Extramural Funding Trends and Support of Core Values

The NIDDK's core values emphasize maintaining a vigorous investigator-initiated R01 research portfolio, supporting pivotal clinical studies and trials, preserving a stable pool of talented new investigators, and continuing to foster exceptional research training and mentoring opportunities, consistent with the vision of NIDDK Director, Dr. Griffin P. Rodgers (see Director's Message).

At the NIDDK's May 2012 Advisory Council meeting, NIDDK Deputy Director Dr. Gregory Germino highlighted these values and reviewed the NIDDK's resource focus on areas supporting them.

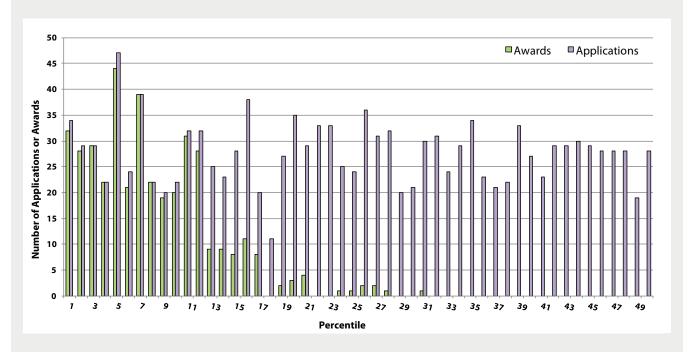
Following that presentation, the NIDDK generated additional data on application and funding trends to help our research community understand application and funding dynamics over recent years and demonstrate the NIDDK's commitment to research and programs associated with the NIDDK's core values. The Institute posted these data on the NIDDK website and has since updated them annually. The data shown here were recently updated to include Fiscal Year (FY) 2017.

NIDDK Funding Outcomes for Fiscal Year 2017 and Historical Application and Funding Trends

With the exception of Figure 8 (which includes initiative data), the data in all charts exclude initiatives (i.e., Requests for Applications, or RFAs), grants funded through the Special Statutory Funding Program for Type 1 Diabetes Research, and funds appropriated through the American Recovery and Reinvestment Act (ARRA).

Most charts and tables in this report show data for the past 10 Fiscal Years. In Figures 4-7, the time horizon is expanded to include Fiscal Years starting in 1997, the year before the start of the doubling of the NIH budget from Fiscal Years 1998 through 2003. This expansion provides some perspective on application and funding trends occurring through the doubling period and then in the post-doubling era. Figures 11-12 are focused on Early Stage Investigators and build upon an initial set of charts that include data starting in FY 2010.

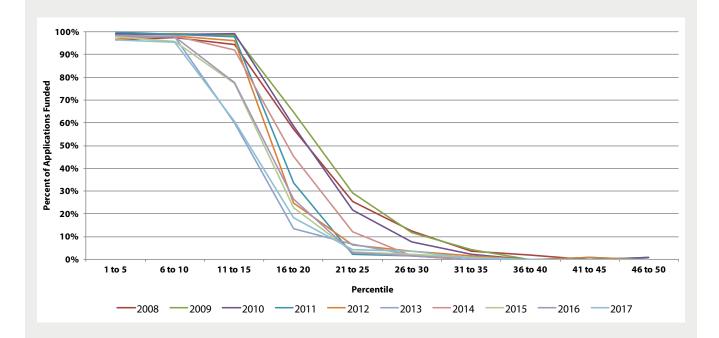
Number of NIDDK Competing R01 Applications Scoring Within the Top 50th Percentile and Number of NIDDK Percentiled R01 Applications Funded in FY 2017



<u>Note:</u> "Applications" shown in the chart above include all R01 applications that scored 50th percentile or better. Unscored applications, scored applications with no percentiles, and applications scoring above the 50th percentile are not shown. (Fifty percent [n=1,397] of the applications received were unscored, scored but did not receive a percentile, or scored above the 50th percentile.) No unscored applications were funded in FY 2017.

The NIDDK nominal payline in FY 2017 was the 12th percentile for established investigators and the 17th percentile for Early Stage Investigators (ESIs). The payline and additional programmatic scrutiny for R01 applications requesting more than \$500,000 in direct costs are substantially more stringent. These data show that the NIDDK adheres closely to its payline, but does exercise programmatic discretion to include a limited number of programmatically important applications.

NIDDK Competing R01 Application Funding Curves for FYs 2008-2017



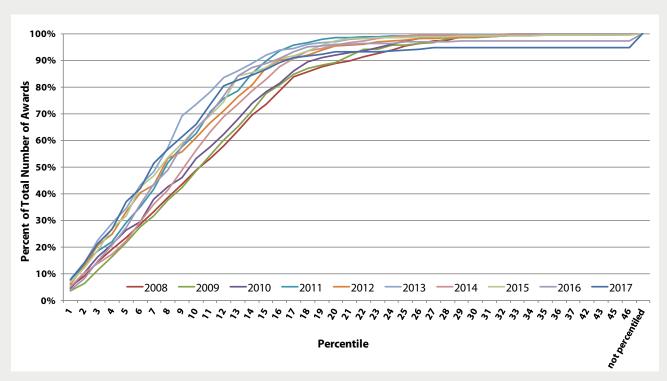
To generate the data for Figure 2, RO1 applications were placed into "percentile bins" as follows: bins 1 to 5 include all applications with percentile scores from 0.1 to 5.0, bins 6 to 10 include applications with percentile scores from 5.1 to 10.0, etc. Only RO1 applications that scored 50th percentile or better were included in the analysis.

The data demonstrate steep deflections in the percentage of applications funded at or above the nominal payline for each year. The R01 paylines for the years included in Figure 2 are shown in the table to the right.

Fiscal Year	General Payline	\$>500K Payline	New Investigator Payline	Early Stage Investigator (ESI) Payline	ESI First Competitive Renewal Payline
2008	17	11	19	-	-
2009	17	11	19	-	-
2010	17	11	19	-	-
2011	15	10	17	-	-
2012	13	9	13	18	-
2013	11	7	11	16	-
2014	13	8	13	18	-
2015	13	8	13	18	15
2016	13	8	13	18	15
2017	12	7	12	17	15

Note: In FY 2012, the NIDDK began focusing on Early Stage Investigators (ESIs; see definition on the NIH "New and Early Stage Investigator Policies" webpage at http://grants.nih.gov/grants/new_investigators/index.htm), a subset of New Investigators. For more information on the benefits that the NIDDK conveys to ESIs, see the NIDDK New and Early Stage Investigators page at https://www.niddk.nih.gov/research-funding/process/apply/new-early-stage-investigators (See also Figures 11 and 12.)

Cumulative Percentage of R01 Awards Across Percentiles (FYs 2008-2017)



Only funded R01 applications are considered in the data set used to generate Figure 3. Percentile bin size equals one percentile and there is no overlap between bins. Percentiles with decimal places were summed into the next highest integral percentile as follows: 0.1-0.9 was summed into 1, 1.1-1.9 was summed into 2, etc. These cumulative funding data again demonstrate that the vast majority of R01 applications funded by the NIDDK fall within the payline, but that the NIDDK does exercise programmatic discretion to include a limited number of programmatically important applications. Note that in FY 2016 and FY 2017 a limited number of R01 applications in response to specific Funding Opportunity Announcements received a priority score, but not a percentile score. Some of these applications were funded and hence included in this chart. No unscored/streamlined applications were funded in FY 2017.

Number of Competing NIDDK R01 Applications (Including Resubmissions) Received for Funding Consideration in FYs 1997-2017

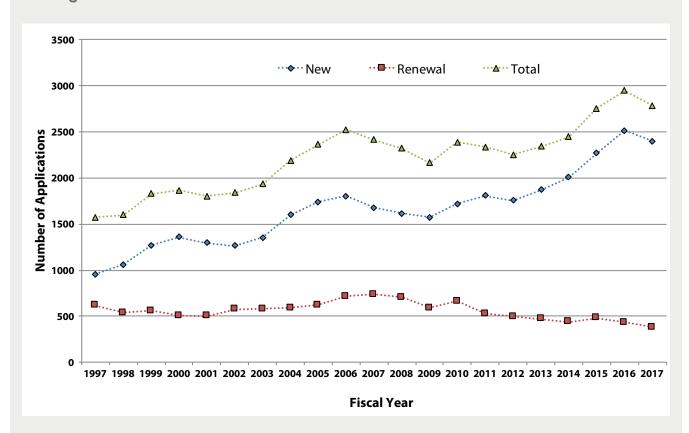
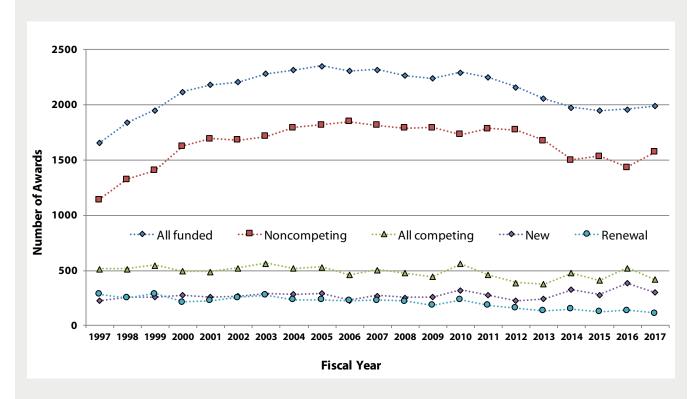


Figure 4 shows a substantial increase in the number of competing R01 applications received by the NIDDK between FYs 1997 and 2017. After some years of relatively flat growth (FYs 2006-2012), the number of competing R01 applications received by the NIDDK increased in FYs 2013-2016. This pattern of growth in R01 application numbers in successive years was not sustained in FY 2017. The observed increases between FYs 1997 and 2006 and between FYs 2013 and 2016 were primarily due to increases in the number of new (Type 1) applications. The number of competing renewal applications showed some fluctuation between FYs 1997 and 2017, but overall the number of renewal applications has slightly decreased.

Number of NIDDK R01 and R37 Grants (Competing and Non-competing) Funded in FYs 1997-2017



During the doubling of the NIH budget (FYs 1998-2003), the total number of R01 and R37 grants funded by the NIDDK increased significantly. After leveling off following the doubling, the number of R01 and R37 grants funded by the NIDDK has declined since FY 2007. Prior to FY 2009, slightly fewer than half of the competing grants funded by the NIDDK were new (Type 1) awards in most years. However, since FY 2009 that proportion has risen to 72 percent (in FY 2017).

Overall NIDDK Expenditures (Includes Direct and Facilities and Administrative Costs) on R01 and R37 Awards (Competing and Non-competing) in FYs 1997-2017

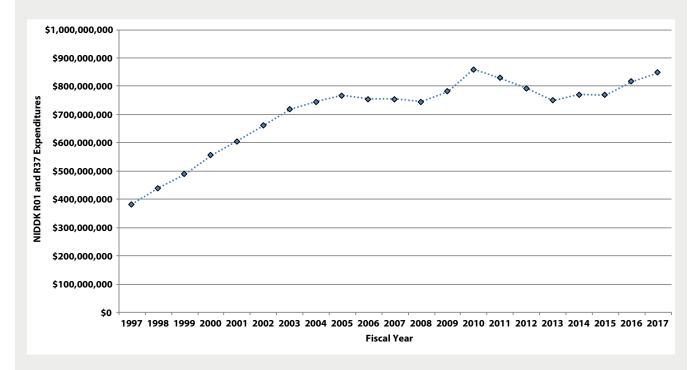


Figure 6 shows that NIDDK expenditures on R01 and R37 grants have more than doubled (121 percent increase) since FY 1997. This is because the NIDDK is funding a larger number of these awards (Figure 5) and because the median cost of an R01 has increased substantially (Figure 7).

Median Total Costs (Includes Direct and Facilities and Administrative Costs) of NIDDK R01 and R37 Grants (Competing and Non-competing) in FYs 1997-2017

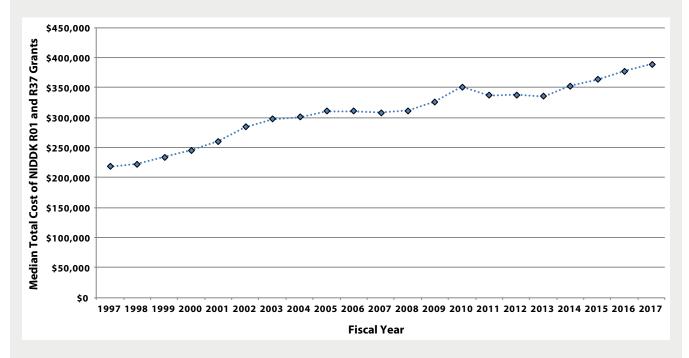


Figure 7 illustrates that the median cost of RO1 and R37 awards has increased approximately 78 percent since FY 1997.

NIDDK Extramural Research Funding by Category (Competing and Non-competing) in FYs 2008-2017

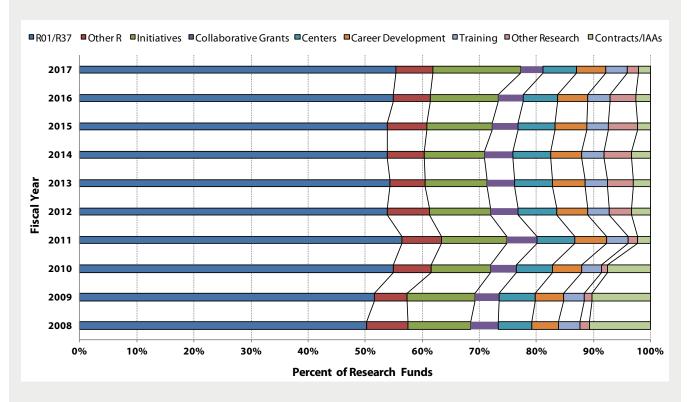


Figure 8 shows that relative funding levels of most NIDDK extramural research categories have remained fairly stable since FY 2008.

NIDDK Portfolio Categories:

- R01/R37 Investigator-initiated (excludes R01s responding to NIDDK RFAs)
- **Other R** Includes other R activities (*i.e.*, R03, R13, R15, R18, R21, R34, SBIR/STTR, *etc.*) but excludes R24s and applications submitted to NIDDK RFAs
- Initiatives Awards made in response to NIDDK RFAs; includes most NIDDK large clinical trials and consortia
- Collaborative Grants P01s and R24s that are not "mini-Centers"
- Centers Includes all non-P01 P awards and R24 "mini-Centers"
- Career Development Includes all Ks (including K99/R00)
- Training Includes all F and T activities
- Other Research Everything not captured in the other categories
- Contracts and Interagency Agreements (IAAs) Includes some large clinical studies

Maintaining a Stable Pool of NIDDK Investigators—Number of Investigators Supported by at Least One R01 or R37

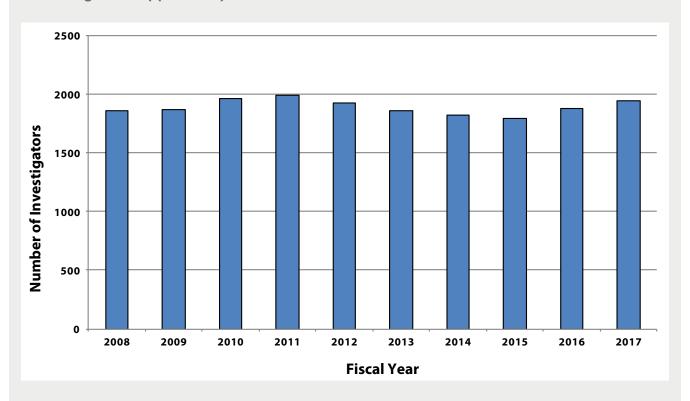


Figure 9 shows that the number of principal investigators (Pls) supported by at least one R01 or R37 remained relatively stable between FYs 2008 and 2017, with slight increases from FYs 2010-2012 and FYs 2016-2017. It should be noted that in FY 2008, NIH, for the first time, began making multiple principal investigator R01 awards to support team science projects. The observed increases in numbers of Pls supported by the NIDDK immediately following FY 2008 are largely attributable to multiple Pl R01 awards. The reduction in the number of Pls supported by the NIDDK from FYs 2012-2015 may be the result of more stringent paylines, as well as other factors, during that period.

Preserving a Stable Pool of New Investigators—Number of NIDDK New Investigator R01 Applications and Awards

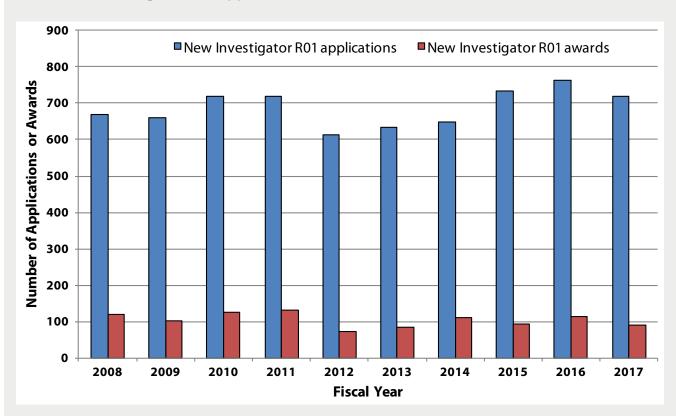
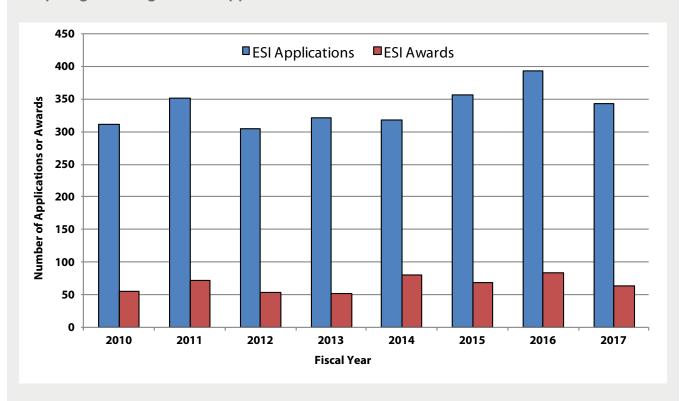


Figure 10 shows that over the last decade, the numbers of New Investigator (NI) applications and awards have remained fairly stable, fluctuating around about 100 per year. It should be noted that these data count applications and awards, not persons. The NIH issued a policy in 2008 to encourage early transition to funding independence for New Investigators within 10 years of completing their terminal research degree or their medical residency (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-121.html). This policy was modified or superseded by subsequent notices. The current policy, the Next Generation Researchers Initiative (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html), began in 2017. The NI definition includes all investigators who are new to NIH, both those who qualify as Early Stage Investigators (ESIs) and those who do not. ESIs are the focus of Figures 11 and 12.

Preserving a Stable Pool of New Investigators—Number of NIDDK Early Stage Investigator R01 Applications and Awards



Comparison of Figures 10 and 11 shows that while Early Stage Investigator (ESI) applications fell in FY 2012 essentially in proportion to the total drop in New Investigator applications, the proportional drop in number of awards to ESIs was not as great. This is attributable in part to the NIDDK's differential payline for ESI applications (see table accompanying Figure 2 and the NIDDK New and Early Stage Investigators page at https://www.niddk.nih.gov/research-funding/process/apply/new-early-stage-investigators). Although there is moderate fluctuation from year to year in the numbers of ESI applications and awards, the differential payline is contributing to a healthy success rate for these applications.

Preserving a Stable Pool of New Investigators (NIs)—Percent of NIDDK NI Applications Submitted and Awards Received by Early Stage Investigators (ESIs)

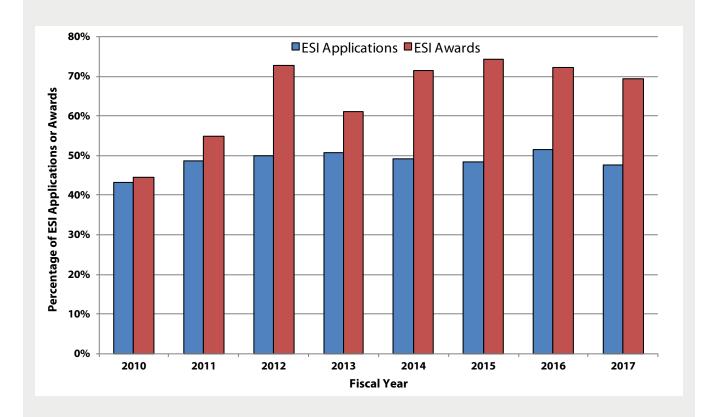
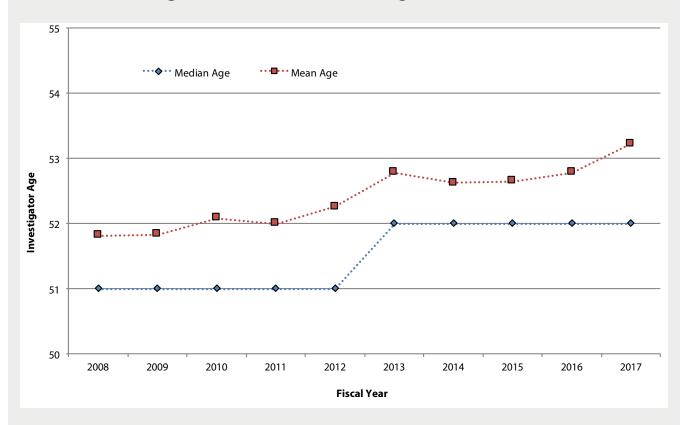


Figure 12 shows that the NIDDK's differential payline for ESIs from FYs 2012-2017 (see table accompanying Figure 2 and the NIDDK New and Early Stage Investigators page at https://www.niddk.nih.gov/research-funding/process/apply/new-early-stage-investigators) has been effective in enhancing ESI representation among NI awards. ESI applications comprise about 49 percent of all NI applications received since FY 2011. The ESI differential payline instituted in 2012 has increased the number of awards to ESIs, so that about 68 percent of awards to NIs are awarded to ESIs. NIs who do not qualify as ESIs are paid according to the nominal payline each fiscal year.

Median and Mean Ages of NIDDK R01 and R37 Investigators



Over the past 10 years, the median ages of investigators holding R01 or R37 awards (competing and non-competing) increased by 1 year, and mean age of these investigators has increased by 1.4 years. Mean age increased gradually from FYs 2008 through 2013, then held relatively constant from FYs 2013 through 2016. In FY 2017, mean age increased to approximately 53.2 years, continuing the overall upward trend over time. Median age increased from 51 to 52 in FY 2013 and has remained constant since then.

Support Pivotal Clinical Studies and Trials—NIDDK Human Subjects Research Funding as a Proportion of All Extramural Research Funding

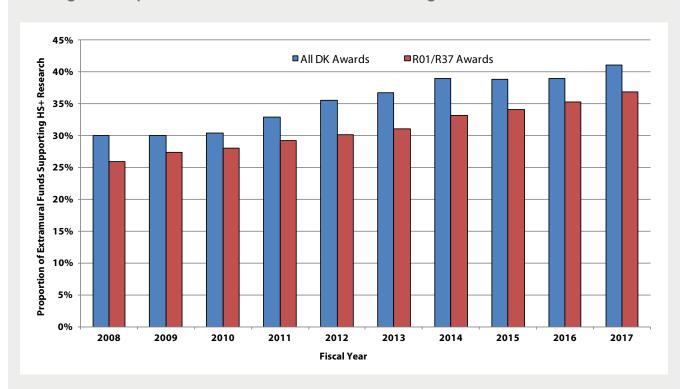


Figure 14 demonstrates that the NIDDK continues to commit a substantial proportion of its research funding to the support of clinical research involving human subjects. The proportion of NIDDK funds supporting Human Subjects research has increased steadily over the last 10 years, from 30 percent of all NIDDK-funded research in FYs 2008-2010 to about 40 percent in FYs 2014-2017. This same steady increase was seen in the fraction of R01 and R37 funding for human subjects research. For the purpose of this analysis, we used the definition described in Kotchen et al., 2004 (<u>JAMA</u> 291: 836-843, doi:10.1001/jama.291.7.836, 2004) and included all studies coded as using human subjects (HS+). We are monitoring this trend to be sure that we maintain an appropriate balance between clinical and basic research.

FIGURES 15A TO 15E

Figures 15A To 15E: The NIDDK Is Committed to Training the Next Generation of Scientists

Figures 15A through E demonstrate that the NIDDK's commitment to training and developing the careers of the next generation of scientists remains strong.

Figure 15A: NIDDK Fellowship (F), Career Development (K), and Training (T) Awards as a Percent of Total Extramural Research Funding

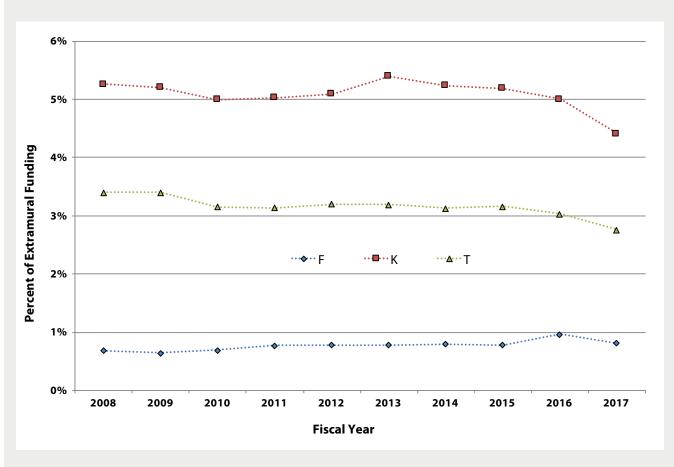


Figure 15A shows that overall support of training and career development programs has remained fairly stable since FY 2008. Funding for K awards has remained stable at about \$72 million a year since FY 2010, though in FY 2017 this represented a slightly lower proportion of the overall extramural research budget.

FIGURE 15B

Numbers of NIDDK Fellowship (F), Career Development (K), and Training (T) Awards by Fiscal Year

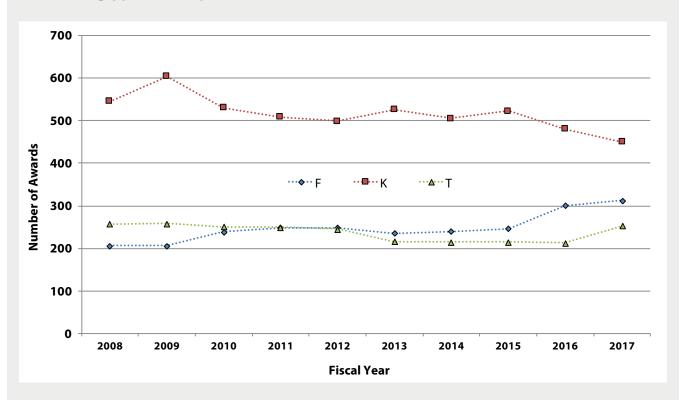


Figure 15B shows that the numbers of NIDDK F and T awards increased slightly in FY 2017, while the number of K awards dipped somewhat in FY 2017 for a second year in a row. Trends in specific K mechanism awards that contributed to this effect are shown in detail in Figure 15C. In addition, salary cap increases implemented in FY 2017 for competing and non-competing K08 and K23 awards may have contributed to this slight decrease in K award numbers.

FIGURE 15C

Numbers of NIDDK Career Development (K) Awards by Activity and Fiscal Year

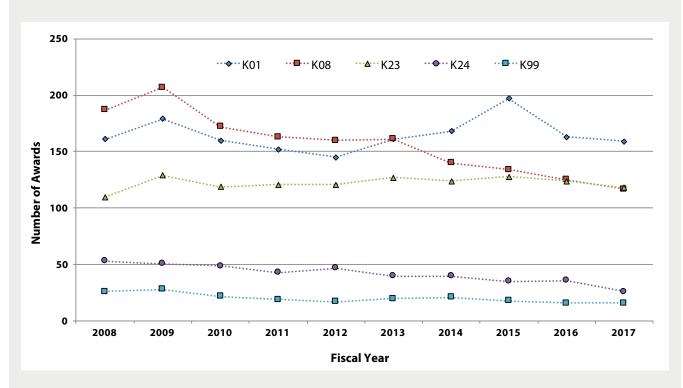


Figure 15C shows that the numbers of NIDDK K08 (Mentored Clinical Scientist Development Awards) and K24 (Midcareer Investigator Awards in Patient-Oriented Research) have decreased since FY 2008; the numbers of other K mechanism awards have shown no such overall trend. (FY 2017 was the last year that NIDDK accepted K24 applications, and no new NIDDK K24 awards are expected starting FY 2018.)

FIGURE 15D

Numbers of NIDDK Career Development (K) Applications by Activity and Fiscal Year

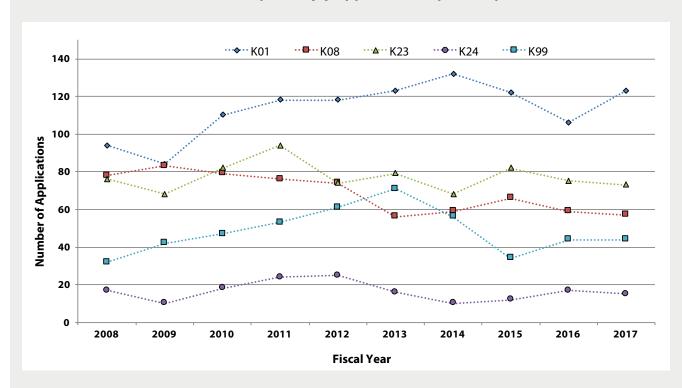


Figure 15D shows that K application numbers have fluctuated over time with some overall indication of declining numbers of K08 applications and increasing numbers of K01 applications. Other K application types show some year-to-year fluctuations or short-term trends but relatively comparable numbers of applications overall between FY 2008 and FY 2017.

FIGURE 15E

Numbers of NIDDK Training (T32) Award Slots by Fiscal Year

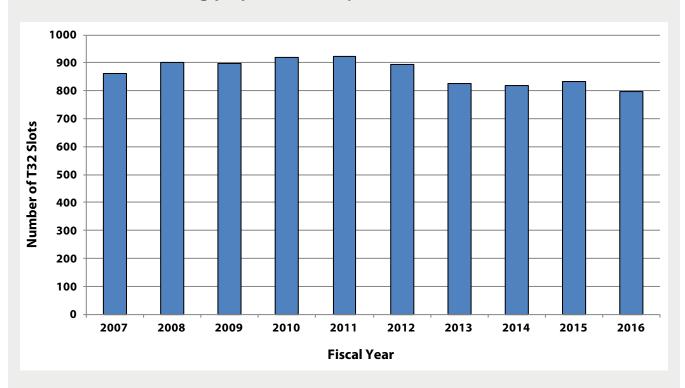


Figure 15E illustrates that the number of NIDDK T award training slots has remained relatively stable. The NIDDK will continue to monitor carefully its training and career development programs to identify factors behind trends and to ensure appropriate balance.

<u>Note:</u> T32 awards made in FY 2017 continue into FY 2018. The total number of T32 slots are reported at the end of the award period. Therefore, the FY 2017 information on T32 slots will not be available until later in FY 2018; thus, unlike the other charts in this section, FY 2017 data are not included here.