



August 2018

NIH RESEARCH

Action Needed to Ensure Workforce Diversity Strategic Goals Are Achieved

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Why GAO Did This Study

NIH's success depends on its ability to attract, retain, develop, and otherwise support biomedical investigators—including those employed in its intramural research program as well as those working in its extramural program at universities, academic health centers, and other research institutions. For decades, the agency has faced challenges in supporting early career investigators and those from underrepresented groups, including ethnic and racial minorities and women. The 21st Century Cures Act included provisions that NIH coordinate policies and programs to promote early research independence and enhance the diversity of the scientific workforce.

The act also contained a provision that GAO examine NIH's efforts. GAO reviewed the actions NIH has taken to support (1) investigators beginning their biomedical careers; and (2) investigators from underrepresented groups and women. GAO analyzed NIH data from fiscal years 2013 through 2017 on grant funding for investigators by career phase and demographic status. GAO also reviewed relevant laws and NIH policies, programs, and initiatives, and interviewed NIH officials and stakeholders from the scientific research community.

What GAO Recommends

The Director of NIH should develop quantitative metrics, evaluation details, and time frames to assess NIH's efforts to diversify its scientific workforce against its diversity strategic plan goals, and take action as needed. HHS agreed with GAO's recommendation.

View GAO-18-545. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The National Institutes of Health (NIH), within the Department of Health and Human Services (HHS), plays a prominent role in the nation's biomedical research. While it employs investigators in its intramural research program, over 80 percent of its budget supports its extramural program, primarily through grant funding to investigators at other research institutions. Given this, NIH has a vested interest in supporting a robust national biomedical workforce, but the agency has acknowledged that the environment is highly competitive and many investigators find that it takes years to obtain the type and amount of funding that typically spurs research independence. GAO's analysis found that extramural investigators who had received at least one large NIH research grant during fiscal years 2013 through 2017 were more likely to receive such grants in subsequent application cycles than investigators who had not yet received such grants. In response to the 21st Century Cures Act, enacted in December 2016, NIH introduced an initiative to prioritize these grants for (1) early stage investigators, who are beginning their careers and have never received a large research grant, and (2) intermediate stage investigators, who are within 10 years of receiving their first large grant as an early stage investigator. However, it is too early to assess this new initiative, which was introduced in August 2017. NIH is currently considering revising the program to include investigators whose careers are more advanced.

NIH implemented recommendations made by internal advisory bodies to support investigators from racial and ethnic groups considered by NIH to be underrepresented in biomedical research. GAO's analysis shows disparities for underrepresented racial and ethnic groups, and for female investigators, from 2013 through 2017. For example, in 2017, about 17 percent of investigators from underrepresented racial groups—African Americans, American Indians/Alaska Natives, and Native Hawaiian/Pacific Islanders combined—who applied for large grants received them. In contrast, about 24 percent of Hispanic or Latino applicants, an underrepresented ethnic group, received such grants. Asians and whites—well represented groups—were successful in receiving large grants about 24 and 27 percent of the time, respectively. Though women represent about half of all doctorates in biological science, GAO found that women investigators employed by NIH in its intramural program comprised about one-quarter of tenured investigators. NIH has taken positive steps such as establishing the position of Chief Officer of Scientific Workforce Diversity, who in turn created a strategic workforce diversity plan, which applies to both extramural and intramural investigators. The plan includes five broad goals for expanding and supporting these investigators. However, NIH has not developed quantitative metrics, evaluation details, or specific time frames by which it could measure the agency's progress against these goals.

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Abbreviations

HHS	Department of Health and Human Services
LRP	Loan Repayment Program
NGRI	Next Generation Researchers Initiative
NIH	National Institutes of Health
non-R01e	non-R01 equivalent
R01e	R01 equivalent

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

August 10, 2018

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The National Institutes of Health (NIH), within the Department of Health and Human Services (HHS), is the nation's leader in supporting biomedical research.¹ Its mission is to advance scientific knowledge and innovation that enhances health, lengthens life, and reduces illness and disability. The agency plays a prominent role in researching life processes and many diseases and conditions, including those that are among the leading causes of death both in the United States and globally. In fiscal year 2018, NIH invested over \$37 billion in medical research. NIH relies, in part, on biomedical scientists, known as "investigators," who are employed by the agency in its intramural research program. However, most of the agency's budget—over 80 percent—is devoted to funding research that supports investigators and research personnel working at universities, medical schools, and other research institutions in its extramural research program.² Given NIH's prominent role in biomedical research, its success depends on its ability to attract, retain, develop, and otherwise support a robust national biomedical workforce, at the agency as well as in the overall biomedical field. Through its research grants NIH provides a significant source of financial support for investigators

¹In this report, "biomedical" refers to the full range of biological, biomedical, behavioral, and health sciences supported by NIH.

²Intramural investigators are NIH-employed scientists conducting research in NIH laboratories and clinics. Extramural investigators are scientists and research personnel working at universities, academic health centers, and other research institutions who receive grants and other funding from NIH to conduct research important to the agency.

participating in its extramural research program. In addition, the agency provides certain incentives, such as its Loan Repayment Program (LRP), which, according to NIH, offers educational loan repayment benefits to qualifying intramural or extramural investigators conducting research in NIH mission-critical research areas.

However, over the past several decades, NIH and its stakeholder community have been concerned about the long-term growth and stability of the nation's biomedical research workforce. For example, some have reported on the challenges extramural investigators face when beginning careers in this field. NIH has acknowledged that the environment is highly competitive and many investigators may find that it takes years to obtain the type and amount of funding that typically spurs research independence.³ A review of NIH's research grants going back to 1982 has shown a steady drop in the number of investigators younger than age 46, despite a period when funding for NIH almost tripled.⁴ Even with long-standing congressional support for early research independence and NIH funding, investigators at the early stages of their careers find it increasingly difficult to obtain their first large NIH research grant, and retain that support in subsequent years, according to NIH.

Reports have shown that increasing the number of investigators from diverse backgrounds can help maintain a stable U.S. biomedical research workforce and contributes greatly to scientific innovation; however, some have reported that achieving a diverse scientific workforce has been a challenge.⁵ Though women have seen gains in some scientific fields, they continue to lag behind men in academic and professional advancement. Further, the representation of some racial and ethnic minority groups in the biomedical sciences remains at low levels despite public and private initiatives to increase the diversity of the nation's biomedical research workforce. Certain racial groups have been found by research institutions and government agencies to be underrepresented in the biomedical

³Research independence refers to a stage when investigators have proven they can successfully develop and design research projects, obtain funding, and manage their own laboratories.

⁴Michael Levitt and Jonathan M. Levitt, "Future of Fundamental Discovery in U.S. Biomedical Research," *Proceedings of the National Academy of Sciences* (Mar. 10, 2017).

⁵See, for example, National Academies of Sciences, Engineering, and Medicine, *Expanding Underrepresented Minority Participation: America's Science and Technology Talent at the Crossroads* (Washington, D.C.: 2011), 4, 20.

research workforce.⁶ For example, the number of American Indians and Alaska Natives, African Americans or blacks, and Native Hawaiian and Pacific Islanders working in the biomedical sciences was reported by the National Academies of Sciences, Engineering, and Medicine to be disproportionately low relative to their representation in the general population. Hispanics and Latinos were also reported by the National Academies to be an underrepresented ethnic group in biomedical research.⁷ NIH considers the following racial groups to be underrepresented in biomedical research: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. For this report, we use the same definitions.

The 21st Century Cures Act (Cures Act), which was enacted in December 2016, included provisions that NIH coordinate efforts to promote and provide opportunities for investigators beginning their biomedical research careers through the Next Generation Researchers Initiative (NGRI). NIH launched this initiative and announced details regarding its implementation in August 2017. The Cures Act also included new authorities for NIH to expand its LRP—a recruitment and retention tool for both intramural and extramural investigators—to help the agency address gaps in certain research areas and also in the nation’s biomedical research workforce. The act also provides the NIH Director with the authority to raise the maximum annual loan repayment amount. Additionally, the law included a provision that we examine NIH’s efforts to support—that is attract, retain, and develop—investigators beginning their biomedical research careers as well as those from underrepresented groups, such as women, racial and ethnic minorities.⁸

⁶ *Expanding Underrepresented Minority Participation*, 22, and National Science Foundation, *Women, Minorities, and Persons with Disabilities in Science and Engineering 2015*, Special Report NSF-15-311 (Arlington, Va.: revised 2017), 2.

⁷ Whites and Asians are not considered to be underrepresented in biomedical science research based on reports from NIH and the National Science Foundation. In this report, we refer to whites and Asians as “well represented” groups.

⁸ Pub. L. No. 114-255, §§ 2021-2022, 130 Stat. 1033, 1051-1054 (2016).

This report examines the actions NIH has taken to support investigators

(1) beginning their biomedical research careers; and

(2) from underrepresented groups.

For both of our audit objectives, we reviewed relevant laws, policies, research studies, and reports about the agency's efforts and initiatives to support investigators in the beginning of their biomedical research careers, investigators from underrepresented groups, and biomedical research workforce diversity. Given the lack of data exclusive to the newly implemented Next Generation Researchers Policy—which was called for in the Cures Act and had been in place less than a year at the time we did our work—we reviewed data on NIH research grants and the demographics of the biomedical research community from fiscal years 2013 through 2017. This allowed us to provide information on NIH's funding of certain grants both before and after the enactment of the Cures Act in 2016, and to describe the agency's recent efforts to attract, retain, and develop early career investigators and biomedical research workforce diversity. We examined NIH data in the following ways:

- To identify the support provided to extramural investigators and research funding trends by gender and racial and ethnic group, we examined data on NIH applications, applicants, awardees, and awards for research project grants, career development grants, and LRP payments.⁹
- To identify trends in the representation of women and racial and ethnic groups, we examined data on the NIH intramural and extramural workforce.¹⁰

We assessed the reliability of these data by reviewing related documentation, performing data reliability checks (such as examining the data for missing values and checking values against other

⁹Most NIH funding applications are submitted by, and awarded to, institutions where the investigator is employed. However, because the investigators typically prepare the applications and conduct the work, we refer to investigators as submitting and receiving the awards. Similarly, we analyzed data based on funds awarded to applicants, not to institutions.

¹⁰For this report, underrepresented racial groups include: Black or African American, Alaskan Native or American Indian, and Native Hawaiian and other Pacific Islander. Hispanics and Latinos are an underrepresented ethnic group.

documentation), and interviewing relevant agency officials with knowledge of NIH's biomedical grants programs. On the basis of these steps, we determined that the data were sufficiently reliable for the purposes of our reporting objectives.

Finally, we interviewed relevant NIH officials about the agency's efforts to attract, retain, and develop investigators beginning their research careers and enhance diversity in the biomedical research workforce. We also interviewed stakeholders from a variety of entities within the scientific research community to obtain their perspectives on NIH's efforts. Their comments are not representative of the views of the scientific research community and our reporting of stakeholders' comments should not be interpreted as an endorsement of their views.¹¹ We considered NIH's actions to address these workforce challenges in the context of federal internal control standards for monitoring and evaluation, and best practices for strategic workforce planning and diversity management.¹²

We conducted this performance audit from October 2017 to August 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹¹We interviewed stakeholders from the following 10 organizations: the Federation of American Societies for Experimental Biology, the Association of American Medical Colleges, National Medical Association, the National Organization for the Professional Advancement of Black Chemists and Chemical Engineers, the Society for the Advancement of Chicanos/Hispanics and Native Americans in Science, the Association for Women in Science, the NIH Black Scientists Network, the National Postdoctoral Association, Rescuing Biomedical Research, and the National Academies of Sciences, Engineering, and Medicine. We also interviewed two university professors that have extensively studied the biomedical research workforce: Donna Ginther, PhD, Professor of Economics, University of Kansas, and Paula Stephan, PhD, Professor of Economics, Georgia State University.

¹²See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. See also GAO, *Diversity Management: Expert-Identified Leading Practices and Agency Examples*, GAO-05-90 (Washington, D.C.: Jan. 14, 2005) and GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, GAO-04-39 (Washington, D.C.: Dec. 11, 2003).

Background

NIH Institutes and Centers and Biomedical Research

NIH, which had total budgetary resources of \$32 billion in fiscal year 2016, is comprised of the Office of the Director and 27 institutes and centers that focus on specific diseases, particular organs, or stages in life, such as childhood or old age.¹³ As the central office at NIH, the Office of the Director establishes agency policy and is responsible for overseeing the institutes and centers to ensure that they operate in accordance with NIH's policies. The institutes and centers accomplish their missions primarily through extramural research programs. Most extramural research funding is provided for investigator-initiated research projects for which researchers, through their institutions, submit applications in response to NIH announcements. In addition to these announcements, the institutes and centers may issue more narrowly scoped solicitations, through request for proposals, for research targeting specific areas.

All extramural research project applications are to follow NIH's process of peer review, which includes two sequential levels of review. The first level involves non-governmental experts assessing the scientific merit of the proposed applications and assigning them a priority score. The second level involves advisory councils at the institute or center associated with the grant application, that, in addition to scientific merit, consider the institutes' and centers' missions and strategic plan goals and public health needs. Advisory councils review grant applications and their scores, and, based on this review, make recommendations about which

¹³Each institute and center has its own director and staff, as well as its own advisory council or board, which provides support and oversight. The institutes and centers are directly responsible for overseeing the intramural and extramural investigators they support. Most institutes and centers receive a specific appropriation from Congress to support their respective missions, research, and training.

grant applications should be awarded funding.¹⁴ The director of each institute or center makes the final extramural funding decisions.¹⁵

NIH investigators also conduct research through NIH's intramural research program. These efforts accounted for approximately 10 percent of NIH's total budgetary resources of \$32 billion in fiscal year 2016. NIH employs about 3,600 investigators working in its own laboratories and clinics. In addition, this research relies on another 6,000 investigators at various stages of research training who come to NIH for a few years to work as non-employee trainees, including about 2,500 who are postdoctoral fellows. According to NIH officials, intramural investigators are generally not allowed to apply for extramural or private grants, because their salaries are funded with the agency's appropriations.

Career Path of Independent Extramural Investigators

The career path to become an independent extramural investigator generally consists of students completing graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency. When postdoctoral research is completed, the researcher will generally seek opportunities to become an investigator at a medical research center or as a faculty member at a university and begin the process of obtaining academic tenure—that is, a full-time, permanent faculty position. Once the postdoctoral researcher becomes a faculty member, he or she can generally begin applying for large NIH research project grants. Some researchers may become affiliated with other types of research institutions and also apply for grants.

¹⁴See 42 U.S.C. §§ 282(b)(9) (the Director of NIH must ensure that NIH research undergoes peer review and advisory council review); 289a(a) (peer review); 289a-1(a)(2) (advisory council review). Peer review groups are to assess each proposed research project taking into account the following criteria, among other pertinent factors: (a) its significance, (b) the adequacy of its approach and methodology, (c) its innovativeness and originality, (d) the qualifications and experience of its principal investigator and proposed staff, (e) the scientific environment and reasonable availability of resources for it, (f) the adequacy of its plans to include both genders, minorities, children, and special populations as appropriate for its scientific goals, (g) the reasonableness of its budget and duration, and (h) the adequacy of its proposed protections for humans, animals, and the environment. 42 C.F.R. § 52h.8 (2017).

¹⁵NIH may not approve or fund any application unless it has been recommended for approval by a majority of the members of the initial peer review group and a majority of the voting members of the advisory council. The initial peer review groups recommend applications for approval by means of the scoring system. 42 U.S.C. § 289a-1(a)(2).

Investigators in medical research centers and university faculty are generally dependent on external funding to cover the cost of their research. Although biomedical investigators may be funded by other federal agencies—such as the National Science Foundation—and nonfederal sources, studies have shown that NIH is the most likely source of government funding for biomedical research.¹⁶

NIH Grants

NIH's research support for extramural investigators includes research project grants, fellowships, training grants, and career development grants. Some of the main funding mechanisms provided to institutions by NIH that fund investigators beginning their research careers include the following extramural grants:

- **Large grants.** NIH awards large renewable research project grants: R01 and R01-equivalent (R01e) grants.¹⁷ According to NIH, in fiscal year 2016, the average size of large grants was typically in excess of \$460,000 total. R01 and R01e grants are NIH's most common type of grant, according to NIH. They are generally the largest type of grant available to investigators beginning their careers and, for purposes of this report, are therefore referred to as "large" grants. Large grants provide 3 to 5 years of financial support for discrete, specified research projects. According to NIH, it is generally expected that within that period a project can be completed, results published, and sufficient time will remain for the investigator to prepare a subsequent application for a renewal or new award before funding ends.
- **Smaller grants.** While some non-R01 equivalent (non-R01e) grants may match or exceed the amount of some R01e grants, they are generally of a lesser amount and, for purposes of this report, are therefore referred to as "smaller" grants.¹⁸ According to NIH, in fiscal year 2016, smaller grants were, on average, amounts that ranged from about \$61,000 to about \$1.1 million total. These grants provide limited funding for a relatively short period of time to support a variety

¹⁶See Levitt and Levitt, "Future of Fundamental Discovery in U.S. Biomedical Research," 1.

¹⁷In this report, R01 and R01-equivalent grants are referred to as "large" grants and include the following research grant activity codes: R01, R37, RF1, DP2 and R35 grants.

¹⁸Smaller NIH research grants include the following activity codes: R00, R03, R15, R21, R25, R34, R36, R41, R43, R55, R56, R90, RL5, RL9, SC2, SC3, U43, UT1, X01, R13, S10, S15, S21, and S22 grants.

of exploratory or developmental projects, including pilot or feasibility studies, collection of preliminary data, and secondary analysis of existing data.

- **Career development grants.** Also known as K-series grants, these grants are intended to provide mentored research opportunities and career enhancement experiences to support investigators or postdoctoral fellows at various stages of their research careers.¹⁹ NIH's data show that in fiscal year 2016, career development grants were, on average, about \$178,000 total.

Extramural Investigator Career Status	NIH generally classifies the career status of an extramural investigator based on whether the investigator has received a large NIH research grant. NIH considers early career investigators to be those who meet the definition of early stage and intermediate stage investigators. ²⁰ NIH also recognizes established and “other” investigators among those who apply for research grants. Table 1 lists NIH extramural investigators’ career stages and descriptions of these stages.
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Table 1: Investigator Career Stages

Career stages	Description
Early stage investigators	Have completed graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency, whichever date is later, within the preceding 10 years, and who have not previously competed successfully for a large NIH research grant.
Intermediate stage investigators	Have received his or her first large NIH research grant as an early stage investigator within the last 10 years.
Established investigators	Have received one or more large NIH research grants.
Other investigators	Have not yet competed successfully for a large NIH research grant. Investigators in this group may have previously received funding from sources other than NIH.

Source: GAO summary of National Institutes of Health (NIH) information. | GAO-18-545

Note: We consider large NIH grants to be R01 and R01-equivalent grants. In addition, we use the terms early stage investigators, intermediate stage investigators, established investigators, and other investigators to refer to groups of investigators that NIH refers to as early stage, early established, established, and new investigators, respectively. Although both early stage investigators and other investigators have not yet successfully competed for a large NIH research grant, we are treating them separately and the data we reviewed reflects these four categories of investigators. Specifically, other investigators fall outside the 10-year window that would qualify them for early stage investigator status. NIH is currently considering developing new terms to refer to these groups.

¹⁹Career development grant activity codes include K01, K02, K05, K07, K08, K12, K18, K22, K23, K25, K26, K43, K76, K99, and KL2 grants.

²⁰NIH refers to intermediate stage investigators as “early established investigators.”

According to NIH, it generally takes an early stage investigator up to 2 years to develop a successful application for a large grant and receive funding. Typically, investigators devote between 6 months to 1 year to write their first large NIH grant application. Most of these grants, with a funding period of over 3 years, require significant preliminary data to support the proposed hypothesis contained in the application. In addition, the median average time elapsed for applicants to learn whether they have been awarded a grant is 270 days, or 9 months. According to NIH, because most investigators beginning their careers do not receive large NIH research grants on their first attempt, these investigators might apply for smaller grants. They may also apply for career development grants that are intended to provide mentored research or training opportunities.

Concerns Regarding the Stability and Diversity of the Biomedical Research Workforce

According to research by the National Academies of Sciences, Engineering, and Medicine, and others, the biomedical research workforce is growing older at a rate that is disproportionate to the general American labor force. Some stakeholders in the scientific community have voiced concerns that large NIH research grants that can launch early career investigators are often being awarded to established investigators rather than early stage and intermediate stage investigators. For example, a recent National Academies report pointed out that between 1998 and 2003, the NIH budget grew from \$13 billion to \$27 billion, but the percentage of grants awarded to investigators who were in the early stages of their careers steadily declined.²¹ Many in the field have reported on the need to support investigators who are researching varied biomedical issues in order to maximize the number of new discoveries. Further, stakeholders within the scientific research community have reported on the uncertain path that investigators may encounter early in their careers and the prospect that they will ultimately pursue other career options.²²

Several reports have found that certain racial and ethnic groups are underrepresented in the biomedical research workforce and in science. These reports have also provided data on gender workforce disparities. For example, a 2011 publication by the National Academies of Sciences,

²¹National Academies of Sciences, Engineering, and Medicine, *The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through* (Washington, D.C.: 2018), 32.

²²*The Next Generation*, 2.

Engineering, and Medicine showed that, in 2006, underrepresented minorities made up about 29 percent of the U.S. population, but, in 2007, were awarded about 5 percent of science and engineering doctorates.²³ Other studies have shown significant research funding disparities for investigators from underrepresented groups that apply to NIH for large research grants, such as R01 grants. In 2011, NIH funded a study that examined the association between grant recipients and the applicants' race and ethnicity. The study found that R01 applicants that self-identified as African American were 13 percentage points less likely than white applicants to receive these grants.²⁴ After controlling for other variables—including educational background, training, previous research grants, and publication record—African American applicants were 10 percentage points less likely to be awarded such a grant than a white applicant. Further, while women comprise about half of the postdoctoral graduates for the biological sciences in the United States, studies have shown a disparity in the number of female investigators in senior science research positions at universities.²⁵ This disparity may result in a smaller number of female investigators among NIH grant applicants and may further contribute to their underrepresentation in certain facets of science. However, we previously reported that once female investigators apply for NIH grants, their likelihood of receiving NIH grants is the same as their male counterparts.²⁶

²³ *Expanding Underrepresented Minority Participation*, 4, 20. This report considers the following racial and ethnic minority groups to be underrepresented in science and engineering: African Americans, Native American and Alaskan Natives, Native Hawaiians and Pacific Islanders and Hispanic and Latino Americans.

²⁴ This study focused on R01 grant applicants, which, for purposes of this report, we refer to as large grants. D. K. Ginther, W. T. Schaffer, J. Schnell, B. Masimore, F. Liu, L. L. Haak, and R. Kington, "Race, Ethnicity, and NIH Research Awards," *Science*, vol. 333 (2011).

²⁵ T. J. Ley and B. H. Hamilton, "The Gender Gap in NIH Grant Applications," *Science*, vol. 322 (2008).

²⁶ GAO, *Women in STEM Research: Better Data and Information Sharing Could Improve Oversight of Federal Grant-making and Title IX Compliance*, GAO-16-14 (Washington, D.C.: Dec. 3, 2015).

NIH Has Promoted Efforts to Support Early and Intermediate Stage Investigators, but Those Who Have Not Yet Received a Large NIH Research Grant Remain Less Competitive

NIH Has Promoted Programs and Policies to Support Early and Intermediate Stage Extramural Investigators, but It Is Too Early to Assess Its Most Recent Initiative

Over the last 10 years, NIH has introduced programs and policies to support extramural investigators competing for their first large NIH research grant that leads to research independence. NIH developed certain programs to fund extramural researchers with the goal of stabilizing the biomedical research workforce. These targeted programs were intended to promote support for extramural investigators that had not yet received a large NIH research grant. The various programs include both large and smaller research grants, career development grants, and student loan repayments. Of particular note are the NIH Director's New Innovator Award, which is intended to support investigators beginning their research careers with reviewer-determined highly novel research; and the Director's Early Independence Award, which is intended to support reviewer-determined exceptional investigators who wish to pursue independent research directly, forgoing the traditional postdoctoral training period. In addition, the Pathway to Independence Award provides investigators beginning their research careers with a mentored research experience, which may lead to independent research positions.

Some institutes and centers have established their own programs to support investigators beginning their research careers. For example, a subset of the National Institute of General Medical Sciences' "Maximizing Investigators' Research Award program" targets funding for laboratories led by an early stage investigator. In addition, the National Institute of Arthritis and Musculoskeletal and Skin Diseases' "Supplements to Advance Research from Projects to Programs," supports intermediate stage investigators by providing supplemental funding to existing

research projects to encourage broader innovation and exploration of high-risk ideas.

In addition, NIH's LRP is designed to help recruit and retain highly qualified individuals into biomedical research careers.²⁷ This program provides student loan repayments in return for a commitment to engage in NIH mission-relevant and certain statutorily-defined approved research.²⁸ We examined the funding rates of early stage and intermediate stage extramural and intramural investigators who applied for both initial and renewal LRP payments.²⁹

LRP payments to extramural investigators: The LRP funding rate (awardees/applicants) for extramural investigators applying for total (both initial and renewal) payments between fiscal years 2013 through 2017 was about 50 percent. During this period, 8,186 extramural investigators applied for initial LRP payments and 3,206 received them; 5,131 extramural investigators applied for renewal payments and 3,426 received them. Therefore, the funding rates were 39 percent for initial applicants and 67 percent for renewal applicants. Early stage and intermediate stage investigators had similar funding rates in receiving LRP payments during the 5-year period, though there was some variation each year. Early stage and intermediate stage investigators seeking initial LRP payments had funding rates of about 40 percent and 35 percent, respectively. Both of these categories of investigators seeking renewal LRP payments had a funding rate of 67 percent.

LRP payments to intramural investigators: The LRP funding rate (awardees/applicants) for intramural investigators applying for

²⁷According to NIH, the extramural LRP does not require applicants to have research grant funding from NIH to participate in the program. Participation in the LRP program is based on an applicant's potential to build and sustain a research career. Extramural and intramural investigators who receive LRP payments may apply to renew their participation in the program as long as they meet LRP eligibility requirements. 42 U.S.C. §§ 288-1 (intramural) and 288-2 (extramural).

²⁸Pub. L. No. 114-255, § 2022(a)(4) and (b)(4), 130 Stat. 1033, 1052-1054 (2016).

²⁹NIH officials told us they plan to collect information on early and intermediate stage extramural investigators separately. The agency will intentionally track how these investigators perform, compared to other investigators applying for grants. However, intramural investigators do not compete for grants. Data on LRP payments made to intramural investigators in the early stages and intermediate stages of their careers are therefore combined.

total (both initial and renewal) LRP payments from fiscal years 2013 through 2017 was about 87 percent; 397 intramural investigators applied for both initial and renewal LRP payments, and NIH funded 345 of the applicants. The funding rate for applicants seeking initial LRP payments during this 5-year period was about 83 percent, whereas the funding rate for those applying to renewal LRP payments was 90 percent.

NIH also implemented policies to improve opportunities for early and intermediate stage extramural investigators. For example, to address the concerns about established investigators receiving a disproportionate share of research funds, NIH established its Early Stage Investigator Priority Policy in 2008. The policy specified that early stage investigator status would be considered a factor when applications were being selected for award.³⁰ Studies have shown that under the Early Stage Investigator Priority Policy, grants being awarded to early stage investigators stopped declining and remained flat for several years. They also showed that the field of biomedical research continued to be very competitive for early stage investigators.³¹

However, some have expressed concern that these accomplishments are not sufficient. For example, according to a recent report by the National Academies of Sciences, Engineering, and Medicine, a variety of steps have been taken over the years to address the challenges facing early and intermediate stage investigators, but these efforts have not resolved the underlying problems that make it difficult for them to establish their careers.³²

³⁰Prior to the implementation of its Early Stage Investigator Policy in November 2008, NIH had specified as its goal comparable success rates for “other” and “established” investigators submitting new large NIH research grant applications. It also indicated that half of the “other investigator” pool of career investigators each year should be “early stage investigators.” Other related policies are listed on NIH’s website at <https://grants.nih.gov/policy/early-investigators/history.htm> (accessed Aug. 2, 2018).

³¹See Levitt and Levitt, “Future of Fundamental Discovery in U.S. Biomedical Research,” 1; and B. Alberts, M.W. Kirschner, S. Tilghman, H. Varmus, “Rescuing U.S. Biomedical Research from Its Systemic Flaws,” *Proceedings of the National Academy of Sciences*, vol. 111, no. 16, 5773-5777 (Apr. 22, 2014).

³²*The Next Generation.* The report notes that stakeholders other than NIH, such as universities and research institutions, also need to play a role in developing and implementing solutions to help address the challenges early stage and intermediate stage investigators encounter in establishing their careers.

More recently, the Cures Act required that NIH implement the NGRI, which the agency established in August 2017. NIH's Office of the Director, which oversees the initiative and its implementation, directed the NIH institutes and centers to reprioritize large NIH research grant support for early stage and intermediate stage investigators. The policy's stated goal for fiscal year 2017 was to increase the number of large NIH research grants provided to both early stage investigators and intermediate stage investigators by 200 grants each compared to the number that were awarded in fiscal year 2016. These 400 grants would redirect approximately \$210 million from NIH's base budget to support additional early career investigators in the first year of NGRI's implementation. However, with only one month to implement the policy, NIH did not meet this goal. From fiscal year 2016 to fiscal year 2017, the number of large NIH research grants awarded increased by 57 for early stage investigators and decreased by 2 for intermediate stage investigators. Similarly, the goal to increase funding for the additional 400 grants was not met; funding increased by about \$107 million during this period. Given that this initiative is in the early stages and its goals were set late in fiscal year 2017, it is too early to fully assess the impact of this effort.

According to NIH officials, the agency is in the process of reevaluating which investigators should be the focus of the NGRI initiative and may revise the program to include investigators whose careers are more advanced. NIH officials stated that the NGRI policy's intention to direct more research funding to early stage investigators will remain in place. However, NIH's NGRI Working Group no longer designates intermediate stage investigators—or what it calls “early established investigators”—as a distinct group. NIH's current definition—that of being within 10 years of receiving a first large NIH research grant as an early stage investigator—includes investigators who could have completed their graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency between 15 and 20 years ago. According to NIH officials, NIH's working group is considering broadening this definition even further. It is concerned that intermediate stage investigators, facing increasing pressure to secure additional sources of research funding to prevent the closure of their laboratories if their first large NIH research grant is not renewed, could lose all NIH support and become likely to leave the biomedical research workforce. Therefore, the working group is considering a different approach for all established investigators, with a focus on all meritorious investigators (regardless of career stage) who are doing high quality research, yet are still at risk for losing all NIH funding. Specifically, NIH officials said the working group

plans to reevaluate ways that it can provide additional, prioritized support to these investigators in order to further their career trajectories. The working group may recommend to NIH that the NGRI be expanded to also target support for certain investigators whose careers are in more advanced stages, rather than just those in the early stages of their careers.

In addition, NIH has not yet implemented the expansion of its LRP as directed by the Cures Act.³³ The Cures Act amended the LRP by increasing the eligible annual loan repayment amount from a maximum of \$35,000 to a maximum of \$50,000. The act also gave the NIH Director the discretion to amend the research categories that are eligible for intramural or extramural loan repayment based on emerging scientific priorities or workforce needs. The agency has established a working group to provide recommendations to the NIH Director regarding any suggested structural changes and associated timelines for implementation. NIH officials told us that they are awaiting recommendations from this working group on how to use the agency's new authorities. They said that they expect to implement program changes to the LRP, as permitted by the Cures Act, by fiscal year 2020.

³³NIH offers several LRPs that provide student loan repayment to intramural and extramural investigators who are engaged in certain statutorily defined intramural and extramural research programs. The intramural LRPs support three research categories including (1) clinical research by individuals from disadvantaged backgrounds, (2) AIDS research, and (3) general research. The extramural loan repayment program supports five research categories including (1) clinical research, (2) minority health and health disparities research, (3) contraception and infertility research, (4) pediatric research, and (5) clinical research by individuals from disadvantaged backgrounds.

Investigators Who Had Received at Least One Large NIH Grant Had Higher Funding Rates for All Grant Types Compared to Those Who Had Not

Our analysis shows that intermediate stage investigators are more successful at competing for grants than early stage investigators.³⁴ Our examination of the trends of NIH grant data showed that the applicant funding rates (awardees/applicants) for investigators who had previously received an initial large NIH research grant was greater than the applicant funding rates for investigators who had never received such a grant.³⁵ We analyzed 5 years of grant data to determine an overall perspective of funding rates from fiscal years 2013 through 2017. We found that intermediate stage and established investigators—groups comprised of investigators who had already received their first large grant award—had greater applicant funding rates for all three grant types compared to early stage and other investigators. For example, we found that in fiscal year 2017, the most recent year for which data were available, intermediate stage investigators had funding rates that were comparable to those of established investigators. Investigators that had not yet been awarded their first large NIH research grant—early stage investigators and other investigators—were not as successful when competing for large NIH research grants, small grants, or career development grants.³⁶ (See table 2.)

³⁴NIH uses the term “successful” to indicate that investigators applied for and received competitively awarded grants.

³⁵We use the term “initial” throughout the report to describe NIH’s grant applications. NIH classifies initial grant applications as Type 1 grants, and competitive renewal grant applications are classified as Type 2 grants. Specifically, Type 2 grant applications are requests for additional funding for a period subsequent to that provided by a current award.

³⁶Other investigators are those who have not yet competed successfully for a large NIH research grant.

Table 2: NIH Grant Funding Rates (Awardees/Applicants), by Grant Type and Extramural Investigator Career Stage for Fiscal Year 2017

NIH grant type	Percentage of applicants receiving awards (Awardees/Applicants)			
	Established investigators	Intermediate stage investigators	Early stage investigators	Other investigators
Large research grants	29 (3,761/13,193)	30 (1,284/4,315)	25 (1,053/4,258)	15 (951/6,186)
Smaller research grants	30 (2,048/6,751)	30 (661/2,169)	20 (896/4,578)	16 (1,475/9,517)
Career development grants	51 (70/137)	45 (30/66)	32 (751/2,326)	25 (194/778)

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Notes:

The analysis of large NIH research grants in this table includes investigators that were awarded their first, or initial, large NIH research grant and those who received a renewal of a large NIH research grant, combined.

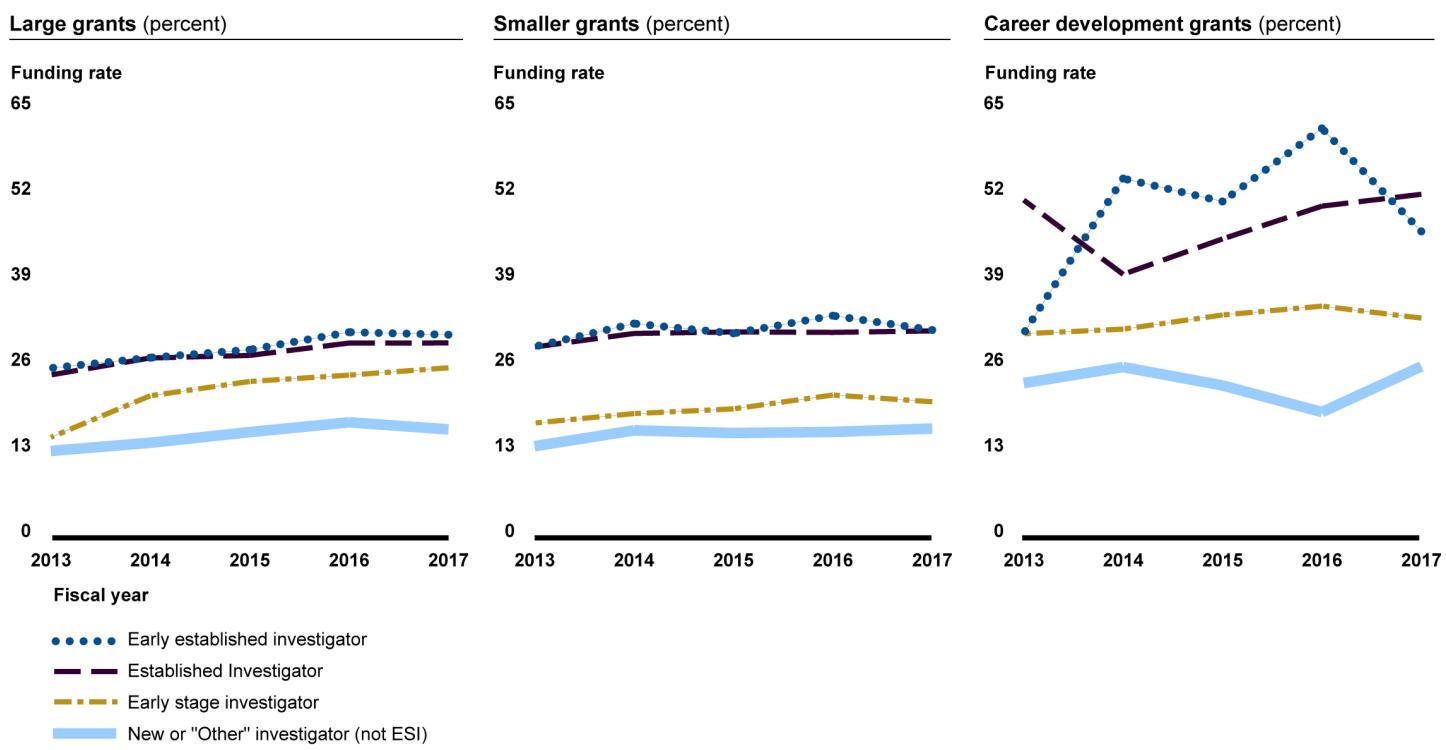
These percentages reflect the funding rates of each of NIH's career investigator cohorts. Early stage investigators have completed graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency, whichever date is later, within the preceding 10 years, and have not previously competed successfully for a large NIH research grant. Intermediate stage investigators have received their first large NIH research grant as an early stage investigator. Established investigators have received one or more large NIH research grants. Other investigators have not yet competed successfully for a large NIH research grant. Investigators in this group may have previously received funding from sources other than NIH and be at varying stages in their careers.

We consider large NIH research grants to be R01 and R01-equivalent (R01e) grants and smaller grants to be non-R01e grants. R01 and R01e grants are the most common grants used to support research and funds typically support labs, equipment, and salaries for the research. Non-R01e grants include smaller, exploratory, or developmental grants. Career development grants refer to K-series grants, which are intended to provide mentored training or career development support to investigators beginning their research careers.

We also found that over time—from fiscal years 2013 through 2017—intermediate stage investigators and established investigators had greater applicant funding rates for all three grant types compared to early stage and other investigators. Of the investigators that had not yet been awarded their first large NIH research grant, early stage investigators were more successful in competing for NIH grants than the other investigators that were outside of the 10-year period of having completed their graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency. For instance, we found that early stage investigator funding rates ranged from about 5 to 11 percentage points lower than intermediate stage or established investigators for each of the five fiscal years examined. Similarly, other investigator funding rates ranged from about 12 to 14 percentage points

lower than intermediate stage or established investigators for each of the five fiscal years examined. (See fig. 1.)

Figure 1: NIH Grant Funding Rates Awarded to NIH's Extramural Investigators, by Grant Type, Investigator Career Stage, and by Percent for Fiscal Years 2013 through 2017



Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Notes:

Early stage investigators have completed graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency, whichever date is later, within the preceding 10 years, and have not previously competed successfully for a large NIH research grant. Intermediate stage investigators have received their first large NIH research grant as an early stage investigator. Established investigators have received one or more large NIH research grants. Other investigators have not yet competed successfully for a large NIH research grant. Investigators in this group may have previously received funding from sources other than NIH and be at varying stages in their careers.

We consider large NIH research grants to be R01 and R01-equivalent (R01e) grants and smaller grants to be non-R01e grants. R01 and R01e grants are the most common grants used to support research and funds typically support labs, equipment, and salaries for the research. Non-R01e grants include smaller, exploratory, or developmental grants. Career development grants refer to K-series grants, which are intended to provide mentored training or career development support to investigators beginning their research careers.

Finally, we found that during this 5-year period, two of the four extramural investigator groups were more likely to receive large, small, and career

development grants than the other two groups. Specifically, investigators beginning their research careers—the early stage and intermediate stage investigators—were more likely to receive these grants. Although early stage investigators were more likely than intermediate stage investigators to apply for smaller research grants (about 4,500 applicants compared to about 2,000 applicants, respectively) and career development grants (about 2,000 applicants compared to about 50 applicants, respectively), intermediate stage investigators were still more successful in competing for these grants, as well as the large NIH research grants. For more information on the trends in the number of grants awarded to early stage and intermediate stage investigators, by award type, for fiscal years 2013 through 2017, see appendix I.

NIH Has Taken Steps to Support a Diverse Scientific Workforce, but Disparities Persist and Its Diversity Efforts Have Not Been Fully Evaluated

NIH Established Working Groups and Programs to Support Investigators from Underrepresented Groups

Over the last 7 years, NIH established advisory groups and other programs to determine how best to support extramural and intramural investigators from underrepresented groups.³⁷ NIH’s Working Group on Diversity in the Biomedical Research Workforce was established in response to the 2011 NIH study that examined the association between R01 grant recipients and the applicants’ race and ethnicity.³⁸ NIH directed

³⁷ NIH considers the following racial groups to be underrepresented in biomedical research: American Indians or Alaska Natives, Blacks or African Americans, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Though not represented in the data we analyzed, NIH also considers the disabled and individuals from economic and educationally disadvantaged backgrounds as underrepresented populations in biomedical, clinical, and behavioral and social sciences.

³⁸ Ginther, Schaffer, Schnell, Masimore, Liu, Haak, and Kington, “Race, Ethnicity, and NIH Research Awards,” 1015. R01 grants are one type of “large” NIH grant that provides an investigator 3 to 5 years of financial support for discrete, specified research projects.

the group to provide recommendations to improve retention of underrepresented minorities, the disabled, and scientists from disadvantaged backgrounds. In June 2012, the working group issued 13 recommendations, which, we found that NIH uses as the foundation of some NIH-wide efforts to diversify the extramural and intramural biomedical research workforce.³⁹ Other advisory groups that have examined or are currently examining related topics include the following:

- NIH Working Group on Women in Biomedical Careers was established in 2007 in response to a report from the National Academies of Sciences, Engineering, and Medicine on barriers women in biomedical science experience in advancing their careers.⁴⁰ It produced a workshop and report in 2008 on best practices for sustaining the careers of women in biomedical research;
- Addressing Gender Inequality in the NIH Intramural Research Program Action Task Force was established in 2016 in response to data showing women are underrepresented in top NIH research positions. It produced recommendations in 2017 aimed at ensuring that female and male investigators have equal opportunities in the intramural research program at NIH, among other things;⁴¹ and
- African-American/Black R01 Funding Disparities Working Group was established in response to the 2011 NIH study that found a funding disparity between blacks and whites applying for R01 grants. This group analyzed data on the funding rates of applicants that self-identify as African American or black compared to other racial groups.⁴²

³⁹National Institutes of Health, *Draft Report of the Advisory Committee to the Director Working Group on Diversity in the Biomedical Research Workforce* (Bethesda, Md.: June 2012).

⁴⁰National Academies of Sciences, Engineering, and Medicine, *Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering* (Washington, D.C.: 2007).

⁴¹According to NIH officials, the task force recommendations align with general principles of institutional change and transparency in data collection and public dissemination and, therefore, apply to other underrepresented groups.

⁴²See Ginther, Schaffer, Schnell, Masimore, Liu, Haak, and Kington, "Race, Ethnicity, and NIH Research Awards," 1015. The African-American/Black R01 Funding Disparities Working Group focuses solely on the R01 research grant and not R01 equivalent research grants.

NIH has acted on some of the advisory groups' recommendations. For example, in response to recommendations made by the Diversity in the Biomedical Research Workforce advisory group, the agency hired a Chief Officer of Scientific Workforce Diversity in 2014; implemented the three-tiered Diversity Program Consortium, which includes the Building Infrastructure Leading to Diversity program, the National Research Mentoring Network, and the Coordination and Evaluation Center; and established a permanent advisory group on diversity.⁴³ NIH also developed a "toolkit" that includes training modules to educate intramural investigator search committee members on biases that can lead to a less diverse workforce, among other things.⁴⁴ In fiscal year 2017, NIH created an Equity Committee to address recommendations made by the Addressing Gender Inequality in the NIH Intramural Research Program Action Task Force to further examine concerns about parity between male and female intramural investigators and other diversity issues.

Other NIH-wide policies and programs may also help to attract, retain, and develop investigators from underrepresented groups. The 24 NIH institutes and centers that fund research and the Office of the Director provide funds for its investigators, called research supplements, to recruit graduate students, postdoctoral fellows, and others from underrepresented racial and ethnic groups, as well as those with disabilities and from economically disadvantaged backgrounds.⁴⁵ These funds provide graduate students, postdoctoral fellows, and others an opportunity to conduct research and be mentored by an investigator supported by the specific NIH institute or center or office. Some

⁴³The Building Infrastructure Leading to Diversity program provided training grants to 10 universities to learn how to attract students from diverse backgrounds into the biomedical research workforce. The National Research Mentoring Network matches mentors from various scientific disciplines to students and postdoctoral researchers to enhance their training and career development. It also provides professional networking opportunities and opportunities to master grant writing skills.

⁴⁴The training addresses situations such as search committee members preferring that prospective investigators have advanced degrees from certain leading research institutions and have published work in specific scientific journals. These biases may cause the search committee member to disregard investigators from other, more diverse institutions, such as historically black colleges and universities, adversely affecting the diversity of the workforce. These biases also have implications for extramural investigators seeking NIH research grants.

⁴⁵Research supplements may also be used to recruit and provide research opportunities to high school students, undergraduates, and early-stage investigators from racial and ethnic groups underrepresented in the biomedical research workforce.

stakeholders we interviewed said that the agency's LRP also may help to retain investigators from underrepresented groups, noting that the student loan debt for African American or black graduate students is higher than that of white graduate students.⁴⁶ Physicians from a professional organization we interviewed said that the LRP helps to attract physician scientists from underrepresented groups into research careers. Physicians we interviewed stressed the importance of the LRP to attract physician scientists into research careers, because these scientists often have significant medical school debt. Our analysis of extramural LRP data showed that, in 2017, African Americans or black, non-Hispanics had a funding rate of about 34 percent for receiving an LRP payment. White, non-Hispanic applicants had a funding rate for receiving an LRP payment of about 52 percent.⁴⁷ More recently, the National Academies of Sciences, Engineering, and Medicine recommended that NIH make the LRP available to all individuals pursuing biomedical physician-scientist researcher careers, regardless of their research area or clinical specialty. They also suggested NIH increase the monetary value of loan repayment to reflect the debt burden of current medical trainees.⁴⁸ Some stakeholders said that NIH's family friendly policies, such as reimbursement for child care expenses and parental leave, may also help address work-life balance issues for female investigators that may otherwise forego some research duties to care for young children.⁴⁹

Additionally, many—at least 17 of 27—of NIH's institutes and centers have established their own policies and programs to attract, retain, and develop investigators from underrepresented groups. For example, the National Cancer Institute initiated the Continuing Umbrella of Research Experiences program to provide training and career development opportunities to enhance and increase diversity in the cancer research workforce. This program offers research opportunities and development to future and current scientists from underrepresented groups from middle

⁴⁶J. Scott-Clayton and J. Li, "Black-White Disparity in Student Loan Debt More Than Triples After Graduation," *Evidence Speaks Reports*, vol. 2, no. 3 (Washington, D.C.: Brookings Institution, 2016).

⁴⁷Our analysis of LRP data includes investigators that were awarded their first, or initial, loan repayment amount and those who received a loan repayment renewal combined.

⁴⁸*The Next Generation*, 10.

⁴⁹For more information on NIH's Family Friendly Initiatives, see https://grants.nih.gov/grants/family_friendly.htm (accessed Aug. 2, 2018).

school students to investigators who have yet to achieve research independence.⁵⁰

NIH Research Funding and Workforce Data Shows that Disparities Persist for Underrepresented Groups

NIH Research Grant Applicants

Although NIH has implemented numerous diversity-related efforts, our analysis of NIH research grant funding and intramural workforce data from fiscal years 2013 through 2017 shows that some disparities persist for investigators from underrepresented racial and ethnic groups, and for female investigators.

Our analysis of NIH data shows that investigators from underrepresented racial and ethnic groups comprise a small percentage of applicants. For example, in fiscal year 2017, applicants from underrepresented racial groups—that is, American Indian or Alaskan Native, African American or black, and Native Hawaiians and Pacific Islanders—were 0.2 percent, 1.8 percent, and 0.1 percent, respectively, of all applicants for large NIH research grants.⁵¹ Applicants from underrepresented ethnic groups—Hispanics or Latinos—comprised 4.3 percent of the applicants for large NIH research grants.⁵² (See table 3.) In contrast, white applicants were about 64 percent of all applicants for large NIH grants in fiscal year 2017. Investigators from underrepresented racial and ethnic groups also comprise a smaller number of applicants than other groups for smaller NIH grants and career development grants.

⁵⁰For more information on NIH programs related to enhancing biomedical research workforce diversity, see <https://researchtraining.nih.gov/> and <https://extramural-diversity.nih.gov/> (accessed Aug. 1, 2018).

⁵¹NIH considers the following racial groups to be underrepresented in biomedical research: American Indians or Alaska Natives, Blacks or African Americans, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. NIH also considers the disabled and individuals from economic and educationally disadvantaged backgrounds as underrepresented populations in biomedical, clinical, and behavioral and social sciences.

⁵²Data from the National Science Foundation shows that, in 2014, about 8 percent of science and engineering doctoral degrees were awarded to black, Hispanic, and Alaska Native or American Indian graduates.

Table 3: Applicants for Large NIH Research Grants by Racial and Ethnic Group for Fiscal Years 2013 through 2017

	Fiscal year Number (percentage of NIH Total)				
	2013	2014	2015	2016	2017
<i>Underrepresented racial group</i>					
American Indian or Alaska Native	51 (0.2)	50 (0.2)	47 (0.2)	41 (0.2)	50 (0.2)
Black or African-American	425 (1.7)	416 (1.6)	435 (1.7)	481 (1.8)	505 (1.8)
Native Hawaiians and other Pacific Islanders	18 (0.1)	17 (0.1)	20 (0.1)	18 (0.1)	20 (0.1)
<i>Underrepresented ethnic group</i>					
Hispanic or Latino	1,034 (4.1)	984 (3.9)	1,062 (4.1)	1,171 (4.3)	1,194 (4.3)
<i>Well represented racial group</i>					
Asian	5,266 (20.7)	5,379 (21.2)	5,674 (21.7)	6,060 (22.2)	6,482 (23.2)
White	16,918 (66.4)	16,807 (66.2)	17,210 (65.7)	17,842 (65.3)	17,774 (63.6)

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Notes:

NIH considers the following racial groups to be underrepresented in biomedical research: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Whites and Asians are not considered by NIH to be underrepresented in biomedical science research. In this report, we refer to whites and Asians as "well represented" groups.

Applicants for NIH large grants are permitted to self-select a racial group and ethnicity group on their grant applications. Therefore, applicants in the Hispanic or Latino group may also be counted in one of the racial groups. Additional applicants identified as multiracial or did not specify their race. These applicants represented about 1 percent and about 10 percent, respectively, of all applicants in each of these years; therefore, the data presented may underestimate the actual number of applicants from underrepresented groups.

We consider large NIH research grants to be R01 and R01-equivalent grants.

Among grant applicants from underrepresented racial groups, African American or black applicants were consistently the largest group represented.⁵³ For example, in 2017, among underrepresented racial groups, African American or black applicants were named as investigators on about 88 percent of applications for large NIH research grants, about 89 percent of applications for smaller NIH grants, and about

⁵³ NIH considers the following racial groups to be underrepresented in biomedical research—that is, groups whose numbers in the biomedical sciences are disproportionately low relative to their numbers in the general population: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Whites and Asians are not considered to be underrepresented in biomedical science research. In this report, we refer to whites and Asians as "well represented" groups.

92 percent of career development grant applications. Hispanics and Latinos were about 5 percent of applicants for smaller NIH grants and about 6 percent of applicants for career development grants in 2017.

According to data published by the National Science Foundation in 2017, women represent slightly more than half of all doctorates in biological sciences. However, from 2013 through 2017, women represented less than one-quarter of all tenured NIH intramural investigators.⁵⁴ For example, in 2017, 191, (23 percent) of NIH's 822 intramural tenured investigators were women. In addition, in 2017, 79, (37 percent), of NIH's 211 tenure-track intramural investigators were women. Further, in fiscal years 2013 through 2017, nearly one-third of all extramural investigators that applied for large grants were women. (See table 4.) Nearly one-third of all applicants for smaller research grants, and close to half of all applicants for NIH career development grants, were women. (See app. II for information on the number of smaller and career development grant applicants by racial and ethnic groups and gender.)

Table 4: Applicants for Large NIH Research Grants by Gender for Fiscal Years 2013 through 2017

Gender	Fiscal year				
	2013	2014	2015	2016	2017
Men	17,106 (67.2)	16,924 (66.6)	17,405 (66.5)	17,895 (65.4)	18,064 (64.6)
Women	7,682 (30.2)	7,736 (30.5)	7,930 (30.3)	8,519 (31.2)	8,808 (31.5)
No gender identified	687 (2.7)	744 (2.9)	844 (3.2)	932 (3.4)	1,080 (3.9)
Total	25,475	25,404	26,179	27,346	27,952

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: We consider large NIH grants to be R01 and R01-equivalent grants.

Stakeholders from 8 of the 12 entities we interviewed suggested potential reasons why the number of NIH research grant applicants among underrepresented racial and ethnic groups and for women may be limited. Attrition of biomedical science doctoral students and early career investigators from these groups is one explanation. Some stakeholders said that, while in graduate school, students from these groups may be

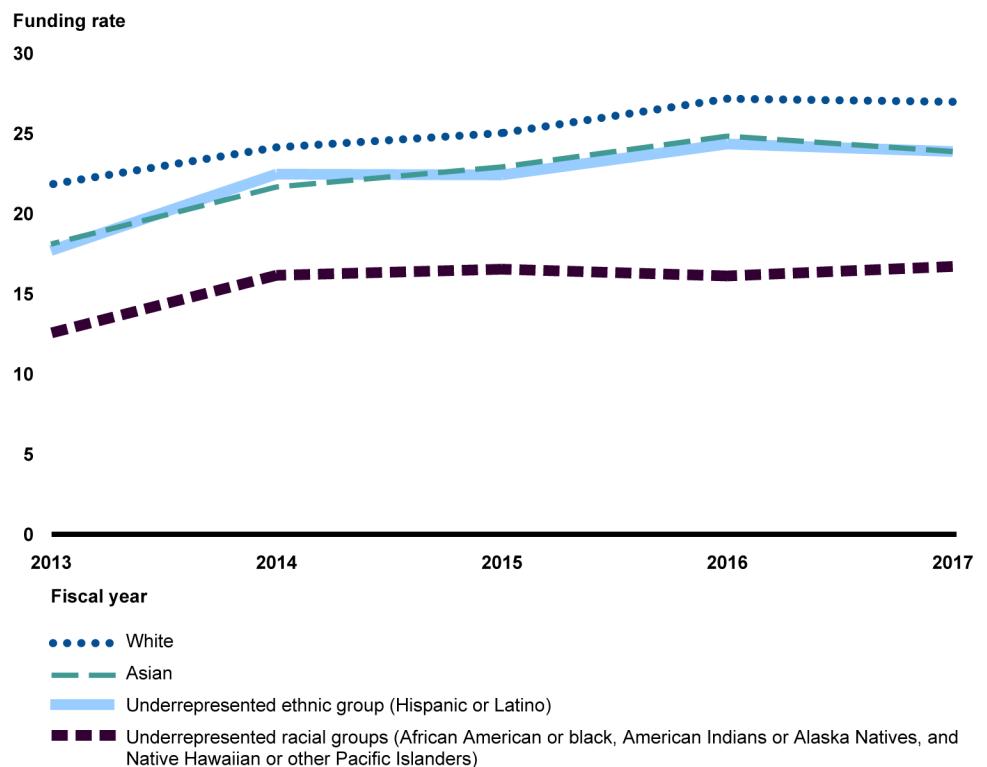
⁵⁴Intramural researchers at NIH are considered to be either on a tenure track or tenured. Tenured intramural investigators may have a permanent position at NIH. Some stakeholders we interviewed and research has noted the lack of women in tenure-track positions at universities; however, they said those opportunities have steadily increased over time, especially for women from underrepresented racial groups.

discouraged from pursuing a biomedical research career as a result of implicit bias that they encountered with their mentors. Some stakeholders said lower numbers among women investigators is the result of decisions of some to start a family in the early stages of their careers, and further noted the difficulty in re-entering the biomedical research workforce. In addition, some stakeholders said that students from underrepresented groups may lack exposure to a sufficiently rigorous education in mathematics or the sciences prior to entering college, resulting in the low numbers of biomedical researchers from these groups. Others said the low numbers of investigators from these groups makes studying this issue difficult due to a small sample size. Additional administrative demands placed on individuals who pursue careers as investigators also affect the number of applicants. For example, some stakeholders said that once investigators from an underrepresented group attain faculty positions—particularly if there are few faculty members from such groups—they are frequently tasked with additional administrative duties. We were told that, often, they are selected because they may be one of a handful of members of underrepresented groups at some institutions. Their additional duties include participation on institutional committees as well as mentoring, particularly undergraduate or graduate students from underrepresented groups. In addition, representatives of one stakeholder group said that some research faculty from underrepresented groups feel additional pressure to participate in such activities, because their absence would be more apparent and they worry that this may adversely affect them. Stakeholders also told us that additional duties are time consuming and leave less time to devote to applying for grant funding. They said that some biomedical graduate students from underrepresented groups decide to pursue other fields, because of the competing demands associated with being an academic, such as grant writing and teaching responsibilities.

NIH Research Grant Applicant Funding Rates

Our analysis of NIH data from fiscal years 2013 through 2017 also shows that the funding rate for applicants from underrepresented racial groups applying for large and small NIH grants lags behind that of white applicants. For example, in fiscal year 2017, the applicant funding rate for large grants was about 17 percent for underrepresented racial groups and about 24 percent for Hispanics and Latinos. The funding rate for white applicants was about 27 percent. (See fig.2.)

Figure 2: Large NIH Research Grant Applicant Funding Rate (Awardees/Applicants) by Racial and Ethnic Group for Fiscal Years 2013 through 2017



Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Notes:

NIH considers the following racial groups to be underrepresented in biomedical research—that is, groups whose numbers in the biomedical sciences are disproportionately low relative to their numbers in the general population: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. Whites and Asians are not considered by NIH to be underrepresented in biomedical science research. In this report, we refer to whites and Asians as “well represented” groups. Additional applicants identified as multiracial or did not specify their race. These applicants represented about 1 percent and about 10 percent, respectively, of all applicants in each of these years, and are not represented in this figure. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research.

We consider large NIH grants to be R01 and R01-equivalent grants. The analysis of large NIH research grants in this figure includes investigators that were awarded their first, or initial, large NIH research grant and those who received a renewal of a large NIH research grant, combined.

Among underrepresented racial groups, African American or black applicants consistently had a lower funding rate for large and smaller grants than well represented groups during this period (see table 5).

Table 5: Large NIH Research Grant Awardees and Funding Rate by Racial and Ethnic Group for Fiscal Years 2013 through 2017

	Fiscal year				
	Number of awardees (funding rate)				
	2013	2014	2015	2016	2017
<i>Underrepresented racial group</i>					
American Indian or Alaska Native	# (19.6)	12 (24.0)	15 (31.9)	# (22.0)	# (10.0)
Black or African-American	52 (12.2)	63 (15.1)	63 (14.5)	75 (15.6)	87 (17.2)
Native Hawaiians and other Pacific Islanders	# (0.0)	# (17.7)	# (25.0)	# (16.7)	# (20.0)
<i>Underrepresented ethnic group</i>					
Hispanic or Latino	183 (17.7)	221 (22.5)	238 (22.4)	285 (24.3)	285 (23.9)
<i>Well represented racial groups</i>					
Asian	953 (18.1)	1,165 (21.7)	1,300 (22.9)	1,505 (24.8)	1,547 (23.9)
White	3,692 (21.8)	4,056 (24.1)	4,306 (25.0)	4,845 (27.2)	4,794 (27.0)

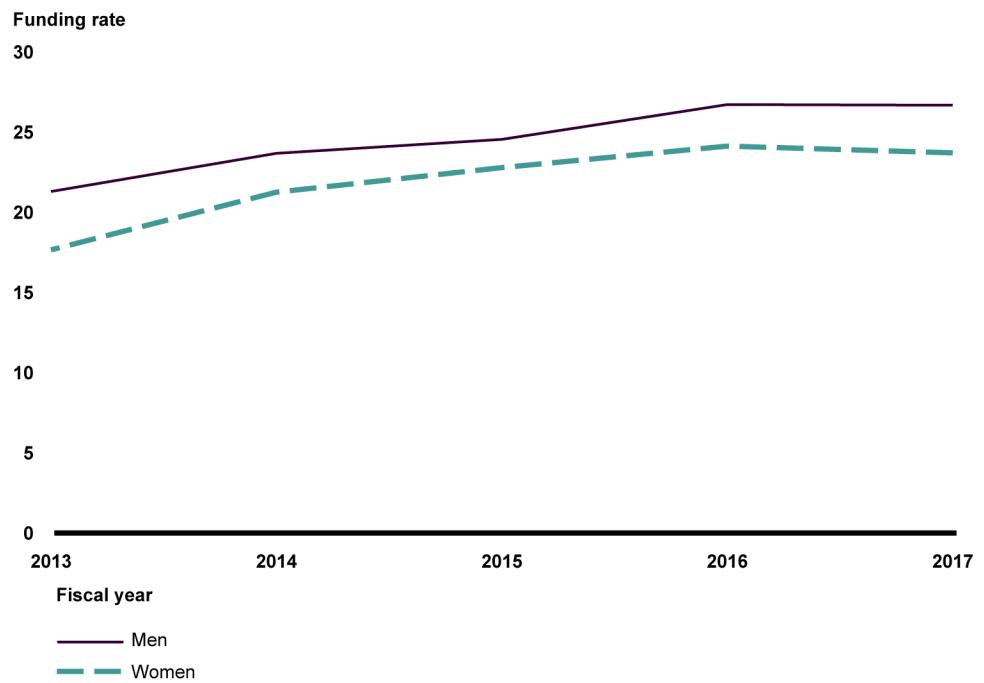
Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: NIH considers the following racial groups to be underrepresented in biomedical research—that is, groups whose numbers in the biomedical sciences are disproportionately low relative to their numbers in the general population: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. Whites and Asians are not considered by NIH to be underrepresented in biomedical science research. In this report, we refer to whites and Asians as “well represented” groups. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Additional applicants identified as multiracial or did not specify their race. These applicants represented about 10 to 11 percent of all applicants in each of these years; therefore, the data presented may underestimate the actual number of applicants from underrepresented groups. We consider large NIH grants to be R01 and R01-equivalent (R01e) grants. We use “#” to denote that the number of awardees was less than or equal to 11.

The applicant funding rate for career development grants for underrepresented racial groups increased from about 22 percent to about 32 percent from fiscal years 2013 to 2017, and, for Hispanic and Latino applicants, from about 30 percent to about 36 percent during the same period. The applicant funding rate was about 34 percent for white applicants throughout this period.

The large grant funding rate for female investigators was slightly lower than male investigators. (See fig. 3.)

Figure 3: Large NIH Research Grant Applicant Funding Rate (Awardees/Applicants) by Gender for Fiscal Years 2013 through 2017



Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

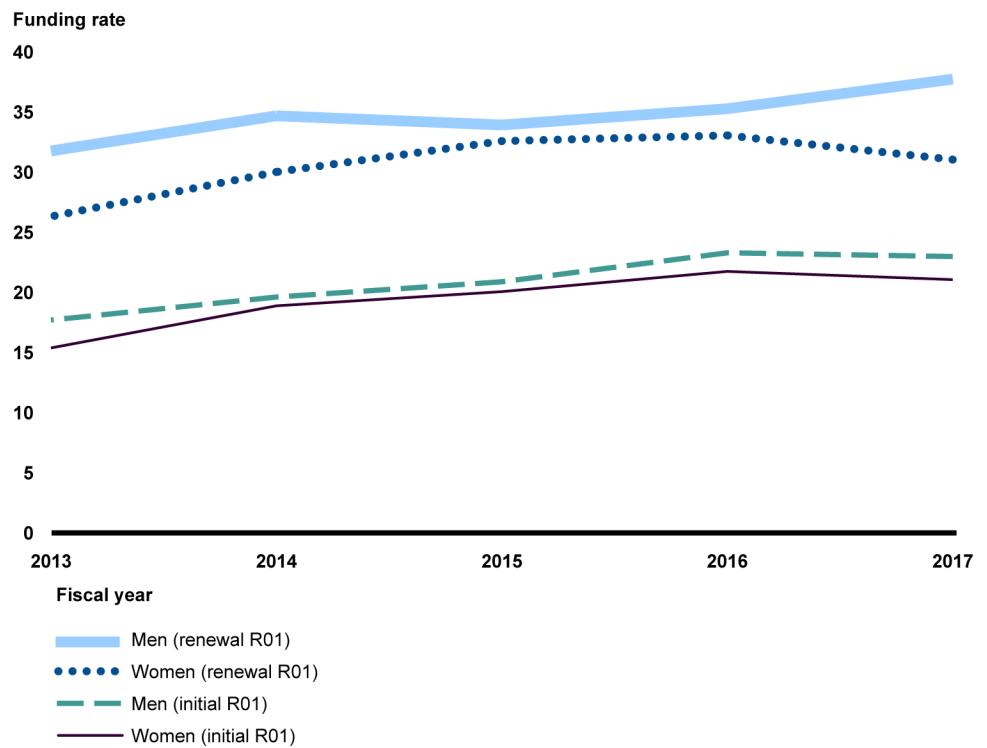
Note: We consider large NIH grants to be R01 and R01-equivalent grants. The funding rate for large NIH grant applicants who did not identify a gender ranged from about 7 percent in 2013 to about 13 percent in 2017.

When looking exclusively at R01 grants, as opposed to all large grants, research has shown that women are less likely to have their initial R01 grant renewed.⁵⁵ Our analysis of R01 grant renewal funding showed that, in fiscal year 2017, the R01 grant renewal funding rate for female applicants was about 31 percent compared to about 38 percent for male applicants. (See fig 4.) According to research by NIH, some applicants that are unsuccessful in obtaining an initial R01 grant may have greater success if they reapply; however, some stakeholders we interviewed said women, and some underrepresented racial groups, are less likely to reapply for an initial R01 grant if they are unsuccessful with their first

⁵⁵Ley and Hamilton, “The Gender Gap,” 1473, and J. R. Polhaus, H. Jiang, R. M. Wagner, W. T. Schaffer, and V. W. Pinn, “Sex Differences in Application, Success, and Funding Rates for NIH Extramural Programs,” *Academic Medicine*, vol. 86, no. 6 (2011).

attempt. (See app. III for information on the applicant funding rates for smaller grants and career development grants by gender.)

Figure 4: Applicant Funding Rate (Awardees/Applicants) for Select Initial and Renewal Large Grants by Gender for Fiscal Years 2013 through 2017



Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: The large NIH grant reflected in this figure is the R01 grant only and does not reflect R01 equivalent grants.

Many stakeholders attributed the underrepresented groups' lower funding rates to two factors. First, many stakeholders cited a perceived implicit bias within the peer review process, which they said may affect the funding rates for investigators from underrepresented racial and ethnic groups. They stressed that, many times, peer reviewers approve grants for investigators from top tier institutions that they are familiar with and are reluctant to provide high scores to grant applications from other institutions. Some stakeholders advocated for anonymizing grant

applications to some extent to address this issue.⁵⁶ NIH's Center for Scientific Review—the center responsible for organizing peer reviews for grants—is conducting a study that anonymizes certain large grant applications, and a training module on implicit bias is currently being offered to NIH peer reviewers.⁵⁷ In addition, NIH's African American/Black R01 Funding Disparities Working Group has conducted an analysis on the R01 funding disparities for African American or black applicants from fiscal years 2010 through 2015, and is currently pursuing several efforts to address its findings. Lower grant application priority scores and application resubmission rates among African American or black applicants were among their findings. The working group is also pursuing a randomized control trial to assess the effect of mentoring and coaching on R01 resubmissions and award rates. Second, some stakeholders told us that only a very small percentage of biomedical science professors at top tier research schools are from underrepresented racial or ethnic groups. Some stakeholders suggested that many investigators from underrepresented groups seeking grants are affiliated with institutions outside of the top tier that may lack the infrastructure, grant writing support, and mentoring opportunities, which could help ensure their success. As a consequence, many investigators from underrepresented groups are at a disadvantage compared to their peers at top tier institutions, according to the stakeholders we interviewed.

The Effect of NIH's Efforts to Strengthen Diversity Is Unclear; Assessments of Some Targeted Efforts Are Incomplete, and Strategic Goals Lack Quantitative Metrics and Time Frames

Although NIH has taken steps to address concerns about the diversity of the biomedical research workforce, its accomplishments have not been fully evaluated.

⁵⁶An anonymous grant application is intended to mask the personal identity and other information associated with the applicants (e.g., name, race, institution, where they were trained, and research collaborators). However, some stakeholders told us that peer reviewers are nonetheless sometimes able to determine the identity of the applicant based on the nature of the research.

⁵⁷The recent National Academies of Sciences, Engineering, and Medicine report recommends that NIH continue to improve the peer review process by continuing to test effective practices to reduce the effects of implicit bias in peer review and to increase the diversity of reviewers. *The Next Generation*, 84-85.

Stakeholders Reported Mixed Views on NIH's Efforts to Strengthen Diversity

Positive comments from some stakeholders we interviewed included praise for the steps NIH has taken to diversify the biomedical research workforce, the value of the National Research Mentoring Network, and the research supplements and other training grants offered by NIH's centers and institutes, which provide opportunities for students and postdoctoral fellows from underrepresented groups to work with established investigators. NIH's support of conferences and programs, such as the Annual Biomedical Research Conference for Minority Students and the Institutional Research and Academic Career Development Award, was also well regarded by stakeholders. They also noted NIH's commitment to diversity and willingness to investigate diversity issues through advisory groups, and commended the agency on working to address recommendations from the Working Group on Diversity in the Biomedical Research Workforce, including hiring a Chief Officer of Scientific Workforce Diversity. Some stakeholders were actively engaged in working with NIH on diversity issues. For example, some physicians from an organization we interviewed said they are working with the National Institutes on Minority Health and Health Disparities on issues related to research workforce diversity.

Stakeholders, though, also offered less favorable views and characterized NIH's efforts as stagnant, ineffective, or in need of better coordination. For example, some stakeholders

- suggested that for NIH's National Research Mentoring Network, the matching of mentees to mentors could be improved or mentioned uncertainty about the program;
- questioned how often research supplements are utilized, or noted that better mentoring and follow-up after the postdoctoral fellow's work is completed is warranted;
- reported that while their organizations initially collaborated with the scientific workforce diversity office, that office is not very active or communication eventually dissipated;
- expressed concern about NIH's outreach to minority serving institutions and organizations, such as historically black colleges and universities, when it began creating programs like the Building Infrastructure Leading to Diversity program and the National Research Mentoring Network and for other efforts; and
- stressed that NIH should collaborate more with organizations that represent underrepresented groups, which have already implemented

Multiple Assessments of Targeted Diversity Efforts Are Ongoing

programs shown to be effective in engaging these communities in biomedical research.⁵⁸

According to NIH officials, evaluations of various NIH efforts are ongoing and have not been completed. Some examples include the following:

- Data collection and analysis by the Diversity Program Consortium's Coordination and Evaluation Center began in 2017, and is ongoing.
- In 2017, NIH's Center for Scientific Review began conducting a study to anonymize R01 grant applications from African American or black and white applicants to detect potential reviewer bias during peer review.⁵⁹ The results of this study are expected in 2019.
- An evaluation of the National Cancer Institute's Continuing Umbrella of Research Experiences program, which provides training and career development opportunities to enhance diversity in the cancer research workforce, was submitted for publication in a scientific journal and is currently pending review.

Some NIH institutes and centers have conducted evaluations of their specific diversity efforts. For example, in 2015, the National Institute of General Medical Sciences analyzed the research supplements provided to graduate students and postdoctoral fellows from underrepresented racial and ethnic groups between 1989 and 2006.⁶⁰ The study found that about 65 percent of graduate students and postdoctoral fellows supported by the program entered research careers in academia, industry, and government research. About 41 percent of doctoral graduates and 45 percent of postdoctoral fellows supported by this program entered careers in academic research or teaching compared to about 43 percent of the U.S. doctoral degree workforce. In 2011, the National Institute on Aging evaluated its research supplement program and found that the NIH research grant applicant success rate of former participants from 2002 to

⁵⁸For example, some stakeholders we interviewed implemented or are affiliated with programs to help retain and mentor underrepresented students studying science as undergraduates and in graduate school.

⁵⁹The study focuses solely on the R01 research grant and not R01 equivalent research grants—that is, NIH research grants similar to the R01 grant that are or have been historically used as funding vehicles to launch an independent research career.

⁶⁰A. Hall, A. Milos, O. Mickey, A. Oh, and J. Shoemaker, "NIGMS Analysis of Supplements to Enhance Diversity 1989-2006," May 25, 2015, accessed May 30, 2018, <https://www.nigms.nih.gov/Research/mechanisms/Documents/DSPOutcomesReport5282015.pdf>.

NIH Has Developed a Scientific Workforce Diversity Strategic Plan, but It Does Not Include Quantitative Metrics or Time Frames to Assess the Progress of Its Strategic Goals

2010 was about 21 percent. The average research grant success rate for National Institute on Aging grants was about 18 percent during this same period.

In 2016, NIH's Chief Officer of Scientific Workforce Diversity established a 5-year strategic plan that describes the agency's five workforce diversity goals and supporting objectives. The strategic plan includes goals and objectives that apply to both extramural and intramural investigators. During the course of our audit work, NIH updated this plan to describe progress made on each of its diversity goals, which are to:

- expand scientific workforce diversity as a field of inquiry,
- build and implement evidence related to diversity outcomes,
- understand the role of sociocultural factors in biomedical recruitment and retention,
- sustain nationwide workforce diversity with seamless career transitions, and
- promote the value of scientific workforce diversity.

NIH officials provided us with performance measures that its scientific workforce diversity office will use to gauge the agency's progress in achieving each of its five strategic plan's goals. However, these items outline the particular areas that NIH plans to evaluate, rather than provide quantitative metrics, evaluation details, or time frames associated with any of the areas by which to evaluate progress in fulfilling the goals of the strategic plan. For example, for the first scientific workforce diversity goal "expand scientific workforce diversity as a field of inquiry" one of the performance measures is "number of publications stored in the scientific workforce diversity office's online database." Neither the strategic plan nor the additional documentation that NIH provided specifies a quantitative metric for the number of publications to be stored in its database and the time frame for doing so. Similarly, for the second scientific workforce diversity goal, to "build and implement evidence related to diversity outcomes" one of the performance measures identified by NIH is to compare the large grants awarded to African American or black scientists to those received by scientists who are white or from other racial and ethnic groups. However, there is no description in either the strategic plan or the additional documentation provided by NIH that indicates how and when these comparisons will be made, how the results of these comparisons will be assessed, and what will be considered as fulfilling this goal. All of the other areas or "performance measures"

associated with each of the five goals also do not include such details or time frames. According to documentation provided by NIH its strategic plan does not explicitly list “specific metrics” because they will be defined within “the implementation phase of the plan.” However we are at the midpoint of the implementation of NIH’s 5-year plan, which covers the period of 2016 through 2020. As of May 2018, these specific metrics were not yet available.

Without quantitative metrics, evaluation details, or time frames for assessing the agency’s performance against the five goals in its strategic plan, NIH will be unable to hold itself accountable for fulfilling its goals. This is inconsistent with best practices for strategic workforce planning, which call for agencies to monitor and evaluate their progress toward their human capital goals.⁶¹ These best practices also call for performance metrics to be specified at the outset to avoid a biased determination of what counts as “success” after the results are known. Further, this is inconsistent with federal internal control standards for monitoring, which require that an agency evaluate and document the results of ongoing monitoring to determine whether its management strategies are effectively supporting its objectives, or need corrective action.⁶² NIH’s establishment of goals and associated areas of future evaluation are positive steps, but absent specific measures by which to hold itself accountable, the agency will not have a basis to judge its success.

Conclusions

NIH’s ability to fulfill its mission of advancing scientific knowledge and innovation to enhance health, lengthen life, and reduce illness and disability is dependent on its success in sustaining a thriving and diverse workforce. For decades, concerns have been raised by the biomedical research community about NIH’s ability to support investigators beginning their research careers. Similar concerns have been expressed regarding support for investigators from groups underrepresented in the sciences, including those from racial and ethnic groups and women. While the agency has taken many steps during this time, disparities in its research grant funding persist. NIH has conducted some evaluations of individual programs and activities, but these have been relatively narrow in focus and the results of many efforts are not yet available. More recently, NIH has taken positive steps such as by establishing the position of Chief

⁶¹See GAO-04-39.

⁶²See GAO-14-704G.

Officer of Scientific Workforce Diversity, who in turn, created a strategic workforce diversity plan and related goals and identified areas of future evaluation. However, NIH does not have quantitative metrics, evaluation details, and time frames to assess its progress in meeting its strategic workforce diversity goals. Without these elements, NIH's ability to assess how its diversity strategic plan goals are being achieved is hindered. Thus, NIH is missing an opportunity to better position itself to support underrepresented groups and address longstanding disparities.

Recommendation for Executive Action

The NIH Director should develop quantitative metrics, evaluation details, and specific time frames to assess its current efforts to support investigators from underrepresented groups against its scientific workforce diversity strategic goals, and use the results of its assessment to guide any further actions. (Recommendation 1)

Agency Comments

We provided a draft of this report to HHS for comment. In its written comments, which are reproduced in appendix IV, HHS concurred with our recommendation and outlined the steps NIH is taking to implement it. Notably, for example, HHS indicated that NIH is establishing time frames to assess its progress in meeting its workforce diversity goals. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.



Marcia Crosse
Director, Health Care

Appendix I: Trends in the Number of Grants Awarded to Early Career Extramural Investigators by Award Type, for Fiscal Years 2013 through 2017

Table 6 provides details on the number of grants awarded, number of awardees and award type for early stage and intermediate stage investigators from fiscal year 2013 through fiscal year 2017.

Table 6: Number of Grant Applicants, Awardees, and Funding Rates of NIH Early Stage Investigators and Intermediate Stage Investigators, by Award Type, for Fiscal Years 2013 through 2017

Grant type	Fiscal year	Early stage investigators			Intermediate stage investigators		
		Number of applicants	Number of awardees	Funding rate (awardees / applicants)	Number of applicants	Number of awardees	Funding rate (awardees / applicants)
Large grants	2013	3,867	548	14.17	3,597	888	24.69
	2014	3,886	796	20.48	3,381	888	26.26
	2015	3,788	858	22.65	3,370	926	27.48
	2016	4,179	987	23.62	4,230	1,275	30.14
	2017	4,258	1,053	24.73	4,315	1,284	29.76
Smaller grants	2013	4,467	730	16.34	1,878	525	27.96
	2014	4,574	813	17.77	1,857	584	31.45
	2015	4,435	820	18.49	1,809	542	29.96
	2016	4,875	1,004	20.59	2,199	718	32.65
	2017	4,578	896	19.57	2,169	661	30.47
Career development grants	2013	1,752	524	29.91	60	18	30.00
	2014	2,055	629	30.61	43	23	53.49
	2015	2,076	680	32.76	46	23	50.00
	2016	2,337	797	34.10	54	33	61.11
	2017	2,326	751	32.29	66	30	45.45

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Notes: Early stage investigators have completed graduate level education (i.e., research doctorate or clinical doctorate), postdoctoral research, or medical residency, whichever date is later, within the preceding 10 years, and have not previously competed successfully for a large NIH research grant. Intermediate stage investigators have received their first large NIH research grant as an early stage investigator.

We consider large NIH grants to be R01 and R01-equivalent (R01e) grants and smaller grants to be non-R01e grants. R01 and R01e grants are the most common grants used to support research and funds typically support labs, equipment, and salaries for the research. Non-R01e grants include smaller, exploratory, or developmental grants. Career development grants refer to K-series grants, which are intended to provide mentored training or career development support to investigators beginning their research careers.

Appendix II: Total Number of Applicants for Smaller Grants and Career Development Grants for Fiscal Years 2013 through 2017

Tables 7 through 10 provide details on the demographics of NIH grant applicants during fiscal years 2013 through 2017.

Table 7: Applicants for Smaller NIH Grants by Racial and Ethnic Group for Fiscal Years 2013 through 2017

	Fiscal year				
	2013	2014	2015	2016	2017
<i>Underrepresented racial group</i>					
American Indian or Alaska Native	41	43	43	43	61
Black or African-American	525	568	649	652	644
Native Hawaiians and other Pacific Islanders	16	23	28	20	20
<i>Underrepresented ethnic group</i>					
Hispanic or Latino	930	1,005	1,002	1,060	1,057
<i>Well represented racial groups</i>					
Asian	4,326	4,779	4,895	5,104	4,797
White	12,887	13,503	13,093	13,498	12,755

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: NIH considers the following racial groups to be underrepresented in biomedical research: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Additional applicants identified as multiracial or did not specify their race. These applicants represented less than 1 percent and about 21 percent, respectively, of all applicants in each of these years; therefore, the data presented may underestimate the actual number of applicants from underrepresented groups. We consider smaller grants to be non-R01 equivalent grants.

Table 8: Applicants for Smaller NIH Grants by Gender for Fiscal Years 2013 through 2017

Gender	Fiscal year				
	2013	2014	2015	2016	2017
Men	13,336	13,967	13,527	13,727	12,921
Women	7,066	7,320	7,180	7,392	7,090
No gender identified	2,057	2,353	2,424	2,845	3,004
Total	22,459	23,640	23,131	23,964	23,015

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: We consider smaller grants to be non-R01 equivalent grants.

**Appendix II: Total Number of Applicants for
Smaller Grants and Career Development
Grants for Fiscal Years 2013 through 2017**

Table 9: NIH Career Development Grant Applicants by Racial and Ethnic Group for Fiscal Years 2013 through 2017

	Fiscal year				
	2013	2014	2015	2016	2017
<i>Underrepresented racial group</i>					
American Indian or Alaska Native	#	12	#	12	#
Black or African-American	119	127	126	162	163
Native Hawaiians and other Pacific Islanders	#	#	#	#	#
<i>Underrepresented ethnic group</i>					
Hispanic or Latino	181	165	211	205	211
<i>Well represented racial groups</i>					
Asian	659	721	746	716	755
White	1,783	1,826	1,854	1,808	1,833

Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: NIH considers the following racial groups to be underrepresented in biomedical research: Blacks or African Americans, American Indians or Alaska Natives, and Native Hawaiians and other Pacific Islanders. NIH considers Hispanics and Latinos to be an ethnic group underrepresented in biomedical research. Additional applicants identified as multiracial or did not specify their race. These applicants represented about 2 percent and about 12 to 14 percent, respectively, of all applicants in each of these years; therefore, the data presented may underestimate the actual number of applicants from underrepresented groups. Career development grants refer to K-series grants, which are intended to provide mentored training or career development support generally to early and intermediate stage investigators. We use “#” to denote that the number of applicants was less than or equal to 11.

Table 10: NIH Career Development Grant Applicants by Gender for Fiscal Years 2013 through 2017

Gender	Fiscal year				
	2013	2014	2015	2016	2017
Men	1,536	1,558	1,531	1,489	1,517
Women	1,345	1,451	1,456	1,419	1,470
No gender identified	128	172	209	236	320
Total	3,009	3,181	3,196	3,144	3,307

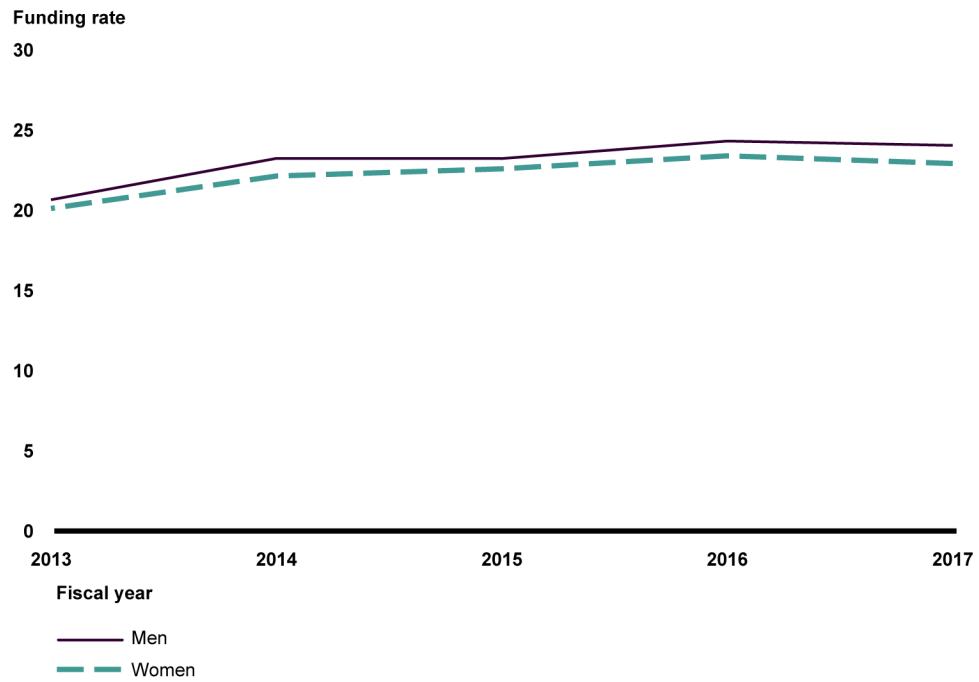
Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: Career development grants refer to K-series grants, which are intended to provide mentored training or career development support generally to early and intermediate stage investigators.

Appendix III: Applicant Funding Rates for Smaller Grants and Career Development Grants for Fiscal Years 2013 through 2017

Figures 5 and 6 provide details on the demographics of NIH grant applicants during fiscal years 2013 through 2017.

Figure 5: NIH Smaller Grant Applicant Funding Rate by Gender for Fiscal Years 2013 through 2017

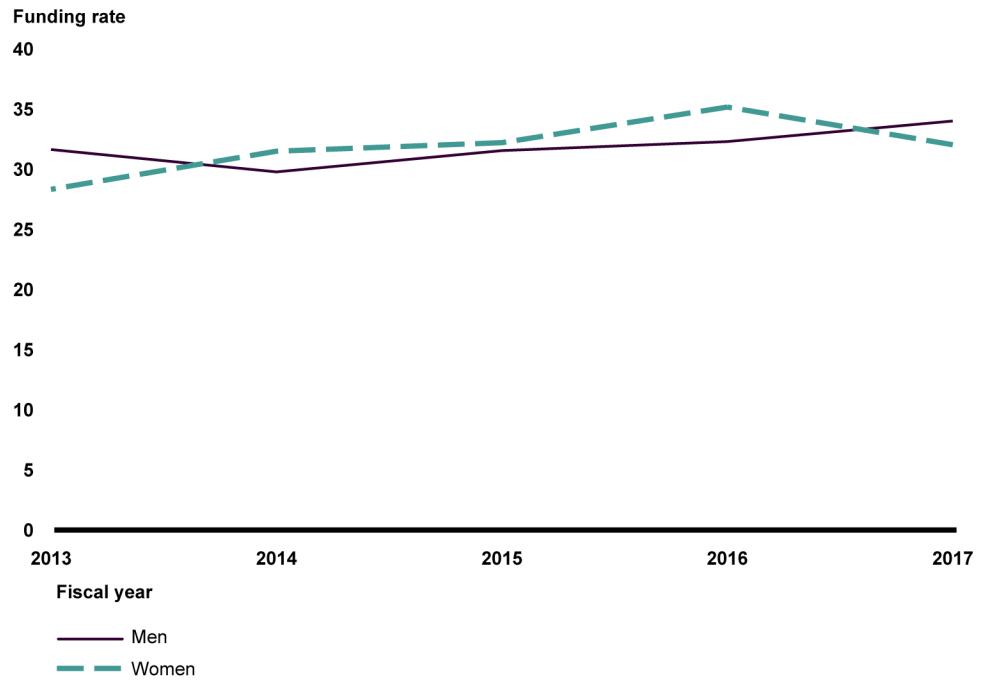


Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: We consider smaller grants to be non-R01 equivalent grants.

**Appendix III: Applicant Funding Rates for
Smaller Grants and Career Development
Grants for Fiscal Years 2013 through 2017**

**Figure 6: NIH Career Development Grant Applicant Funding Rate by Gender for
Fiscal Years 2013 through 2017**



Source: GAO analysis of National Institutes of Health (NIH) data. | GAO-18-545

Note: Career development grants refer to K-series grants, which are intended to provide mentored training or career development support generally to early and intermediate stage investigators.

Appendix IV: Comments from the Department of Health and Human Services

 DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE SECRETARY
Assistant Secretary for Legislation
Washington, DC 20201

JUL 18 2018

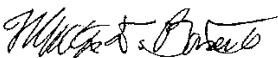
Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "NIH Research: Actions Needed to Ensure Workforce Diversity Strategic Goals Are Achieved" (GAO-18-545).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,


Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE
WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

GAO Recommendation

The NIH Director should develop quantitative metrics, evaluation details, and specific timeframes to assess its current efforts to support investigators from underrepresented groups against its scientific workforce diversity strategic goals, and use the results of its assessment to guide any further actions.

HHS Response

HHS concurs with the GAO's recommendations.

The NIH Director has established quantitative metrics, evaluation details, and specific timeframes to track the elements of the NIH Scientific Workforce Diversity Strategic Plan (See Table appended below). In addition, the NIH Scientific Workforce Diversity (SWD) Office provided GAO with existing evaluation metrics, citing various programs and online resources. Specific examples are listed below in the context of GAO's draft report structure.

- NIH has a framework for evaluation of Scientific Workforce Diversity (SWD) objectives, with the timelines framed as short-term, intermediate-term, and long-term. Quantitative metrics of SWD strategic objectives are guided by the Diversity Program Consortium's Center for Coordination and Evaluation's "hallmarks of success".
- NIH has quantitative and qualitative metrics regarding institutional accountability for equity, derived from recommendations provided by the NIH Addressing Gender Inequality in the Intramural Research Program Action Task Force, which was comprised of several NIH Institute and Center directors and charged by the NIH Director.
- In keeping with its data-driven mission to advance inclusive excellence throughout NIH, SWD pioneered new processes for attracting a pool of diverse applicants to NIH using new outreach methods (Future Research Leaders Conference).
- NIH developed and pilot-tested educational modules on implicit bias that incorporate information about the importance of a diverse workforce and how diversity affects the NIH research mission. NIH uses evaluation metrics to measure effectiveness of the training and its long-term impact on behavioral change such as hiring of diverse talent.
- Consistent with SWD strategic goals for evaluation and tracking, NIH launched additional efforts to narrow the R01/R01e funding gap: i) coaching, mentoring for grant writing, and ii) an anonymization study to assess possible bias in peer review. These new efforts are consistent with the SWD mission to employ data-driven approaches to enhancing diversity in the scientific workforce.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE
WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)**

GOAL 1: Expand Scientific Workforce Diversity as a Field of Inquiry

Objective 1-1. Advance scholarship of scientific workforce diversity

Evaluation metrics measured annually:

1-1.1. Number of applications for NIH grants to understand the role of sociocultural factors on biomedical science conduct and outputs

1-1.2. Number of publications cited on SWD website about relationship of inclusive excellence and biomedicine

1-1.3. Number of Diversity Catalysts Trans-NIH committee meetings focused on this objective

1-1.4. Number of NIH ICs adopting Diversity Catalysts-promoted SWD programs focused on this objective

Objective 1-2. Launch scientific studies on new ideas for promoting diversity inclusion practices

Evaluation metrics measured annually:

1-2.1. Number of NIH Funding Opportunity Announcements on promoting diversity and inclusion practices

1-2.2. Number of NIH funded scientific studies on promoting diversity inclusion practices

1-2.3. Number of published scientific studies on promoting diversity inclusion practices

1-2.4. Number of public or private partnerships that focus on promoting diversity inclusion practices

GOAL 2: Build and Implement Evidence Related to Diversity Outcomes

Objective 2-1. Support evidence-based approaches to training and persistence in biomedical research

Evaluation metrics measured annually or biannually:

2-1.1. Number of new IRP programs/approaches to enable institutional change toward inclusive excellence:

2-1.1.1. NIH Equity Committee (number of ICs reviewed; number of gaps in gender and race/ethnicity representation, resources, salary identified; number of best practices identified)

2-1.1.2. Implicit-bias educational modules: number of search committees, scientific directors, lab/branch chiefs trained

2-1.1.3. Future Research Leaders Conference (Number of participants, race/ethnicity and gender of participants; survey data on program effectiveness; number applying to NIH positions)

2-1.1.4. Central Mentoring Coordinator hire (Number and types of mentoring and faculty-development programs overseen)

Appendix IV: Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)

2-1.1.5. Distinguished Scholars Program cohort model (number, race/ethnicity and gender of nominations and selected participants; qualitative data on effectiveness of faculty development program components; results of BSC reviews; attainment of tenure)

2-1.1.6. Trans-NIH searches (Stadtman, Lasker): number, race/ethnicity and gender of applicants, interviewed investigators, and selected investigators

2-1.1.7. Development and dissemination of SWD Toolkit

Objective 2-2. Coordinate evaluation of NIH-wide diversity programs and interventions

Evaluation metrics measured annually (or upon completion as noted):

2.2.1. Diversity supplements:

2-2.1.1. Proportionate IC investment in Diversity Supplements

2-2.1.2. IC-reported outcomes from supplement awardees (Numbers and proportion that: enter academic research or teaching careers; receive NIH career-development grants; receive NIH research grants)

2-2.2. Diversity Program Consortium CEC-collected data on hallmarks of success:

2-2.2.1. BUILD

2-2.2.2. NRMN

2-2.3. Outcomes of interventions to mitigate funding disparities: measured upon completion of the intervention

2-2.3.1. Anonymized study of potential bias in peer review (Review scores in anonymized vs non-anonymized proposals): Estimated timeframe for reporting 2020

2-2.3.3. Outreach campaign to encourage re-submission of R01 proposals (Re-submission rates; survey data on reasons for research-topic choice; institutional support for grant writing) Estimated timeframe for reporting 2019.

2-2.3.4. Randomized controlled trial to evaluate effect of mentoring/coaching on R01 re-submission behavior and award outcomes. (Primary end-point: Re-submission rates; Secondary endpoints: review scores; funding rate; qualitative data on effectiveness of mentoring and coaching for grant writing); Estimated timeframe for reporting 2021.

2-2.4. Diversity in NIH-funded applicant and awardee pools measured annually by funding mechanism

2-2.4.1. T32

2-2.4.2. F31

2-2.4.3. F32

2-2.4.4. K (disaggregate by K type)

2-2.4.5. R01

2-2.4.6. U

Appendix IV: Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)

GOAL 3: Understand the Role of Sociocultural Factors in Biomedical Recruitment and Retention

Objective 3-1. Document and mitigate sociocultural barriers at individual and institutional levels

Evaluation metrics measured annually:

3-1.1. Number of NIH funding announcements to understand the role of sociocultural barriers on diversity and inclusion in biomedical research

3-1.2. Results of NIH grants awarded on the role of sociocultural barriers and number of best practices and/or evidence-based approaches identified

3-1.3. Number of national presentations, publications, and individual discussions, to academic leadership in the NIH-funded extramural community

Objective 3-2. Provide funding, coordination, and oversight of innovative initiatives to address faculty recruitment and retention

Evaluation metrics measured annually:

3-2.1. Number of implicit-bias educational sessions conducted for search committees, scientific directors, lab/branch chiefs

3-2.2. Change in diversity in IRP applicant pools:

3-2.2.1. Stadtman

3-2.2.2. Lasker

3-2.2.3. IC-level searches

3-2.2.3.1. Change in number of IRP hires from underrepresented groups

3-2.2.3.2. Change in IRP representation:

3-2.2.3.2.a Women

3-2.2.3.2.b Individuals from underrepresented groups

GOAL 4: Sustain Nationwide Workforce Diversity with Seamless Career Transitions

Objective 4-1. Incorporate inclusive excellence in all institutional processes

Evaluation metrics measured annually:

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Appendix IV: Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)

4-1.1. Number of uses of SWD recruitment search protocol to expand diversity of candidate pools

4-1.1.1. Change in diversity of candidate pools for IRP and NIH leadership scientific searches

4-1.2. SWD Toolkit dissemination and use

4-1.2.1. AAMC webinar survey

4-1.2.2. SWD website downloads

4-1.3. Number of implicit-bias educational sessions conducted for peer-review committees

4-1.3.1. Change in behavioral metrics (IAT) of peer-review committee members

4-1.4. Number of meetings of the NIH Equity Committee

4-1.4.1. Number of committee recommendations made

4-1.4.2. Change in resource allocation by ICs for tenure-track investigators

4-1.4.2.a. Women

4-1.4.2.b. Individuals from underrepresented groups

Objective 4-2. Create a national network of partnered institutions, “hubs of innovation,” to assess diversity interventions and develop best practices

Evaluation metrics:

4-2.1. Number of listening sessions and meetings with potential stakeholders Timeframe 2019

4-2.1.1. Academic

4-2.1.2. Government

4-2.1.3. Industry

Objective 4-3. Promote the value of effective mentoring in sustaining careers

Evaluation metrics:

4-3.1. Number of enrollees in Distinguished Scholars Program cohort: (Timeframe for reporting – annually)

4-3.1.1. Number of professional development programs

4-3.1.2. Change in behavioral metrics (IAT) of PIs and IRP leadership

4-3.2. Number of responses to trans-NIH climate survey (Timeframe for reporting 2019)

4-3.2.1. Change in post-survey measurements

4-3.3. Assess mentoring environment

4-3.3.1. Results from Central Mentoring Coordinator interviews

4-3.3.2. Results from the gender inequality task force survey of tenure-track PIs

GOAL 5: Promote the Value of Scientific Workforce Diversity

**Appendix IV: Comments from the Department
of Health and Human Services**

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED: NIH RESEARCH: ACTIONS NEEDED TO ENSURE
WORKFORCE DIVERSITY STRATEGIC GOALS ARE ACHIEVED (GAO-18-545)**

Objective 5-1. Establish and promote NIH as a nationwide diversity leader

Evaluation metrics measured annually:

- 5-1.1. Number of invitations to speak about SWD programs and approaches
- 5-1.2. Number of blogs posted
- 5-1.3. Number of newsletters distributed
- 5-1.4. Readership of blogs
- 5-1.5. Readership of newsletters
- 5-1.6. Website analytics

Objective 5-2. Serve as the NIH focal point for scientific workforce diversity-related information

Evaluation metrics measured annually:

- 5-2.1. Number of requests for SWD Toolkit
- 5-2.2. Number of requests for implicit-bias educational sessions
- 5-2.3. Number of requests for assistance in expanding diversity of candidate pools

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact	Marcia Crosse, (202) 512-7114 or crossem@gao.gov
Staff Acknowledgments	In addition to the contact above, Geri Redican-Bigott (Assistant Director), Carolina Morgan (Analyst-in-Charge), Jackie Hamilton, Toni Harrison, and Drew Long made key contributions to this report. Muriel Brown, Giselle Hicks, and Hayden Huang also made contributions to this report.

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