

FISCAL YEAR	Average GS Grade
2019	12.0
2020	12.0
2021	12.0
2022	12.0
2023	12.0

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Detail of Positions[1]

GRADE	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	$199,300	$203,834	$211,461
General Schedule			
GM/GS-15	68	68	69
GM/GS-14	72	72	74
GM/GS-13	114	114	116
GS-12	65	67	70
GS-11	38	40	42
GS-10	0	0	0
GS-9	26	27	27
GS-8	10	13	13
GS-7	18	22	22
GS-6	3	4	4
GS-5	1	2	2
GS-4	1	2	2
GS-3	0	1	1
GS-2	1	1	1
GS-1	0	0	0
Subtotal	417	433	443
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	2	2	2
Senior Grade	3	3	3
Full Grade	1	1	1
Senior Assistant Grade	1	1	1
Assistant Grade	1	1	1
Subtotal	8	8	8
Ungraded	265	275	281
Total permanent positions	422	438	448
Total positions, end of year	691	717	733
Total full-time equivalent (FTE) employment, end of year	666	691	706
Average ES salary	$199,300	$203,834	$211,461
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	$117,718	$120,396	$124,901

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