

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

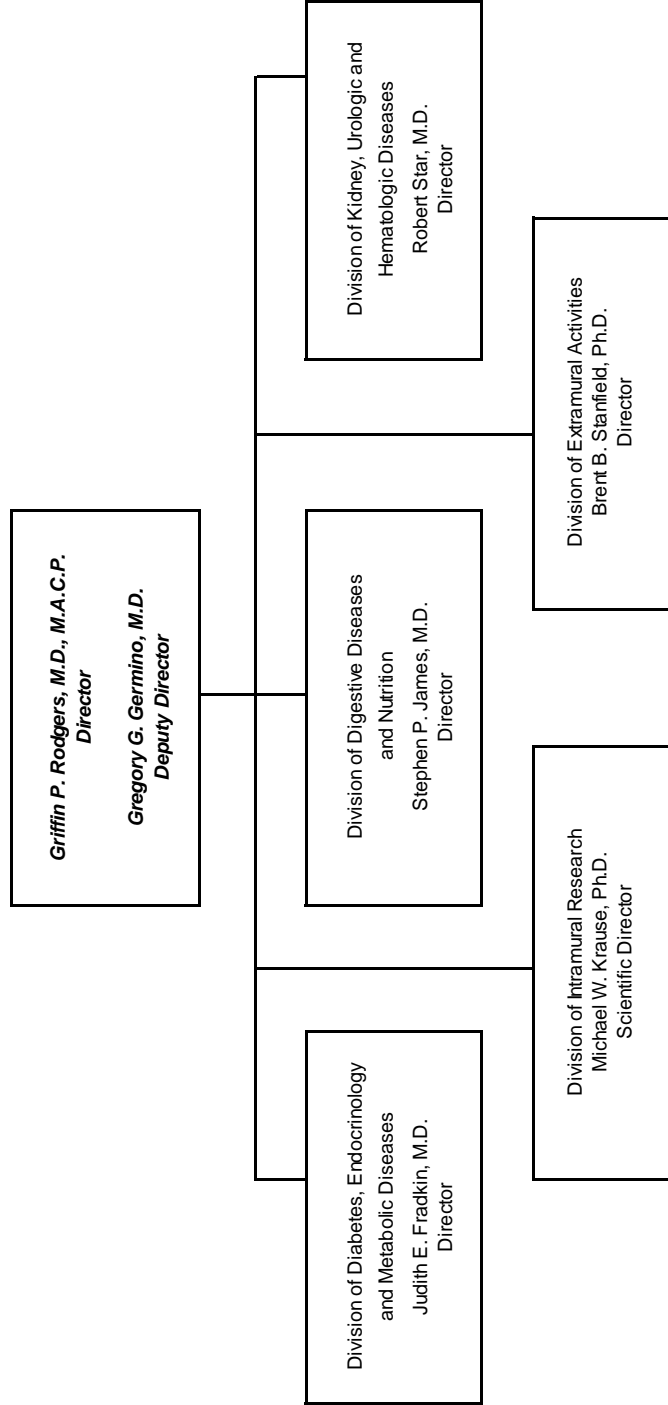
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

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NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases

Organization Structure



NATIONAL INSTITUTES OF HEALTH

National Institute of Diabetes and Digestive and Kidney Diseases

*For carrying out section 301 and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, \$1,449,534,000.*

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

**Amounts Available for Obligation<sup>1</sup>**

(Dollars in Thousands)

Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation	\$1,818,357	\$1,818,357	\$1,449,534
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i> <sup>2</sup>	(150,000)	(139,650)	(150,000)
Rescission	0	-3,457	0
Zika Intra-NIH Transfer	-2,517	0	0
Subtotal, adjusted appropriation	\$1,815,840	\$1,814,900	\$1,449,534
OAR HIV/AIDS Transfers	-2,047	0	0
Subtotal, adjusted budget authority	\$1,813,793	\$1,814,900	\$1,449,534
Unobligated balance lapsing	-55	0	0
Total obligations	\$1,813,738	\$1,814,900	\$1,449,534

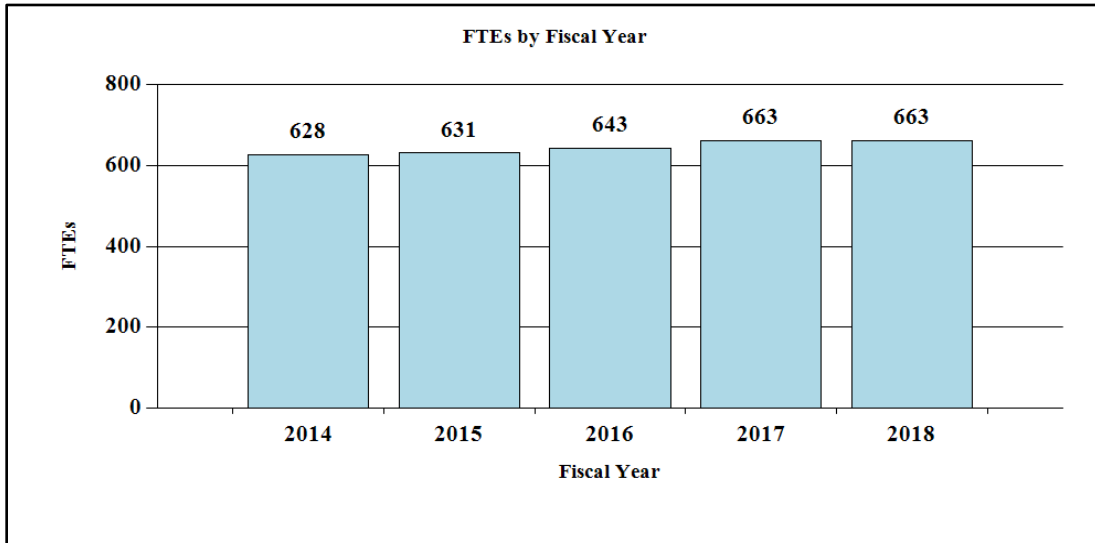
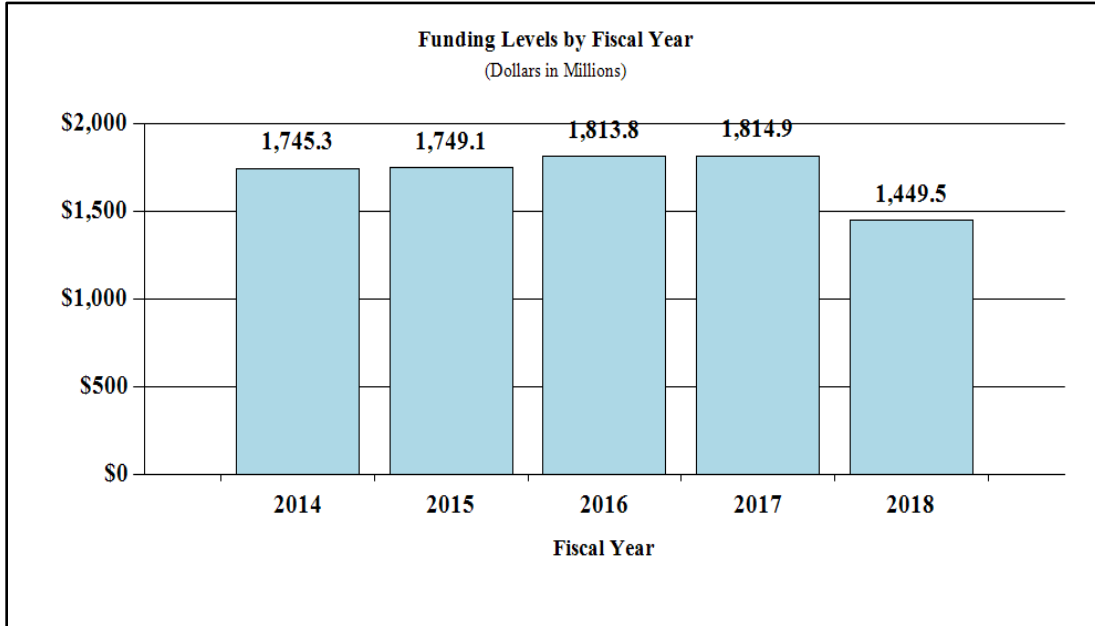
<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:

FY 2016 - \$3,153    FY 2017 - \$4,000    FY 2018 - \$4,000

<sup>2</sup> Mandatory Appropriation for the Special Statutory Authority for Type 1 Diabetes Research in accordance with P.L. 114-10, Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. 1305 note, Title II, Medicare and other health extenders, Sec. 213 (a).

## Fiscal Year 2018 Budget Graphs

### History of Budget Authority and FTEs:



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

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2017 Amount Authorized</b>	<b>FY 2017 CR Annualized</b>	<b>2018 Amount Authorized</b>	<b>FY 2018 President's Budget</b>
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Diabetes and Digestive and Kidney Diseases	Section 401(a)	42§281	Indefinite	\$1,814,900,000	Indefinite	\$1,449,534,000
<b>Total, Budget Authority</b>				<b>\$1,814,900,000</b>		<b>\$1,449,534,000</b>

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

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2008	\$1,858,045,000	\$1,881,893,000	\$1,897,784,000	\$1,855,868,000
Rescission				\$0
2009	\$1,858,487,000	\$1,767,071,000	\$1,755,881,000	\$1,911,338,000
Rescission				\$0
Supplemental				\$9,077,000
2010	\$1,931,494,000	\$1,974,251,000	\$1,940,518,000	\$1,958,100,000
Rescission				\$0
2011	\$2,007,589,000		\$2,004,674,000	\$1,958,100,000
Rescission				\$15,876,196
2012	\$1,987,957,000	\$1,987,957,000	\$1,922,045,000	\$1,950,447,000
Rescission				\$3,402,845
2013	\$1,942,107,000		\$1,947,539,000	\$1,797,044,155
Rescission				\$3,594,088
Sequestration				(\$97,849,260)
2014	\$1,811,786,000		\$1,799,745,000	\$1,894,274,000
Rescission				\$0
Sequestration				(\$10,800,000)
2015	\$1,893,336,000			\$1,899,681,000
Rescission				\$0
2016	\$1,938,133,000	\$1,921,388,000	\$1,975,162,000	\$1,968,357,000
Rescission				\$0
2017 <sup>1</sup>	\$1,966,310,000	\$1,962,093,000	\$2,041,652,000	\$1,968,357,000
Rescission				\$3,457,000
Sequestration				(\$10,350,000)
2018	\$1,599,534,000			

<sup>1</sup> Budget Estimate to Congress includes mandatory financing.

## Justification of Budget Request

### *National Institute of Diabetes and Digestive and Kidney Diseases*

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

Budget Authority (BA):

	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget <sup>1</sup>	FY 2018 +/- FY 2017
BA	\$1,966,310,000	\$1,954,550,000	\$1,599,534,000	-\$355,016,000
Type 1 Diabetes	<u>-\$150,000,000</u>	<u>-\$139,650,000</u>	<u>-\$150,000,000</u>	<u>+\$10,350,000</u>
Labor/HHS:	\$1,816,310,000	\$1,814,900,000	\$1,449,534,000	-\$365,366,000
FTEs	643	663	663	

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

### **Director's Overview**

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to support and conduct research to combat diabetes and other endocrine and metabolic diseases, liver and other digestive diseases, nutritional disorders, obesity, and kidney, urologic, and hematologic diseases. These diseases are chronic, common, costly, and consequential for patients, their families, and the Nation. Diabetes afflicts an estimated 29 million people in the United States, greatly increasing the risk for many serious complications, such as heart disease and kidney failure.<sup>1</sup> Estimates of chronic kidney disease (CKD) show that more than 20 million Americans are affected, and over 660,000 of these have kidney disease severe enough to require kidney replacement therapy.<sup>2</sup> Many urologic diseases are also highly prevalent.<sup>3</sup> Digestive diseases account for an estimated 72 million ambulatory care visits to doctor's offices, outpatient hospital clinics, and emergency departments, as well as 13.5 million hospitalizations with a primary or secondary diagnosis.<sup>4</sup> Obesity affects more than one-third of U.S. adults and about 17 percent of children and adolescents,<sup>5,6</sup> and is a strong risk factor for type 2 diabetes,

<sup>1</sup> Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.

<sup>2</sup> Centers for Disease Control and Prevention. National Chronic Kidney Disease Fact Sheet, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.; U.S. Renal Data System, USRDS 2015 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

<sup>3</sup> NIDDK, NIH/DHHS. Kidney and urologic diseases statistics (<http://kidney.niddk.nih.gov/statistics>), 2010.

<sup>4</sup> Everhart JE, et al. *Gastroenterology* 136: 376-386, 2009.

<sup>5</sup> Ogden CL, et al. *JAMA* 315: 2292-99, 2016.

<sup>6</sup> Flegal et al. *JAMA* 315: 2284-91, 2016.



nonalcoholic steatohepatitis (NASH), and many other diseases. Cystic fibrosis and other genetic diseases within NIDDK's purview are less widespread, but still devastating in their impact. Building on emerging opportunities from past research investments, NIDDK will continue to pursue discovery, clinical, and translational research; research training and career development; and health information dissemination, with continued focus on preserving a robust investigator-initiated research portfolio.

### **Theme 1: Fundamental Science**

In FY 2018, NIDDK will continue its support of multidisciplinary projects studying the gut microbiome; autoimmune diseases such as type 1 diabetes, celiac disease, inflammatory bowel diseases (IBD), autoimmune liver diseases, and some forms of CKD; and metabolic conditions including obesity, type 2 diabetes, and NASH. The NIDDK Kidney Precision Medicine Project (KPMP) will obtain and evaluate human kidney tissue from participants with acute kidney injury (AKI) and CKD, create a kidney tissue atlas, and identify critical cells and pathways as targets for new therapies. NIDDK-supported scientists working in a mouse model identified how inflammatory bowel disease genetic risk variants may abnormally affect the way gut immune cells respond to friendly bacteria in the gut, leading to inflammation.<sup>7</sup> New research in mice has also revealed a key enzyme that acts as a control switch in the brain for eating, which represents a potential new therapeutic target for obesity.<sup>8</sup> Another study identified a novel class of insulin peptide targets that trigger diabetes-causing immune cell attacks in a mouse model of type 1 diabetes, with evidence that such peptides might also trigger an immune response in people.<sup>9</sup> A protein hormone that modulates glucose release into the circulation and that is elevated in humans and mice with insulin-resistance has also been identified. This represents a potential new therapeutic target in type 2 diabetes research.<sup>10</sup>

### **Theme 2: Treatments and Cures**

In FY 2018, NIDDK will continue to support research into the causes of and treatments and cures for human diseases. A recent multiethnic, genome-wide association study has shown that a common gene variant that codes for a glucose transporter protein had a significant impact on the effectiveness of metformin, the first-line drug for type 2 diabetes. These results could have implications for the future of precision medicine in treating type 2 diabetes.<sup>11</sup> In another genetic study, researchers examined data from more than 29,000 men and women of European ancestry and found there may be three types of IBD and not two, as previously thought. These results could offer health care providers more targeted treatments.<sup>12</sup> Another group analyzed the genomes of 96,000 men and women in a multiethnic study and found 38 previously unknown regions of the genome associated with IBD. This sheds light on genetic differences of people with IBD, pointing toward more personalized approaches to treatment.<sup>13</sup> Decades of findings from the long-term, landmark NIDDK-supported Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications follow-on study demonstrate how people with type 1 diabetes can dramatically increase their chances of living long, healthy lives

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<sup>7</sup> Chu H, et al. *Science* 352:1116-20, 2016.

<sup>8</sup> Lagerlof O, et al. *Science* 351: 1293-1296, 2016.

<sup>9</sup> DeLong T, et al. *Science* 351: 711-14, 2016.

<sup>10</sup> Romere C, et al. *Cell* 165: 566-79, 2016.

<sup>11</sup> Zhou K, et al. *Nat. Genet.* 48: 1055-9, 2016.

<sup>12</sup> Cleyneen I, et al. *Lancet* 387: 156-67, 2016.

<sup>13</sup> Liu JZ, et al. *Nat. Genet.* 47: 979-986, 2015.

by practicing early, intensive blood glucose management. In addition, new devices, such as the artificial pancreas, are poised to make such management a reality for many who have not yet attained it.<sup>14,15</sup> Researchers developed a new ultrasonic propulsion technology that can reposition kidney stones in a noninvasive manner and facilitate stone fragment passage in people.<sup>16</sup> A large observational study has shown a particular type of weight loss surgery is more effective than another at inducing long-term type 2 diabetes remission in people who have obesity.<sup>17</sup>

### **Theme 3: Health Promotion and Disease Prevention**

In FY 2018, NIDDK will continue to support research that promotes health and prevents disease. Researchers developed a smartphone application that provides valuable insights into what and when people eat and allowed users to modify their eating behaviors for maximum health benefits.<sup>18</sup> In March 2016, the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary certified that a lifestyle intervention adapted from one proven effective by the landmark NIDDK-led Diabetes Prevention Program (DPP) saved an estimated \$2,650 per participating Medicare beneficiary over 15 months in a Medicare study. The adapted version of the intervention was also developed and tested with NIDDK research support. Based on this finding, CMS determined that the lifestyle intervention will be a covered expense for eligible Medicare recipients starting in 2018, greatly expanding access to this preventive intervention. To address gaps in understanding and treating lower urinary tract symptoms, NIDDK created the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN). In FY 2018, LURN will continue to create and execute protocols designed to improve measurement of self-reported symptoms and generate research tools and data for future studies.<sup>19</sup> The NIDDK-supported Preventing Early Renal Function Loss in Diabetes (PERL) clinical trial will continue investigating whether the drug, allopurinol, can prevent or delay the loss of kidney function in people with type 1 diabetes and very early kidney damage. NIDDK will continue its support of nutrition research and overall health promotion efforts through the recently established NIH Nutrition Research Task Force and development of the first NIH-wide strategic plan for nutrition research.

### **Theme 4: Enhancing Stewardship**

In FY 2018, NIDDK will continue to foster the growth of a diverse biomedical research workforce by providing special funding consideration and mentoring opportunities for talented, young investigators. The training and mentorship opportunities for underrepresented populations offered by the Short-Term Education Programs for Underrepresented Persons and the Network of Minority Health Research Investigators will continue to promote a diverse research pipeline.

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<sup>14</sup>Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular outcomes in type 1 diabetes: the DCCT/EDIC study 30-year follow-up. *Diabetes Care* 39: 686-693, 2016.

<sup>15</sup> Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group. Mortality in type 1 diabetes in the DCCT/EDIC versus the general population. *Diabetes Care* 39:1378-83, 2016.

<sup>16</sup> Harper JD, et al. *J Urol* 195:956-964, 2015.

<sup>17</sup> Purnell JQ, et al. *Diabetes Care* 39: 1101-7, 2016.

<sup>18</sup> Gill S, et al. *Cell Metab* 22: 789-798, 2015.

<sup>19</sup> Yang C, et al. *J Urol* 196: 146-52, 2016.

NIDDK will continue efforts to build a talented urologic scientist workforce through its support of the K12 Urologic Research Career Development Program. Since 2009, this program has supported 28 individual scholars, 15 of whom have completed their training. Of those 15, all but one remain in research or academic medicine. NIDDK will continue to focus on rigor and reproducibility in mouse models through its support of the Type 1 Diabetes Resource at Jackson Laboratories, which serves as an international repository for curation, validation, and distribution of mouse data to the scientific community. The NIDDK Central Repository collects biological samples and data from clinical studies, ensures that the samples are stored under uniform conditions, and provides researchers easy access to samples. This promotes reproducibility and data integrity for future studies, enhancing the value of the research.

Overall Budget Policy: The FY 2018 President's Budget request is \$1,449.534 million, a decrease of \$365.366 million compared with the FY 2017 Annualized CR level. These reductions are distributed across all programmatic areas and basic, epidemiology or clinical research.

## **Program Descriptions and Accomplishments**

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

In FY 2018, NIDDK will continue to support research that makes important contributions to the treatment and prevention of diseases that are associated with the endocrine system and metabolism, such as diabetes. Recent NIDDK-supported research efforts are shedding light on potential new ways to control blood sugar levels in people with type 1 diabetes. In one study, researchers developed a new biomaterial that can protect transplanted insulin-producing  $\beta$  (beta) cells and allow them to function for months in a mouse model of type 1 diabetes without the need for immunosuppression.<sup>20</sup> In another study, scientists generated functional  $\beta$  cells from the skin cells of people with type 1 diabetes, marking a significant step forward toward a cell therapy for this condition and providing a valuable resource for drug screening and studying the development of diabetes.<sup>21</sup> Scientists discovered that human pancreatic islets have four distinct subtypes of  $\beta$  cells, and that islets from people with type 2 diabetes have abnormal percentages of the different subtypes.<sup>22</sup> This research has shed important new light on  $\beta$  cell biology and could be capitalized upon for type 2 diabetes treatment.

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<sup>20</sup> Vegas AJ, et al. Nat Med 22: 306-11, 2016.

<sup>21</sup> Millman JR, et al. Nat Commun. 7: 11463, 2016

<sup>22</sup> Dorrell C, et al. Nat Commun. 7: 11756, 2016.

**Program Portrait: Diabetes Prevention Program Outcomes Study (DPPOS) Phase 3**

**FY 2017 Level: \$7.0 million**

**FY 2018 Level: \$6.3 million**

**Change: - \$0.7 million**

Diabetes places an enormous personal and financial burden on the Nation. More than 29 million people in the U.S. have diabetes and another 86 million adults—more than one in three adults—have pre-diabetes and are thus at risk of developing the disease. Not only is diabetes a major cause of blindness, kidney failure, and amputation, it also doubles the risk of cardiovascular disease, cancer, and dementia, and afflicts 25 percent of nursing home patients. Thus, effective methods of preventing or delaying diabetes is critical to address both the human and economic toll of this disease. To that end, NIDDK's landmark Diabetes Prevention Program (DPP) was a randomized controlled trial that enrolled 3,234 diverse, high-risk participants with pre-diabetes, and demonstrated powerful beneficial effects of both lifestyle intervention and metformin—a safe and inexpensive diabetes medication—in preventing or delaying the onset of type 2 diabetes. The DPP lifestyle intervention reduced diabetes incidence by 58 percent over three years and metformin reduced it by 31 percent. The DPP Outcomes Study (DPPOS) found substantial reductions in type 2 diabetes after 15 years of follow-up; prevention with metformin was cost-saving and lifestyle intervention was highly cost-effective in DPP. Based on this NIH research, Congress established a National DPP at the Centers for Disease Control and Prevention. The Centers for Medicare and Medicaid Services studied a modified version of the DPP lifestyle intervention, found it to be cost saving, and will cover its delivery through Medicare. Building on this remarkably successful study, NIDDK has launched DPPOS Phase 3 to follow 2,778 DPP participants who remain active in the study, including people with and without diabetes. In partnership with the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute on Aging, this new NIDDK study will address unanswered questions about long-term exposure to metformin and lifestyle intervention. DPPOS Phase 3 will study outcomes that are of increasing public health concern in the aging population with pre-diabetes and diabetes, including the potential benefits of metformin on development of cardiovascular disease and cancer.

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

In FY 2018, NIDDK will continue to support programs aimed at improving the treatment and prevention of diseases associated with the digestive system. NIDDK sponsored meetings in 2016 to identify digestive-disease related research opportunities, in collaboration with both federal and non-federal partners. These included a workshop focusing on new directions in research of functional bowel disorders, a workshop addressing new approaches in the research of chronic pancreatitis, and, in conjunction with the National Institute of Biomedical Imaging and Bioengineering, a workshop exploring research opportunities for the use of simulation applications to enhance training for clinicians caring for people with gastrointestinal and urologic conditions. In 2016, a new consortium was established to study the relationships among chronic pancreatitis, diabetes, and pancreatic cancer. NIDDK released two funding opportunity announcements to continue supporting research into genetic factors that contribute to increased susceptibility for developing inflammatory bowel disease. Another funding opportunity

announcement issued in 2016 will support research investigating the interactions between nutrition and human genetics. NIDDK will continue to support the Hepatitis B Research Network, which is testing treatments in at-risk populations of both children and adults, such as Asian Americans and Pacific Islanders, as well as conducting ancillary studies and assembling a large biospecimen repository and clinical database for future studies. A free source of evidence-based information for health care professionals and for researchers studying liver injury associated with prescription and over-the-counter drugs, herbals, and dietary supplements is produced by the NIDDK together with the National Library of Medicine.

**Program Portrait: The Inflammatory Bowel Disease (IBD) Genetics Consortium**

**FY 2017 Level: \$6.10 million**

**FY 2018 Level: \$4.88 million**

**Change: - \$1.22 million**

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 U.S. Not only can the disease be very painful, but it is also usually accompanied by diarrhea, bleeding, and loss of appetite. Severe cases can lead to tears in the gastrointestinal tract. 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. Identifying the genetic contributions to IBD would have important consequences: Not only would it provide opportunities for genetic screening to help individuals seek treatment before symptoms become severe, but it may also shed light on future treatments by identifying possible targets for therapeutics.

NIDDK's IBD Genetics Consortium (IBDGC) was established in 2002 to identify genes that are involved in IBD susceptibility. In collaboration with the International IBD Genetics Consortium, of which it is a member, the IBDGC has enrolled thousands of IBD patients and identified about 200 regions of the human genome that are associated with risk of IBD. This work has provided important new insights into the nature of the disease. Despite several new advances, 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 investigations into the genetic underpinnings of IBD, and to build upon the successes of the initial phase of IBDG, support for the consortium will be renewed in 2017. A goal of the next phase is to not only continue to identify genetic risk regions, but also to precisely identify specific genes and genetic variants that are involved in IBD susceptibility. The consortium will also delve into the development of IBD by investigating the functions of genes thought likely to cause disease.

**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. Discovery, 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 of chronic disease.

In FY 2018, NIDDK will continue to support research aimed at improving the treatment and prevention of kidney, urologic, and hematologic diseases. A recent study demonstrated that "turning off" a single gene called *SH2B3* significantly increased production of human red blood

cells (RBCs) in the laboratory.<sup>23</sup> This finding has the potential to contribute to future efforts to improve RBC production for medical applications such as replacement therapy during acute blood loss as a result of trauma or medical procedures. New research suggests that women with chronic pelvic pain, particularly women with interstitial cystitis/bladder pain syndrome, may have systemic neural changes rather than nerve problems restricted to, for example, the bladder.<sup>24</sup> Two research teams have provided new information regarding how DNA binding proteins help “turn off” production of fetal hemoglobin (HbF), which may enable the development of safe and effective gene therapies that “turn on” HbF production to treat certain red blood cell diseases, such as sickle cell.<sup>25,26</sup> The NIDDK established the Urinary Stone Disease Research Network with the goals of designing randomized clinical trials to investigate the impact of increased fluid intake on the rate of occurrence of urinary stones in adults and children, conducting clinical research to mitigate ureteral stent-related pain, and cataloguing data to create a resource for future researchers.

**Program Portrait: (Re)Building a Kidney**

**FY 2017 Level: \$3.9 million**

**FY 2018 Level: \$2.8 million**

**Change: -\$1.1 million**

Chronic kidney disease (CKD) and acute kidney injury (AKI) pose a substantial public health burden. Even with the best available medical intervention, deteriorating kidney function can require replacement therapies, such as dialysis and kidney transplantation, both of which have considerable morbidity and mortality. Progressive kidney disease involves failure to effectively repair injury, and an inability to regenerate kidney tissue. This places great importance on the development of potential alternative therapies. (Re)Building a Kidney is an NIDDK-sponsored consortium of research projects working to optimize approaches to enhance kidney repair and promote the generation of new nephrons, the functional units of the kidney. The development of such strategies could have a significant impact on the progression of kidney disease. For the first time, investigators have developed laboratory-based procedures to isolate and expand numbers of mouse nephron progenitor cells, capable of differentiating into different cell types, by promoting their self-renewal, and directing them toward a mature cell type. This sets the stage for studies of nephron development with the ultimate goal of tissue repair/replacement.<sup>27</sup> Researchers reported that kidney stem cells isolated from the adult mouse kidney collecting duct can self-renew in the laboratory, and when injected into the mouse kidney, they integrate back into the collecting duct.<sup>28</sup>

The (Re)Building a Kidney consortium’s goal is to coordinate and support studies that will result in the ability to generate or repair nephrons that can function within the kidney. The consortium contains a wide-range of projects including, but not limited to: Identifying and characterizing progenitor cell types, including manipulation toward a kidney cell fate; studying progenitor cells and their microenvironments involved in repair in response to injury; and developing scaffolds on which to target cells and molecules to specific kidney locations and compartments.

**Special Statutory Funding Program for Type 1 Diabetes Research:** Complementing efforts of the Diabetes, Endocrinology, and Metabolic Disease program, the Special Program’s goal is to foster improved treatment, prevention, and a cure of type 1 diabetes and its complications through basic, clinical, and translational research around six scientific goals: 1) identifying genetic and environmental causes of type 1 diabetes (\$30 million); 2) preventing or reversing the

<sup>23</sup> Giani FC, et al. Cell Stem Cell 18: 73-78, 2016.

<sup>24</sup> Chelimsky G, et al. J Urol 196: 429-34, 2016.

<sup>25</sup> Canver MC, et al. Nature 527: 192-197, 2015.

<sup>26</sup> Masuda T, et al. Science 351: 285-289, 2016.

<sup>27</sup> Brown AC, et al. Dev Cell 34: 229-41, 2015.

<sup>28</sup> Li J, et al. J Am Soc Nephrol 26: 81-94, 2015.

disease (\$20.4 million); 3) developing cell replacement therapy (\$23 million); 4) improving management and care (\$39 million); 5) preventing or reducing diabetes complications (\$31 million); and 6) attracting new talent and applying new technologies to research (\$6.6 million) (FY 2018 estimate dollars). Although focused on type 1 diabetes, aspects of this research are relevant to other autoimmune disorders, as well as type 2 diabetes. Both type 1 and type 2 diabetes share impaired function of insulin-producing beta cells of the pancreas along with potential complications, such as heart disease, stroke, blindness, kidney failure, nerve damage, and lower limb amputations. In FY 2017, NIDDK supported new research in several areas, including: advanced clinical trials to test the artificial pancreas device systems in people with type 1 diabetes, as well as research into behavioral and psychosocial factors that affect the use of these devices; analysis of biosamples to identify predictors of autoimmunity and type 1 diabetes in high-risk infants enrolled in The Environmental Determinants of Diabetes in the Young (TEDDY) study; small business research to develop new type 1 diabetes therapeutics and diagnostic technologies; clinical trials networks to test agents to prevent or reverse type 1 diabetes; and, to maximize past investments in clinical research, ancillary studies using archived samples to investigate type 1 diabetes causes, progression, and development of diabetic complications.

The FY 2018 President's Budget request for the Special Statutory Funding Program for Type 1 Diabetes Research is proposed for reauthorization at \$150 million. NIDDK administers the program, but because of its trans-HHS nature, the resources are disbursed among multiple NIH Institutes and Centers as well as CDC.

**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 Native American communities in the region has led to important scientific advances in type 2 diabetes and obesity. For example, NIDDK's IRP is using genomic studies in large cohorts of Southwest American Indians to identify mutations that are linked to an increased risk for obesity and diabetes.<sup>29</sup> IRP research on former Biggest Loser television show competitors demonstrated that lifestyle changes to combat obesity need to be sustained over the long term, suggesting preoccupation with rapid weight loss may be misguided.<sup>30</sup> Other IRP research identified neuronal receptors linked to either increased<sup>31</sup> or decreased food intake,<sup>32</sup> showed that neuromodulation of the prefrontal cortex of the brain can influence energy intake and weight loss,<sup>33</sup> and demonstrated improved methods for detecting prediabetes in African populations.<sup>34</sup> Research training is also an integral component of the IRP. This training occurs in both clinical and basic laboratory research at the high school,

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<sup>29</sup> Baier, LJ, *Diabetes*, 64, 4322-4232, 2015.

<sup>30</sup> Fothergill, *Obesity*, 24, 1612-1619, 2016.

<sup>31</sup> Nakajima, K, *Nat. Commun.*, 7, 10268-10281, 2016.

<sup>32</sup> Li, YQ, *J. Clin Invest.*, 126, 40-49, 2016.

<sup>33</sup> Gluck, ME, *Obesity*, 23, 2149-2156, 2015.

<sup>34</sup> Sumner, AE, *Diabetes Care*, 39, 271-277, 2016.

post baccalaureate, postdoctoral, and clinical fellow level, including summer programs specifically targeting under-represented minorities.

**Research Management and Support (RMS):** RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. Through RMS activities, NIDDK continues to provide administrative support for meritorious discovery, clinical, and translational research and research training efforts, and also continues its health information dissemination and education/outreach activities.



**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Diabetes and Digestive and Kidney Diseases**  
**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2016 Final			FY 2017 Annualized CR			FY 2018 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Diabetes, Endocrinology, and Metabolic Diseases									
Direct:	29	1	30	30	1	31	30	1	31
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	31	1	32	32	1	33	32	1	33
Division of Digestive Diseases and Nutrition									
Direct:	21	2	23	25	2	27	25	2	27
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	21	2	23	25	2	27	25	2	27
Division of Extramural Activities									
Direct:	65	1	66	67	-	67	67	-	67
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	65	1	66	67	-	67	67	-	67
Division of Intramural Research Programs									
Direct:	350	9	359	365	10	375	365	10	375
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	350	9	359	365	10	375	365	10	375
Division of Kidney, Urologic, and Hematologic Diseases									
Direct:	23	-	23	24	-	24	24	-	24
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	23	-	23	24	-	24	24	-	24
Division of Nutrition Research Coordination									
Direct:	1	-	1	-	-	-	-	-	-
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	1	-	1	-	-	-	-	-	-
Office of the Director									
Direct:	139	-	139	137	-	137	137	-	137
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	139	-	139	137	-	137	137	-	137
<b>Total</b>	<b>630</b>	<b>13</b>	<b>643</b>	<b>650</b>	<b>13</b>	<b>663</b>	<b>650</b>	<b>13</b>	<b>663</b>
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2014	12.0								
2015	12.0								
2016	12.0								
2017	12.0								
2018	12.0								

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

**Detail of Positions<sup>1</sup>**

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	185,100	187,210	190,861
GM/GS-15	55	53	53
GM/GS-14	66	67	67
GM/GS-13	102	107	107
GS-12	66	70	70
GS-11	34	35	35
GS-10	0	0	0
GS-9	29	30	30
GS-8	15	16	16
GS-7	22	23	23
GS-6	4	4	4
GS-5	4	4	4
GS-4	0	0	0
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	398	410	410
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	8	7	7
Senior Grade	4	4	4
Full Grade	1	1	1
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	14	13	13
Ungraded	274	284	284
Total permanent positions	400	412	412
Total positions, end of year	687	708	708
Total full-time equivalent (FTE) employment, end of year	643	663	663
Average ES salary	185,100	187,210	190,861
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	102,019	103,947	105,974

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.