Responses to Recommendations in Previous Reports on Biomedical and Behavioral Researchers August 2017

Yasmeen Hussain, Ph.D., and Amanda Field, Ph.D.

prepared for the

Committee on the Next Generation Researchers Initiative

Board on Higher Education and Workforce

Policy and Global Affairs

This paper is not an official report of the National Academies of Sciences, Engineering, and Medicine. Opinions and statements included in this material are solely those of the individual authors and do not necessarily represent the views of the committee or the National Academies.

The Committee on the Next Generation Researchers Initiative is not the first to examine the challenges young investigators face in starting independent research careers. Indeed, over the past few decades, a number of groups have issued high-profile reports examining concerns about the biomedical and behavioral research enterprise and the investigators trained to carry out that research. These reports each contained recommendations that targeted various institutions, career stages, and scientific research organizations, and all were aimed at securing and supporting our nation's biomedical and behavioral research scientists.

The committee recognized early in its work that while a number of previous recommendations have been offered to tackle these concerns, only some of those recommendations actually had seen progress in the ensuing years. This led the committee, early in its deliberations, to pose a series of questions: Which of the previous recommendations had been addressed, and which had not? Of those that had been addressed, had interventions addressed the challenges confronting the biomedical workforce, or had they produced unintended consequences? Answering these questions was instrumental in informing the work of the committee.

The committee collected relevant recommendations from the National Academies of Sciences, Engineering, and Medicine reports dating back to 2005, as well as three National Institutes of Health (NIH) working group reports and a 2015 report from the Federation of American Societies for Experimental Biology (FASEB):

- Bridges to Independence: Fostering the Independence of New Investigators in
 Biomedical Research (2005). National Research Council of the National Academies.
- *Research Training in the Biomedical, Behavioral and Clinical Research Sciences* (2011). National Research Council of the National Academies.
- *Biomedical Research Workforce Working Group Report* (2012). National Institutes of Health.

- Report of the Advisory Committee to the Director Working Group on Diversity in the Biomedical Research Workforce (2012). National Institutes of Health.
- *Physician-Scientist Workforce Working Group Report* (2014). National Institutes of Health.
- *The Postdoctoral Experience Revisited* (2014). National Academy of Sciences, National Academy of Engineering, and Institute of Medicine of the National Academies.
- Sustaining Discovery in Biological and Medical Sciences: A Framework for Discussion (2015). Federation of American Societies for Experimental Biology.

The recommendations from these reports that addressed concerns facing early career investigators fell into seven target areas: postdoctoral practices, diversity in the research workforce, data collection, early career support, faculty support, staff scientist support, and grant review. This paper explores the recommendations in each of these areas in turn.

1. RECOMMENDATIONS ON POSTDOCTORAL PRACTICES

Postdoctoral training has become a nearly de facto requirement for an independent research career in the biomedical and behavioral sciences in the United States. While most U.S.-trained biomedical Ph.Ds. spend fewer than five years in postdoctoral training, significant numbers remain in postdoctoral positions between five and eight years.¹ The postdoctoral experience is nominally considered an opportunity to build skills and experiences to prepare for research independence. According to the 2012 *Postdoctoral Experience Revisited* report, postdoctoral researchers should be receiving advanced training in research, and at the end of the appointment, the postdoctoral researcher should transition to a permanent position accompanied by a change in job duties and compensation. However, prior reports have called out the postdoctoral research stage as a "holding pattern" for young scientists.² As such, the reports we examined made several recommendations germane to postdoctoral researchers.

¹ <u>https://acd.od.nih.gov/documents/reports/Biomedical_research_wgreport.pdf</u>, p. 21; S. Kahn & D.K. Ginther, The impact of postdoctoral training on early careers in biomedicine, Nat Bio, 2017 Jan, 35(1) 90-94.

² Trends in the Early Careers of Life Scientists (1998); Bridges to Independence (2005)

1.1 NIH should enforce a 5-year limit on the use of any funding mechanism to support postdoctoral researchers with the nature of the position, including responsibilities and benefits, changing for those researchers who transition to staff scientist positions after 5 years (normal duration should be 3 years).

> Bridges to Independence (2005) The Postdoctoral Experience Revisited (2014)

While there is no explicit general action by NIH beyond guidance for all supported postdoctoral researchers,³ NIH has instituted time limits for some of its training programs. For example, there is a statutory and regulatory limit on the duration of support for postdoctoral researchers supported by a National Research Service Award (NRSA). The NRSA legislation specifies that total support for postdoctoral researchers may not exceed three years, but waivers are allowed for good cause.⁴ NIH enforces this limit, with any period of additional support on NRSA training grants or fellowships requiring approval from the awarding institute that supports the training grant or fellowship.⁵ In 2014, NIH reduced the eligibility for Pathway to Independence Award Program (K99/R00) applications from 5 years to no more than 4 years of postdoctoral research experience at the time of the initial application or subsequent resubmission. The intent was to further encourage early transition to independence.^{6,7}

Although NIH has taken some steps to impose time limits for postdoctoral appointments, postdoctoral researchers on research grants are almost always employees of their institutions and subject to employment policies at that institution. NIH is limited in its ability to independently modify or require specific changes in employment practices at grantee institutions. That being said, NIH went on record in 2001 supporting a five-year limit on postdoctoral training experiences from any source of federal dollars.⁸ Some institutions have established their own time limits on postdoctoral appointments. In 2008, for example, New York University School of Medicine imposed a 5-year limit on postdoctoral length, including time spent in previous

³ <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-027.html</u>

⁴ 42 USC 288(b)(4), as implemented by 42 CFR §§ 66.106(e) and 66.205(b)

⁵ <u>https://www.law.cornell.edu/uscode/text/42/288</u>

⁶ <u>https://grants.nih.gov/grants/guide/pa-files/PA-14-042.html</u>

⁷ https://nexus.od.nih.gov/all/2013/05/16/more-information-on-the-k99r00-awards/

⁸ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-027.html

postdoctoral experiences. The University of California system and University of North Carolina have reportedly implemented less-strict limits.⁹

1.2 The title of "postdoctoral researcher" should only be applied to those people receiving advanced training in research. Funding agencies should have a consistent designation for "postdoctoral researchers" and require evidence of advanced research training. Institutions should create professional positions for individuals who are conducting research but who are not receiving training, such as permanent staff scientists.

The Postdoctoral Experience Revisited (2014)

There has been no known uniform action on the titles of postdoctoral researchers supported by research project grants. Most universities have policy guidance stipulating that postdoctoral researchers should receive training. Nevertheless, it is not clear whether universities instituted these policies before or after the report's recommendations, and it is not clear whether these policies reflect the extent of training that postdoctoral researchers receive.^{10,11}

However, all postdoctoral researchers supported by NIH NRSA funds via training grants or fellowships are said to be in training. For individuals supported on research grants, the grantee institutions assign the title, and institutions or principal investigators (PIs) assign the duties of the postdoctoral researcher.¹²

1.3 NIH, academic institutions, and research institutions should increase training and mentoring of postdoctoral researchers.

Bridges to Independence (2005) The Postdoctoral Experience Revisited (2014)

Structured training experience for postdoctoral researchers should be provided by requiring individual development plans (IDPs) for all NIH-supported postdoctoral researchers

Biomedical Research Workforce Working Group Report (2012)

⁹ http://www.nature.com/news/the-future-of-the-postdoc-1.17253

¹⁰ http://www.columbia.edu/cu/vpaa/handbook/research.html

¹¹ http://www.hr.virginia.edu/hr-for-you/professional-research-staff/

¹² https://grants.nih.gov/grants/guide/pa-files/PA-16-307.html

Some NIH programs and policies have aimed to increase training experiences for postdoctoral researchers and graduate students. In 2013, NIH encouraged institutions to develop and use Individual Development Plans (IDPs) for postdoctoral researchers and graduate students. In 2014, NIH issued a notice to indicate that NIH annual progress reports received on or after October 1, 2014 must include a section describing how IDPs are used to identify and promote the career goals of graduate students and postdoctoral researchers associated with NIH awards. This is required for research project grants supporting graduate students and postdoctoral researchers and postdoctoral researchers and for all T, F, K, R25, D43, and other awards or award components designed to provide training and professional development opportunities for graduate students and postdoctoral researchers.^{13,14} NIH also launched the K99/R00 Pathway to Independence awards in 2006 in response to the *Bridges to Independence* report and specified a mentoring component and training plan relating to the candidate's career goals.¹⁵

1.4 NIH should increase the proportion of postdoctoral researchers supported by training grants and fellowships.

Bridges to Independence (2005) Biomedical Research Workforce Working Group Report (2012)

The number of T32 and F32 postdoctoral training grants and fellowships has remained relatively constant since these recommendations were made (see section 1.6 for more detail). In 2013, following the Biomedical Research Workforce Report review, NIH declared its intention to increase support for the K99/R00 Pathway to Independence awards, aiming for a 30 percent success rate compared to the 23 percent success rate in 2012 (Figure 1-1).

Outside of the NIH, some private foundations have developed new postdoctoral fellowships. For example, the Simons Foundation responded to the NIH report by developing its Bridge to Independence Award to invest in and support early investigators in autism research.¹⁶ Similarly, the Howard Hughes Medical Institute initiated the Hanna Gray Fellowship Program in 2016 to support researchers for a minimum of two and a maximum of four years of postdoctoral training

¹³ https://biomedicalresearchworkforce.nih.gov/improve.htm

¹⁴ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-113.html

¹⁵ https://www.nih.gov/news-events/news-releases/nih-announces-program-foster-independence-new-investigators, initial funding opportunity announcement: <u>https://grants.nih.gov/grants/guide/pa-files/PA-07-297.html</u>

¹⁶ https://www.simonsfoundation.org/funding/funding-opportunities/autism-research-initiative-sfari/bridge-to-independenceaward-request-for-applications/



Figure 1-1. Trends in the K99 research career development award: Competing applications and awards between 2007 and 2016. SOURCE: NIH IMPAC, Success Rate File.

and up to four years of a tenure-track faculty position at a U.S. institution with a doctoral-level graduate program in the fellow's field of interest.¹⁷ Other privately funded postdoctoral research award programs include the Damon Runyon Fellowship Award,¹⁸ the American Association for Cancer Research Postdoctoral and Clinical Research Fellow Grants,¹⁹ and the American Heart Association Postdoctoral Fellowship.²⁰

The recommendation to increase the proportion of postdoctoral researchers supported by training grants and fellowships has received some resistance from the research community. For example, the Association of Medical and Graduate Departments of Biochemistry (AMGDB) published a response on behalf of its leaders through the American Society for Biochemistry and Molecular Biology (ASBMB) detailing its opposition to the Biomedical Research Workforce report recommendation.²¹ In its response, the AMGDB leaders opposed increasing the number of postdoctoral fellows supported through training grants, asserting that postdoctoral salary support

¹⁷ https://www.hhmi.org/news/hhmi-launches-new-program-early-career-scientists

¹⁸ https://www.damonrunyon.org/for-scientists/application-guidelines/fellowship

¹⁹ http://www.aacr.org/FUNDING/PAGES/POSTDOCTORAL-AND-CLINICAL-RESEARCH-FELLOW-GRANT-RECIPIENTS DFCBB5.ASPX#.WYH6A1GO2RZ

²⁰ <u>http://professional.heart.org/professional/ResearchPrograms/ApplicationInformation/UCM_443314_Postdoctoral-</u> Fellowship.jsp

²¹ http://www.asbmb.org/asbmbtoday/201409/Education/

though R01 grants is a historically effective mechanism to easily and efficiently accommodate productivity and achievement.

1.5 NIH should shift the balance in NRSA postdoctoral training for physicians so that greater proportions are supported through individual fellowships, rather than institutional training grants.

Physician-Scientist Workforce Working Group Report (2014)

Thus far, there is no known action addressing this recommendation.

Physician scientists with professional health degrees are eligible to apply for individual postdoctoral fellowships known as F32 awards and receive special consideration under NRSA legislation if they agree to undertake a minimum of two years of biomedical research.^{22,23,24} Available data indicate that a majority of applicants and awardees for postdoctoral fellowships hold a Ph.D., but the success rate for those physician scientists who apply is similar to that of Ph.D.-only applicants (Figure 1-2). In 2016, the success rate for F32 applicants with the following degrees was 28.1 percent for Ph.Ds., 28.6 percent for M.D.s, and 29 percent for M.D.-Ph.Ds.²⁵



Figure 1-2. Trends in F32 Awards: The success rate for F32 applications by degree between 2011 and 2016. SOURCE: NIH IMPAC, Success Rate File.

²² <u>https://grants.nih.gov/grants/guide/pa-files/PA-16-307.html</u>

²³ https://www.law.cornell.edu/uscode/text/42/288

²⁴ https://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch11.htm

²⁵ <u>https://report.nih.gov/success_rates/index.aspx</u> "Postdoctoral fellowships (F32s): Applications, awards, success rates, and funding, by degree of applicant"

Over the last decade, the number of applications for individual postdoctoral fellowships from physician-scientists has declined, as has the number from applicants with Ph.D. degrees (Figure 1-3). At the same time, NIH has offered opportunities for physician-scientist training through the Clinical Translational Science Awards (CTSA), established in 2006 (eight years prior to recommendation 1-5). Nearly 300 physician-scientists a year receive support to develop their research careers through institutional career development awards associated with CTSAs.²⁶ Other mechanisms, such as institutional K12 awards provided by multiple Institutes and that support both physicians and basic scientists are also available.²⁷ Discussions are ongoing as to the most effective ways to support postdoctoral training of physician scientists through fellowships and

other mechanisms.





Figure 1-3. Trends in F32 applications: Numbers of competing applications (top left: all applicants; top right: medical degree-holding applicants only) and percent of applicants with particular degrees (bottom—all applicants) between 2007 and 2016. SOURCE: NIH IMPAC, Success Rate File.

²⁷ For example: <u>https://grants.nih.gov/grants/guide/pa-files/PAR-16-103.html; https://grants.nih.gov/grants/guide/pa-files/PAR-16-189.html; https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-016.html; https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-010.html; https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-17-010.html</u>

²⁶ <u>https://report.nih.gov/success_rates/index.aspx</u> "Postdoctoral fellowships (F32s): Applications, awards, success rates, and funding, by degree of applicant"

1.6 The total number of NRSA positions should remain at previous fiscal year levels. *Research Training in the Biomedical, Behavioral and Clinical Research Sciences (2011)*

The total number of NRSA postdoctoral positions, which includes both T32 and F32 awards, has remained relatively constant since the report's release in 2011. F32 awards have remained at approximately 500 to 600 awards per year and T32 awards, which each support varied numbers of pre- and/or postdoctoral training slots, have ranged between approximately 300 and 400 awards per year (Figures 1-4 and 1-5).



Figure 1-4. Trends in NRSA awards: (top) Competing applications, awards, and success rates between 1998 and 2016 for F32 postdoctoral fellowships. SOURCE: NIH Data Book; (bottom) Awarded NRSA training and fellowship positions by pre-doctoral and post-doctoral status between 1998 and 2016. SOURCE: NIH Correspondence



Figure 1-5. Trends in T32 Awards: Number of awards between 2007 and 2016. SOURCE: NIH Success Rates.

1.7 Institutions should better communicate career prospects to trainees and facilitate broader educational and training opportunities.

Bridges to Independence (2005) Biomedical Research Workforce Working Group Report (2012) Sustaining Discovery in Biological and Medical Sciences, FASEB (2015)

In 2014, prior to FASEB's release of this recommendation, NIH changed the instructions related to career preparation of individuals supported by NRSA training programs to reflect changes in career opportunities. This change occurred after similar recommendations were made in the Biomedical Workforce Working Group report to the Advisory Committee to the Director of NIH in 2012. The program announcement associated with this change specifies that trainees should receive preparation for research–related careers, as well as research–intensive careers, in various sectors, e.g., academic institutions, government agencies, for-profit businesses, and private foundations.²⁸ The instructions also state that training programs should make available structured career development, advising, and learning opportunities (e.g., workshops, discussions, IDPs).

In 2013, prior to the FASEB report release, NIH launched the "Strengthening the Biomedical Research Workforce" program through the Common Fund as one component of a

²⁸ <u>https://grants.nih.gov/grants/guide/pa-files/PA-16-152.html</u>

trans-NIH strategy to enhance training opportunities for early career scientists that would prepare them for a variety of research-related career options.²⁹ The core component of this program is the NIH Director's Biomedical Research Workforce Innovation Award to enhance biomedical research training, more commonly called the Broadening Experiences in Scientific Training (BEST) awards. These 5-year awards are intended to support innovation in both graduate student and postdoctoral researcher training.³⁰ The first application cycle for BEST was in 2013. Ten awards were issued in fall of 2013 and seven additional awards were made in 2014. However, the BEST program is limited to 17 institutions and no known long-term action has been taken by NIH to continue the program because Common Fund programs are not renewable. Evaluation of the outcomes and dissemination of the best practices beyond the 17 institutions, however, is a key requirement of current the BEST program. Additionally, NIH plans to host a 'Best Practices Meeting' in 2017 to discuss how to disseminate best practices and lessons learned from the BEST Programs.³¹

The NIH has worked with the National Academies on the University Industry Demonstration Partnership (UIDP) to identify and coordinate activities related to enhanced and more targeted career development options for both graduate students and postdoctoral researchers. One example of an activity is a November 2016 workshop that discussed approaches for improving nonacademic career information flow.³²

Some higher education institutions are implementing programs outside of the BEST structure, such as the Biomedical Careers Initiative at Johns Hopkins,³³ to better communicate career prospects to their trainees. Other academic institutions have implemented programs to expand postdoctoral training. For example, the University of Washington instituted the Broadening the Representation of Academic Investigators in Neuroscience (BRAINS) program in 2013, funded by an R25 grant from the National Institute for Neurological Disorders and Stroke, to support professional development of researchers from underrepresented groups.³⁴ An evaluation of the first two cohorts indicated that participation in BRAINS yielded improved professional development confidence and activity, as well as parity in job outcomes for

²⁹ <u>https://commonfund.nih.gov/workforce/fundedresearch</u>

³⁰ <u>http://www.nihbest.org/about-best/</u>

³¹ <u>http://www.nihbest.org/2017best-practices-workshop/</u>

³² https://www.uidp.org/non-academic-pathways/

³³ http://bci.jhmi.edu/About percent20BCI

³⁴ http://depts.washington.edu/brains/program.html

ers

13

underrepresented minority researchers.³⁵ However, there is no evidence of a unified action by research-intensive universities, research institutions, and other host institutions to provide career development opportunities for postdoctoral researchers.

Some other organizations have programs that aim to address the need for career preparation for postdoctoral researchers. NSF piloted the Discovery Corps Fellowship Program to identify new postdoctoral and professional development models that combine research with service-oriented projects.³⁶ However, this program began before the release of the reports, and no known widespread action has been taken by NSF in response to this recommendation. Many professional societies, including the ASBMB, FASEB, AAMC, the American Association for the Advancement of Science (AAAS), the Council of Graduate Schools (CGS), and the Center for Biomedical Career Development, are devoting efforts to broaden career preparation for their members.

1.8 NIH should increase postdoctoral fellow stipends.

Research Training in the Biomedical, Behavioral and Clinical Research Sciences (2011) Biomedical Research Workforce Working Group Report (2012) The Postdoctoral Experience Revisited (2014)

While the recommended stipend levels from the three reports differ, the NIH increased NRSA stipends for starting level postdoctoral trainees and fellows between FY2014 and in FY2017. As of 2017, NIH postdoctoral stipend levels have reached the minimum level recommended by the *Biomedical Research Workforce* report but not the minimum recommended by the *Postdoctoral Research Experience* report. The 2017 NRSA stipends in constant 2012 dollars are at 1975 levels following a period of declining salary levels before 1998 (Figure 1-6).

The Department of Labor proposed a rule that updated overtime regulations by expanding eligibility under the Fair Labor Standards Act (FLSA) to employees earning a salary of less than \$913 per week. However, on November 23, 2016, a United States District judge imposed an injunction, temporarily stopping the rule's enforcement nationwide, in order to have time to determine whether the Department of Labor had the authority to issue the regulation. In response to the FLSA revision, the NIH director announced that NIH will work to raise NRSA awards

³⁵ <u>http://www.lifescied.org/content/15/3/ar49.full</u>

³⁶ https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=6676



Figure 1-6. NRSA Postdoctoral salaries in real and constant dollars (Left: in constant 1975 and 2012 dollars since 1975; Right: in 2012 dollars since 2011). SOURCE: NIH NRSA notices, BLS Inflation Tool for CPI adjustment.

above the threshold³⁷ and the 2017 NRSA starting postdoctoral stipend was increased to \$47,484. Stipends at all other postdoctoral levels were also increased in 2017.

1.9 NIH should increase indirect cost rates on NRSA training grants and K awards. *Research Training in the Biomedical, Behavioral and Clinical Research Sciences (2011)*

NIH reports that it has assessed the costs related to the NRSA program and concluded that many institutional costs normally covered by indirect cost payments can be reimbursed via tuition payments allowed under NRSA. NIH therefore has not taken any further action on this matter.

1.10 Postdoctoral researchers supported on NIH research grants should receive comparable benefits to other employees at the institution.

Biomedical Research Workforce Working Group Report (2012)

Postdoctoral researchers are often considered employees of their institution and are thus subject to institutional policies. Therefore, in direct response to this recommendation, NIH solicited input from the extramural postdoctoral community in early 2014 on benefits currently provided to postdoctoral researchers to identify opportunities to equalize benefits across various

³⁷ http://www.huffingtonpost.com/francis-s-collins-M.D.-Ph.D./fair-pay-for-postdocs-why_b_10011066.html

support mechanisms.^{38,39} The content of the community comments is currently unknown. However, in 2015, NIH conducted a survey of institutions—50 percent responded—to understand benefits for postdoctoral researchers supported on different mechanisms. Responses to the survey indicated that many institutions provide postdoctoral researchers supported on research grants with benefits such as standard health insurance that are comparable to other employees (Figure 1-7). Nevertheless, survey responses also revealed variation across institutions and funding mechanisms.⁴⁰

In response to these survey results, the NIH Office of Extramural Research convened a working group titled "Benefits for National Research Service Award Postdoctoral Researchers" to discuss optimization of benefits provided to postdoctoral trainees and fellows supported on NRSA awards. NIH reports that the group provided recommendations to address the issue and will contribute to an implementation plan in 2017.⁴¹ NIH also issued a notice to clarify that recipients of NRSA awards are eligible for eight weeks of paid family leave.⁴²



Figure 1-7. Survey of health benefits for postdoctoral researchers. SOURCE: NIH Survey of Institutions.

³⁸ <u>https://biomedicalresearchworkforce.nih.gov/docs/Postdoc_survey_sample_letter.pdf</u>

³⁹ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-045.html

⁴⁰ https://nexus.od.nih.gov/all/2015/11/30/update-postdoctoral-benefit-survey/

⁴¹ https://dpcpsi.nih.gov/collaborations/committees.aspx?TID=2#14

⁴² https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-105.html

1.11 Provide new postdoctoral independent research awards at NIH that would complement NRSA.

Bridges to Independence (2005)

NIH established two award mechanisms that address this recommendation: the K99/R00 Pathway to Independence awards and the NIH Director's Early Independence Award (DP5). NIH launched the K99/R00 award in 2006-2007 (more details on the K99/R00 in section 1-13), and NIH has awarded some 200 to 250 K99 awards annually since 2012.⁴³ NIH launched the DP5 award in 2011 to support investigators pursuing independent research directly after completing a terminal doctoral/research degree or clinical residency. NIH has funded approximately 10 to 16 awards annually since 2011.

Relevant NIH programs in existence prior to this recommendation include the Mentored Research Scientist Career Development Award for basic and behavioral scientists (K01), other K awards that support physician scientists to pursue basic, translational (K08) or patients oriented mentored research (K23) with a goal to transition to independence, and the Ruth L. Kirschstein Interdisciplinary Research Training Award (T90) and combined Research Education Grant (R90). The purpose of the K01 is to provide support and "protected time" (over three, four, or five years) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence.⁴⁴ There has been a growth in K01 awards from 82 in 1997 to 202 in 2016.⁴⁵ The K awards that support physician scientists are discussed later in this document.

The T90 and R90 are institutional programs that together support comprehensive interdisciplinary research training programs, but the R90 gives support to those who do not meet qualifications for NRSA support. The T90 component supports postdoctoral researchers through institutional NRSA awards and does not provide individual independent research awards to postdoctoral researchers.⁴⁶

 ⁴³ https://www.nih.gov/news-events/news-releases/nih-announces-program-foster-independence-new-investigators
 ⁴⁴ https://grants.nih.gov/grants/guide/pa-files/PA-14-044.html
 ⁴⁵ https://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=211&catId=16
 ⁴⁶ https://grants.nih.gov/grants/funding/t90.htm

1.12. The citizenship requirement for NRSAs should be modified to provide equal opportunities for non-U.S. citizens.

Bridges to Independence (2005)

17

To be eligible for an NRSA award, individuals must be U.S. citizens, noncitizen nationals of the United States, or lawfully admitted to the United States for permanent residence at the time of the award. This is mandated by NRSA statute 42 CFR 66.103(a); any modification would require legislative action.

There is currently no citizenship requirement for K99 applicants, but significantly more individual postdoctoral NRSA fellowships (approximately 550-650 annually) are awarded than K99s (approximately 200 annually). In addition, NRSA awards support postdoctoral researchers, while the K99/R00 supports postdoctoral researchers transitioning to independent faculty positions. However, research grants such as R01s support significantly more postdoctoral researchers than either NRSAs or K99s. Institutions make the decisions regarding hiring decisions for staff and postdoctoral researchers on R01 or RPG awards and have the ability to hire non-citizens with appropriate visa status. In 2014, 12 percent of postdoctoral researchers in the biomedical, behavioral, social, and clinical sciences were supported by federal traineeships and fellowships, whereas 45 percent were supported by federal research grants.⁴⁷

In 2003, prior to the release of *Bridges to Independence*, NIH created the Ruth L. Kirschstein Interdisciplinary Research Training Award T90 combined with a Research Education Grant (R90) (discussed in section 1.11), which permits research education experiences for individuals who do not meet the qualification for support under the NRSA program.^{48,49}

1.13. NIH should commission an independent evaluation of different models of postdoctoral support.

Bridges to Independence (2005)

Since the release of this recommendation, NIH has conducted various evaluations of postdoctoral support. In 2006, NIH released an independently authored report titled "The Career Achievements of NRSA Postdoctoral Trainees and Fellows" that discussed the value of

⁴⁷ https://report.nih.gov/nihdatabook/, NSF-NIH Survey of Graduate Students and Postdoctorates in Science and Engineering

⁴⁸ https://www.law.cornell.edu/cfr/text/42/66.103

⁴⁹ https://researchtraining.nih.gov/programs/training-grants/T90-R90

independent awards for postdoctoral researchers.⁵⁰ NIH reported in 2016 that successful Research Project Grant (RPG) awardees are more likely to have previously been supported on an F or T award (either predoctoral or postdoctoral).⁵¹ NIH also indicated that the Division of Biomedical Research Workforce (DBRW) is completing an evaluation of the outcomes of F32 fellowship programs between 1996 and 2008.

NIH has been monitoring the progress of its K99 awardees and the extent to which they are identifying appropriate positions, transitioning to the R00 phase of the award, and subsequently applying for R01s. According to NIH, early results have been positive overall. Since its launch, over 2,000 investigators have received the K99 award.⁵² Of the cohort funded in 2007 (183 investigators), 93 percent transitioned into the R00 phase, indicating that they successfully secured an independent research faculty position at an extramural institution within the United States.⁵³ Of those that transitioned to the R00 stage, 59 percent secured an R01 grant by 2014. These results led to a recommendation from the Advisory Committee to the NIH Director (ACD) working group that studied the biomedical research workforce to increase the number of K99/R00 awards beginning in FY 2014.⁵⁴

In 2011, NIH released an independently authored report on an evaluation of outcomes of the NIH Individual Mentored Career Development Award Programs or K awards.⁵⁵ The NIH reports that the DBRW is planning a follow-up evaluation of outcomes of these K awards in 2017-2018.

A 2011 study supported by NIH evaluation funds, but conducted by scholars independent of NIH, found positive impacts of NIH postdoctoral training grants on publication statistics.⁵⁶ This study found, "that for applicants in the neighborhood of the funding cutoff, receipt of an NIH postdoctoral fellowship significantly increases the probability that a new Ph.D. will successfully make the transition to a research career and the number of articles published in the ten years following grant receipt."

⁵⁰ <u>https://researchtraining.nih.gov/resources/data-outcomes-and-evaluations</u>

⁵¹ https://nexus.od.nih.gov/all/2016/11/28/how-many-researchers-were-supported-by-nih-as-trainees/

⁵² https://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=211&catId=16

⁵³ http://datahound.scientopia.org/2014/07/17/my-first-pass-evaluation-of-the-k99-r00-program/

⁵⁴ https://grants.nih.gov/grants/new_investigators/QsandAs.htm#1624

⁵⁵ https://researchtraining.nih.gov/sites/default/files/pdf/K_Awards_Evaluation_FinalReport_20110901.pdf#

⁵⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3158578/

2. RECOMMENDATIONS ON SUPPORTING DIVERSITY

Diversity in the biomedical and behavioral research workforce is critical to ensure that the best and brightest minds have the opportunity to contribute to the realization of national research goals. Yet despite longstanding efforts from NIH and other entities across the biomedical and behavioral research landscape to increase the number of scientists from underrepresented groups, diversity in biomedicine still falls short of mirroring that of the U.S. population. These populations include women, people from traditionally underrepresented minority (URM) groups, and people from disadvantaged backgrounds across the lifespan of a research career.

2-1. There is a need for stronger coordination of diversity-related efforts and evaluation of outcomes at NIH.

Biomedical Research Workforce Working Group Report (2012) *Working Group on Diversity in the Biomedical Research Workforce (2012)* Physician-Scientist Workforce Working Group Report (2014)

To address findings in a series of NIH studies on the diversity of the biomedical workforce, such as minority underrepresentation in biomedical and behavioral research,⁵⁷ NIH director Francis Collins charged the Advisory Committee to the NIH Director (ACD) in 2011 to form a Working Group on Diversity in the Biomedical Research Workforce. This working group was asked to examine and develop effective strategies to increase diversity.⁵⁸

In 2014, NIH created a Scientific Workforce Diversity Office under the Office of the Director and recruited a Chief Officer for Scientific Workforce Diversity (COSWD).⁵⁹ That same year, NIH established the Diversity Program Consortium (DPC), consisting of Building Infrastructure Leading to Diversity (BUILD), the National Research Mentoring Network (NRMN), and the Coordination and Evaluation Center (CEC). The Coordination and Evaluation Center evaluates diversity of NIH-funded workforce and coordinates efforts, as recommended in these three reports.⁶⁰ In total, NIH invested \$31 million into twelve institutions as part of the

⁵⁷ https://www.ncbi.nlm.nih.gov/pubmed/21852498; https://www.ncbi.nlm.nih.gov/pubmed/27306969; https://www.ncbi.nlm.nih.gov/pubmed/23018334; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1677993 https://acd.od.nih.gov/wgd.htm https://diversity.nih.gov/

⁶⁰ https://commonfund.nih.gov/diversity/overview

collaborating NRMN, BUILD, and CEC awards.⁶¹ While the CEC has been established, the results of its work have not been finalized and made public.

In 2016, the Scientific Workforce Diversity Officer and a trans-NIH working group developed and launched a website that consolidates information and opportunities available to individuals from underrepresented backgrounds interested in biomedical careers.⁶²

This committee has not found evidence on whether widespread evaluations and assessments of diversity-related efforts have occurred at NIH.

2-2. NIH should partner with established minority scientific and professional groups to implement a system of mentorship networks for underrepresented minority students.

Working Group on Diversity in the Biomedical Research Workforce (2012)

A nationwide consortium of biomedical professionals and institutions established the National Research Mentoring Network (NRMN) in 2014 to develop a national network for mentors and mentees in biomedical research. NRMN partners with institutions, professional societies/organizations across the nation to diversify the biomedical workforce by the following: (1) Increasing access to mentoring across all career stages; (2) Training mentors, grant writing coaches, and mentees with a focus on cultural responsiveness; (3) Increasing access to research resources and career development opportunities; and (4) Advancing the science of mentoring

2-3. NIH should establish a working group of the ACD of racially and ethnically diverse scientists to provide regular input to the Director of NIH and Institutes regarding the state-of-the-art in effective programs that reduce disparities in research awards.

Working Group on Diversity in the Biomedical Research Workforce (2012)

NIH formed a subcommittee of the ACD Working Group on Diversity on peer review, which held a competition in 2014 to generate ideas to detect bias and strengthen fairness and impartiality in peer review.⁶³ In addition, the NIH is currently piloting anonymization of grant

 ⁶¹ <u>https://nrmnet.net/</u>
 ⁶² <u>https://extramural-diversity.nih.gov/</u>
 ⁶³ <u>https://acd.od.nih.gov/prsub.htm</u>

applications.⁶⁴ A 2016 NIH report found that disparities in funding continue to persist.⁶⁵ For example, the odds of an application from an African-American scientist being funded are 30 percent lower than an application from a white scientist.

2-4. NIH should support infrastructure development of under-resourced institutions with underrepresented minority scientists.

Working Group on Diversity in the Biomedical Research Workforce (2012)

The BUILD program (section 2-1) supports institutional and faculty development in underresourced institutions, including minority-serving institutions. The SCORE program, piloted in 2014, makes research awards to institutions with historical missions or track records focused on training and graduating students from groups nationally underrepresented in biomedical research.66

Another NIH program supporting under-resourced institutions is the AREA award (R15), which provides research grants to PIs at institutions that are not major recipients of NIH support. This program has been in place since 1985.⁶⁷

2-5. NIH should appoint a Chief Diversity Officer and establish an Office of Diversity. *Working Group on Diversity in the Biomedical Research Workforce (2012)*

NIH established the Scientific Workforce Diversity Office (SWD) in 2013, and Dr. Hannah Valantine became Chief Officer for Scientific Workforce Diversity (COSWD) in March 2014. The NIH deliberately specified that the COSWD must be a practicing scientist, and Valantine has an intramural lab in the National Heart, Lung, and Blood Institute (NHLBI), where she pursues clinical research in cardiology.

2-6. NIH should institute a comprehensive search process to diversify intramural tenure-track investigators.

Working Group on Diversity in the Biomedical Research Workforce (2012)

⁶⁴ https://nexus.od.nih.gov/all/2014/05/29/new-efforts-to-maximize-fairness-in-nih-peer-review/

 ⁶⁵ <u>https://diversity.nih.gov/building-evidence/racial-disparities-nih-funding</u>
 ⁶⁶ <u>https://www.nigms.nih.gov/Research/CRCB/SCORE/Pages/default.aspx</u>

⁶⁷ https://grants.nih.gov/grants/guide/pa-files/PA-03-053.html

Thus far, there is no known action to institute a comprehensive search as recommended. The SWD team has taken some action on projects aiming to diversify the intramural NIH scientific workforce. These efforts involve an integrated strategy to enhance recruitment and retention of diverse faculty in the NIH intramural research program (IRP). One strategy focuses on developing and using a recruitment tool to increase the diversity of the NIH faculty applicant pool.⁶⁸ Starting in 2016, NIH IRP also hosted a conference—the Future Research Leaders Conference (FRLC)-to bring highly qualified diverse talent to the NIH campus during the fall NIH Research Festival.⁶⁹ NIH expects this to be an annual conference. Additionally, the NIH SWD group developed implicit-bias education modules for presentations and workshops that explain the concept of implicit bias and present scientific evidence of how such bias may affect judgments and decision-making in scientific contexts.⁷⁰

2-7. RPGs funding graduate student and postdoctoral researcher training should be required to provide information on efforts to increase diversity, as training grants currently do.

Research Training in the Biomedical, Behavioral and Clinical Research Sciences (2011)

The current NIH RPG grant criteria for awards contain no requirement for reporting information on efforts to increase diversity.⁷¹ As mentioned in the recommendation, training grants such as T32s do require a recruitment plan to enhance diversity. Peer reviewers evaluate the plan after the overall score has been determined and require modification of proposals with unacceptable plans.⁷²

3. RECOMMENDATIONS ON COLLECTING DATA

Broad trends in the training, funding, and employment of early career researchers are known, but next order data about the changing nature of research positions, career aspirations, and the prospects for the next generation of investigators are incomplete. Informative and

⁶⁸ <u>https://diversity.nih.gov/programs-partnerships</u>

https://diversity.nih.gov/programs-partnerships/frlc
 https://diversity.nih.gov/programs-partnerships
 https://diversity.nih.gov/programs-partnerships
 https://grants.nih.gov/grants/peer/critiques/rpg.htm

⁷² https://grants.nih.gov/grants/peer/critiques/t32_D.htm

disaggregated data on the biomedical workforce could identify trends in career interests and outcomes of graduate students and postdocs, as well as inform institutional and federal policy. To be useable by all stakeholders, these data would need to be made publicly available and accessible.

3-1. Institutions should collect data on outcomes of their graduate students and postdoctoral researchers and make that data publicly available. Such information should include completion rates, time to degree, and career outcomes for Ph.D. trainees, as well as time in training and career outcomes from postdoctoral researchers over a 15-year period.

> Bridges to Independence (2005) Biomedical Research Workforce Working Group Report (2012) Postdoctoral Experience Revisited (2014) Sustaining Discovery in Biological and Medical Sciences (2015)

23

Thus far, there is uneven implementation of this recommendation. Graduate and medical schools track information at varying levels of detail and frequency and make it publicly available to varying degrees. Multiple university administrators who presented to the committees spoke to these different approaches to data collection and release. Some institutions collected and published graduate student and/or postdoctoral data before the release of these reports, and there is no clear evidence that tracking expanded in response to these recommendations. Examples of institutions collecting graduate and postdoctoral data and sharing it with the public include the University of California at Berkeley, Stanford University, University of California in San Francisco, and University of Michigan.⁷³

Following the *Bridges to Independence* report, the NIH Health Reform Act of 2006 (P.L.109-482) was signed into law. Section 403C of the law stipulates that institutions receiving NIH-funded training grants are required to report doctoral completion rates and time to degree annually to both the NIH director and applicants to graduate programs at those institutions. In 2009, this requirement was added to the program statistics section of NIH Training Data Tables, which universities must complete to renew training grants, and became a new assurance

⁷³ <u>https://graduate.ucsf.edu/aggregate-data; http://web.stanford.edu/dept/pres-provost/irds/Ph.D.jobs; http://grad.berkeley.edu/doctoral-alumni-outcomes/placement-survey/; https://secure.rackham.umich.edu/academic_information/program_statistics/</u>

requirement, which universities must fulfill in order to be eligible for training grants.^{74,75,76} However, the recommendations outlined in the latter three reports pointed to the inadequacy of these data in helping students make educational and career decisions. For example, the 2015 *Sustaining Discovery* report cited a need for information on career outcomes for graduate students and for basic information such as postdoctoral researchers' time in training to be made available, but these data are not yet required.

As the *Biomedical Research Workforce Working Group Report* articulated, "aggregate level data [are] necessary to determine the number of people in various positions, but individuallevel data and longitudinal individual data would make it possible to identify the characteristics and trajectories of individuals and is important for rigorous modeling and evaluation." As this report points out, NSF's Graduate Student Survey, Survey of Earned Doctorates, and Survey of Doctorate Recipients omit large portions of the postdoctoral population for structural reasons. In addition, these surveys include only doctorate-granting institutions, not research centers and national labs, and only US-trained doctorates. NSF's Scientists and Engineers Statistical Data System (SESTAT) and Bureau of Labor Statistics Occupational Employment Statistics (BLS OES) data also have limitations for gathering data on industrial employment of biomedical researchers, including a four-year lag and no disaggregation by education level.

The following summarizes specific data recommendations—not responses—by report:

• *Sustaining Discovery in Biological and Medical Sciences*: Institutions should publish data on career outcomes of each department's graduate students and postdocs. This information should be readily available to prospective graduate students and applicants. Institutions can collect this information using their fundraising offices and social media resources. This information should include completion rate, time to degree, career outcomes for Ph.D. trainees, and time in training and career outcomes from postdoctoral researchers over a 15-year period. Each institution should collect and prominently display this information on its website.

⁷⁴ https://www.congress.gov/109/plaws/publ482/PLAW-109publ482.pdf

⁷⁵ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-141.html

⁷⁶ Note: In 2015, NIH released a series of new data tables for institutions receiving NIH training grants to complete in conjunction with their applications and progress reports. These data tables ask that institutions collect and report the following information for their trainees: degree completion and dates, career outcomes, and research support over a 15-year period. (See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-112.html and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-112.html and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-112.html and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-112.html and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-007.html)

The Postdoctoral Experience Revisited: Every institution that employs postdoctoral researchers should collect data on the number of currently employed postdocs and where they go after completion and should make this information publicly available. NSF should serve as the primary curator for establishing and updating a database system that tracks postdoctoral researchers, including non-academic and foreign trained postdocs. Host institutions should be consistent with their labeling of postdoctoral researchers, keep track of new hires and departures, and conduct exit interviews to determine career outcomes, and they should make this information available publicly. This activity should be coordinated through a postdoctoral office and take advantage of new technology,

25

- *Biomedical Research Workforce Working Group Report*: Institutions receiving NIH funding should collect information on the career outcomes of both their graduate students and postdoctoral researchers and provide this information to prospective students and postdoctoral researchers and NIH. Such information should include completion rates, time to degree, career outcomes for Ph.D. trainees, and time in training and career outcomes from postdoctoral researchers over a 15-year period. Institutions should display these outcome data prominently on their web sites. This will require institutions to track the career paths of their students and postdoctoral researchers over the long-term. One way to do this would be for an institution to assign graduate students and incoming postdoctoral researchers and postdocs throughout their careers. This could be part of a unique researcher identification (ID) system that would allow tracking of all researchers throughout their career. The ID would need to relate to any NIH ID assigned to the individual.
- Bridges to Independence: Data about all career stages of the biomedical workforce must include the growing population of staff scientists and other non-tenure-track researchers. Moreover, data collection strategies should also be constructed to allow for disaggregated information to detect different trends between sub-populations of the biomedical research

including social media.

⁷⁷ https://orcid.org/

workforce. The committee encourages institutions to collect and make available information about the career outcomes of recent postdoctoral researchers.

3-2. NIH, NSF, and other federal agencies should address data gaps and collect ongoing information on the biomedical and scientific workforce.

Bridges to Independence (2005) Biomedical Research Workforce Working Group Report (2012) Working Group on Diversity in the Biomedical Research Workforce report (2012) Physician-Scientist Workforce Working Group Report (2014) The Postdoctoral Experience Revisited (2014)

Using the eRA Commons ID and Research Performance Progress Report (RPPR), NIH started tracking postdoctoral researchers participating in NIH-funded grants in 2009 and graduate students participating in NIH-funded grants in 2013.^{78,79} NIH has also automated the tabulation of the subsequent institutions and grants of trainees on training grants, degree completion and dates, career outcomes, and research support over a 15-year period.⁸⁰ NIH developed the SciENcv network to help researchers update their CVs as well as keep track of researchers' activities.⁸¹ NIH also supported the development of IPUMS Higher Ed, a publicly available tool released in 2016 that harmonizes multiple NSF datasets—the National and International Survey of Doctoral Researchers (SDR) databases and Survey of College Graduates (NSCG) and National Survey of Recent College Graduates (NSRCG) databases—from 1990-2013. This system provides a user-friendly data extraction system to track career trajectories of Ph.Ds. across different occupations, including in academia, government, industry, and other types of research involvement.

NSF and NIH co-sponsored the development of a Survey of Postdocs at Federally Funded Research Development Centers in 2005 and in 2015 piloted a Survey of Early Career Doctorates to understand the employment of individuals who earned doctorates within the past ten years.^{82,83} A summary of the Survey of Early Career Doctorates is available, and detailed data are

⁷⁸ <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-140.html</u>

⁷⁹ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-097.html

⁸⁰ https://era.nih.gov/services_for_applicants/other/xTract.cfm; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-

^{112.}html; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-007.html

⁸¹ <u>https://www.ncbi.nlm.nih.gov/sciencv/</u>

⁸² https://www.nsf.gov/statistics/srvyffrdcpd/#sd

⁸³ https://www.nsf.gov/statistics/srvyecd/#sd&tabs-1

forthcoming.⁸⁴ While these data collection tools take major steps in the recommended direction, additional efforts may be required to fully address and define workforce data needs.

3-3. NIH should create a permanent unit in the Office of the Director that works with the extramural research community to coordinate data collection and analysis of the workforce and evaluate NIH policies.

Biomedical Research Workforce Working Group Report (2012)

27

NIH established a Division of Biomedical Research Workforce Programs (DBRW) in 2013 to collect and analyze biomedical research workforce data. DBRW works with the Office of Director through the Office of Extramural Research.⁸⁵

4. RECOMMENDATIONS TO SUPPORT EARLY CAREER **INVESTIGATORS**

The success of the biomedical research enterprise depends on the uninterrupted entry of well-trained, skilled, and motivated scientists. However, recent trends in employment and funding opportunities reflect a hypercompetitive atmosphere for independent research careers, potentially dissuading or discouraging trained researchers from remaining in biomedical research after years of training.

4-1. NIH should address the gap in RPG award rates between new and established investigators.

Physician-Scientist Workforce Working Group Report (2014)

The success rates of new and established investigators receiving R01 funding equivalent to an RPG, where "new" denotes investigators who have not previously received an R award, was 14 percent vs. 16 percent, respectively, in 2014; 16 percent in both groups in 2015; and 16 percent vs 18 percent in 2016. It is unclear if there is a consistent gap in success rates to address (Figure 4-8), though the absolute number of established investigators supported on R01s is markedly greater than that of new investigators (Figure 4-9).

 ⁸⁴ <u>https://www.nsf.gov/statistics/srvyecd/</u>
 ⁸⁵ <u>https://biomedicalresearchworkforce.nih.gov/create-office.htm</u>



Figure 4-8. Success rates for new (type1) R01-equivalent grants, by career stage of investigator. SOURCE: NIH Data Book.



Figure 4-9: Number of investigators supported on competing Research Project Grants, by career stage of investigator. SOURCE: NIH Data Book.

NIH is aware of concerns that the percentage of mid-career investigators with RPGs has been declining in recent years⁸⁶ and has recently proposed limitations to the research funding provided to individual investigators to partially address this.⁸⁷ NIH also recently proposed a Next Generation Researcher Initiative which addresses concerns about mid-career investigators.⁸⁸

4-2. NIH should double the number of NIH Director's Early Independence awards.

Biomedical Research Workforce Working Group Report (2012)

The number of Director's Early Independence (DP5) awards, which fund doctoral-level researchers directly entering independent research careers without a postdoctoral training period, grew from 10 in 2011 to 16 in 2016, which is an increase but not a doubling.⁸⁹

4-3. NIH should establish a program to promote innovative research by scientists transitioning into their first independent positions. These grants would replace the K22 awards, and NIH should make 200 grants annually of \$500,000 each, payable over 5 years.

Bridges to Independence (2005)

29

There is no indication that the K22 award program has been fully removed or replaced among institutes at NIH, and many institutes still support the K22.⁹⁰ However, NIH initiated the Pathway to Independence awards (K99 and R00) in 2007 in response to this recommendation and awards approximately 200 K99s each year in accordance with the recommendation. In the K99 phase of the award, the awardee receives salary up to \$100,000 per year, plus fringe benefits, and research support up to \$25,000 per year that may vary by the awarding institute.⁹¹

⁸⁶ <u>http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0168511</u>

⁸⁷ https://www.nih.gov/about-nih/who-we-are/nih-director/statements/new-nih-approach-grant-funding-aimed-optimizingstewardship-taxpayer-dollars

⁸⁸ https://www.nih.gov/about-nih/who-we-are/nih-director/statements/launching-next-generation-researchers-initiativestrengthen-biomedical-research-enterprise

⁸⁹ <u>https://report.nih.gov/success_rates/Success_ByActivity.cfm</u>

⁹⁰ http://grants.nih.gov/grants/guide/rfa-files/PAR-16-202; http://grants.nih.gov/grants/guide/pa-files/PAR-16-140.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-220.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-267.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-293.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-340.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-389.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-434.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-389.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-434.html; http://grants.nih.gov/grants/guide/pa-files/PAR-16-389.html

⁹¹ https://grants.nih.gov/grants/guide/contacts/parent_K99_R00.html

In the R00 phase of the award, the awardee receives total costs of \$249,000 per year for up to three years, half of the recommended funding level.⁹²

4-4. NIH should establish a New Investigator R01 grant where the "preliminary results" section is replaced by "previous experience" to encourage higher-risk proposals.

Bridges to Independence (2005)

The NIH Director's New Innovator Award (DP2) has existed specifically for early career researchers since 2007, and in August 2012 NIH clarified in the Funding Opportunity Description that the emphasis for this award is on innovation rather than preliminary data. The total funding dedicated to these awards is \$80 million for 33 awards in fiscal year 2017,⁹³ a funding level that has changed over time—for example, \$106 million funded 45 awards in 2015, and \$132 million funded 56 awards in 2016.⁹⁴

As of 2009, NIH reviews R01 equivalent grant applications from new or early stage investigators separately from grant applications from established investigators. NIH advises reviewers to expect less preliminary data from new investigators than they do from more experienced PIs.^{95,96}

4-5. NIH should establish a physician-scientist-specific granting mechanism to facilitate transitions to research independence. This program should be similar to the K99/R00 program.

Physician-Scientist Workforce Working Group Report (2014)

NIH released a request for information in 2014 to assess how a K99/R00 program for physician-scientists would work.⁹⁷ In 2016 NIH added a section to the K99/R00 Funding Opportunity Announcement stating explicitly that Physician Scientists are eligible to apply.⁹⁸ In

⁹² https://www.nhlbi.nih.gov/research/training/programs/postdoc/pathway-parent-k99-r00

⁹³ https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-16-004.html

⁹⁴ https://report.nih.gov/success_rates/Success_ByActivity.cfm

⁹⁵ <u>https://grants.nih.gov/policy/new_investigators/index.htm</u>

⁹⁶ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html

⁹⁷ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-009.html

⁹⁸ https://grants.nih.gov/grants/guide/pa-files/PA-16-077.html

August 2017 NIH announced that National Institute of Allergy and Infectious Diseases (NIAID) is offering a physician-scientist-targeted version of the K99/R00.⁹⁹

K08 and K23 awards are individual career development awards for physician scientists and are designed to provide a period of mentored research and a pathway to research independence.¹⁰⁰ They differ from the K99-R00 in that they do not have a linked individual R00 award.

In 2016, NIH hosted three workshops to discuss potential new initiatives to support physician-scientists. The discussions at these workshops contributed to a paper in *Academic Medicine* describing recommended initiatives (in press).

4-6. NIH should double the number of Pathway to Independence awards (K99/R00) and shorten eligibility for applying from five years to three years of postdoctoral experience.

Biomedical Research Workforce Working Group Report (2012)

As of 2014, eligible K99 applicants must have fewer than four years of postdoctoral experience, down from fewer than five years in 2011. This change was intended to hasten the transition to independence.¹⁰¹ The number of K99 awards has increased, but not doubled, since the release of the report in 2012 (Figure 1-1).¹⁰²

4-7. NIH should expand the K24 mentoring award mechanism to include basic sciences and adapt the award to provide opportunities for mid-career faculty to mentor early-stage investigators.

Research Training in the Biomedical, Behavioral and Clinical Research Sciences (2011)

Not all NIH institutes offer the patient-oriented K24 award. For example, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) withdrew from participation in 2017, and the National Eye Institute (NEI), National Institute of Biomedical Imaging and

⁹⁹ <u>https://grants.nih.gov/grants/guide/pa-files/PAR-17-329.html</u>

¹⁰⁰ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-009.html#

¹⁰¹ http://www.sciencemag.org/careers/2013/05/nihs-pathway-independence-award-aims-younger

¹⁰² http://www.sciencemag.org/careers/2013/05/nihs-pathway-independence-award-aims-younger

Bioengineering (NIBIB), and National Institute of Dental and Craniofacial Research (NIDCR) have not participated since 2009.^{103,104}

Currently, there is no mid-career nvestigator mentoring award for basic research, and no apparent move or Request for Information to begin the process.

4-8. NIH should establish a renewable R01-like grant for small science projects (<\$100k) open to researchers who do not have PI status on another research grant. Bridges to Independence (2005)

Currently, NIH does not provide a renewable R01-like grant for small research projects.

NIH's R03 grant was established in 2003, prior to the report release. It supports small pilot projects of under \$50,000 and less than two years, but it does not specify the PI's grant status, is not renewable, and is smaller than this report recommends. The *Bridges to Independence* report noted that R03s are "generally not sufficient for supporting an entire research laboratory, leading new investigators attracted to such programs—because of the lack of preliminary data—scrambling to find funding from many different sources."

4-9. Non tenure track "soft money" researchers should have a budgetary safety net that provides time to reapply for grant support if their funding lapses. The NIH contribution to this safety net should be expanding R55 Shannon awards to provide merit-based bridge awards.

Bridges to Independence (2005)

In 2005, the R56 High Priority Short Term Award replaced the R55 Shannon Award, which had provided \$100,000 over two years to PIs whose grant applications were scored highly but not funded, to strengthen their proposals for resubmission. The R56 award also provides interim funding of up to two years and includes support for gathering data to reapply for NIH research grants. In 2004, the year before report release, NIH funded 10 R56 awards at a total award

¹⁰³ <u>https://grants.nih.gov/grants/guide/pa-files/PA-09-037.html</u>, <u>https://grants.nih.gov/grants/guide/pa-files/PA-10-061.html</u>; <u>https://grants.nih.gov/grants/guide/pa-files/PA-14-047.html</u>; <u>https://grants.nih.gov/grants/guide/pa-files/PA-16-206.html</u>; <u>https://grants.nih.gov/grants/guide/notice-files/NOT-DK-17-005.html</u>

¹⁰⁴ A list of current participating institutes is available at <u>https://grants.nih.gov/grants/guide/pa-files/PA-16-206.html</u>

amount of \$500,005. In FY 2016, NIH funded a total of 332 R56 grants at a total award amount of \$146,697,228, representing a significant expansion of the bridge award mechanism.^{105,106}

4-10. NIH should expand loan repayment programs to all students pursuing biomedical physician-scientist researcher careers and increase the amount of loans forgiven to reflect the debt burden of current trainees.

Physician-Scientist Workforce Working Group Report (2014)

In 2015, one year after the report release, the NIH Loan Repayment Program (LRP) contributed \$360,000 in additional funds towards these 2-year awards for physician scientists, funding approximately the same number of applicants at the same mean award level of \$51,000. For comparison, 79 percent of new award recipients had educational debt greater than \$50,000. However, 2015 is the last year NIH released LRP data, and it is possible that funding levels have changed since then.¹⁰⁷

In 2016, the 21st Century Cures Act (Public Law 114-255) authorized increases in the amount of LRP to a maximum of \$50,000 per year and granted the NIH Director authority to expand the number of LRPs to reflect workforce and research needs.¹⁰⁸ NIH does not appear to have expanded access by physician-scientists to LRPs beyond the current programs for which they are eligible: clinical research, pediatric research, health disparities research, contraception and infertility research, and clinical research for individuals from disadvantaged backgrounds.¹⁰⁹

5. RECOMMENDATIONS TO SUPPORT FACULTY

As research funding becomes increasingly hypercompetitive, even highly productive faculty researchers with established records of success with NIH grants may experience lengthy gaps in

¹⁰⁵ <u>https://grants.nih.gov/grants/funding/r56.htm</u>

https://report.nih.gov/success_rates/Success_ByActivity.cfm
 https://www.lrp.nih.gov/data-reports

https://www.congress.gov/114/bills/hr6/BILLS-114hr6rfs.pdf

¹⁰⁹ https://www.lrp.nih.gov/data-reports

renewal support, thereby disrupting successful research careers and sometimes even leading to closure of research laboratories. Lower success rates lead faculty researchers to devote more of their time to writing proposals, which in turn leads to more time and effort expended in the grant procurement process instead of research.

5-1. NIH should consider a long-term approach to reduce the percentage of funds from NIH sources used for faculty salary support.

Biomedical Research Workforce Working Group Report (2012)

In July 2013, NIH administered a pilot survey at nine institutions to obtain data on the percentage of salary covered by NIH grant dollars, but NIH has not taken any policy actions since the survey. NIH indicated to the committee its concerns about the burden on respondents completing the survey and the variability in levels of soft-money support across different types of faculty positions and different types of institutions, such as research hospitals, institutions without a medical school, and independent research institutes. NIH does not anticipate collecting additional data.¹¹⁰ This type of data is being collected directly through U-Metrics, and expansion of those efforts will eventually provide detailed information about the proportion of salary derived from federal grants.

The National Institute of General Medical Sciences' (NIGMS) Maximizing Investigator Research Awards (MIRA; R35) program recommends that, "Because most institutions expect some commitment from investigators to administrative, teaching and/or clinical duties, any salary support for the Program Director (PD)/PI requested on the grant should generally be less than 51 percent of the PD/PI's annual salary and should in no case be more than the actual research effort the PD/PI will devote to the grant."¹¹¹ Individual NIH institutes have different policies on this; the R35 administered by the National Cancer Institute (NCI),¹¹² for example, suggests but does not require that institutions will commit 20 percent of PI salary, and the R35

¹¹⁰ <u>https://biomedicalresearchworkforce.nih.gov/discussion.htm</u> <u>https://grants.nih.gov/grants/guide/pa-files/PAR-17-094.html</u>; <u>https://grants.nih.gov/grants/guide/pa-files/PAR-17-190.html</u> <u>https://grants.nih.gov/grants/guide/pa-files/PAR-16-411.html</u>

administered by the National Institute of Neurological Disorders and Stroke (NINDS)¹¹³ has no stipulation on salary support.

5-2. Congress should increase the NIH salary cap contingent upon a reduced Facilities and Administrative (F&A) cost recovery at higher salary levels.

Sustaining Discovery in Biological and Medical Sciences (2015)

35

The NIH salary cap is set by appropriations law at Executive Level II of the Federal Executive pay scale. The NIH Executive Level II salary cap was increased from \$183,300 to \$185,100 under the Consolidated Appropriations Act, effective January 10, 2016 and to \$187,000 effective January 8, 2017. However, this is in line with previous annual increases, and it does not take into account a reduced F&A cost recovery.¹¹⁴ Congress has not passed legislation related to reduced F&A cost recovery at higher salary levels.¹¹⁵

6. RECOMMENDATIONS TO SUPPORT STAFF SCIENTISTS

The U.S. biomedical workforce depends heavily on the labor of temporary trainees, such as graduate students and postdocs, leading to the current disequilibrium in the research enterprise given that few academic research positions exist for these trained researchers to enter. To address this imbalance and promote sustainability in the workforce, some groups have suggested the greater utilization of staff scientists in lieu of trainees. Staff scientist positions are non-training positions for Ph.D. scientists interested in running a core facility or serving as a senior researcher in one or multiple laboratories.

6-1. Encourage NIH study sections to be receptive to grant applications that include staff scientists and urge institutions to create position categories that reflect the value and stature of these researchers.

Biomedical Research Workforce Working Group Report (2012)

¹¹³ https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-17-020.html

¹¹⁴ <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-045.html</u> <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-048.html</u>

¹¹⁵ https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-045.html

NIH implemented a change in the instructions to reviewers that directs them to focus on qualifications of applicants rather than job title.¹¹⁶

6-2. The research community should employ more staff scientists and consider more extensive use of career technicians.

Sustaining Discovery in Biological and Medical Sciences (2015)

The committee was unable to find evidence of a systematic change in the employment of staff scientists and career technicians in the research community stemming from this recommendation. On November 4, 2016, NIH announced a pilot program to fund the salary and some travel expenses of 50 to 60 staff scientists over 18 months using the R50 "research specialist" award.¹¹⁷

In 2015, NIH examined research grant progress reports and determined that NIH research grants do support a substantial number of staff scientists. NIH examined the 50,885 grant projects funded in FY 2009 and identified 23,329 individuals, out of the 247,457 total individuals on grants, with the title staff scientist.¹¹⁸

7. RECOMMENDATIONS ON GRANT REVIEW

Since 1946, the expert review by scientific peers has guided NIH funding of scientists in biomedical research. In 2009, NIH introduced a set of five criteria—approach, significance, investigator, innovation, and environment—to guide the peer review of grant applications. The most meritorious applications are discussed by a study section of reviewers comprising research peers who then assign scores for each of the criteria and an overall impact score. There is no absolute correspondence between the impact score of a proposal and whether NIH funds it. In its report, the Working Group on Diversity in the Biomedical Research Workforce acknowledged that peer review is an imprecise tool for selecting awards, and in light of the existence of some evidence suggesting that peer review may be subject to reviewer biases, called for further exploration of peer review and its impact on the workforce.

¹¹⁶ <u>https://biomedicalresearchworkforce.nih.gov/encourage.htm</u>

¹¹⁷ http://www.sciencemag.org/news/2015/03/cancer-institute-plans-new-award-staff-scientists, https://grants.nih.gov/grants/guide/pa-files/PAR-17-049.html

¹¹⁸ http://www.fasebj.org/content/early/2015/11/30/fj.14-264358.full.pdf

7-1. NIH should establish a new Working Group of the ACD composed of experts in behavioral and social sciences and studies of diversity with a special focus on determining and combating real or perceived biases in the NIH peer review system. Working Group on Diversity in the Biomedical Research Workforce (2012)

NIH established the ACD Diversity Working Group Subcommittee on Peer Review in response to this recommendation. The Subcommittee on Peer Review is charged with examining all hypotheses, including the role of unconscious bias, related to disparities in research awards at NIH (See section 2-3). The subcommittee will provide advice on potential interventions to ensure the fairness of the peer review system.¹¹⁹

7-2. NIH should design an experiment to determine the effects of anonymizing applications with respect to applicant identity as well as that of an applicant's institution.

Working Group on Diversity in the Biomedical Research Workforce (2012)

NIH indicated in 2012, after this recommendation was made, that it intended to pilot a program to anonymize applications¹²⁰ and indicated in 2014 that these tests were in progress.¹²¹ NIH has not released the results. In addition, the Center for Scientific Review (CSR) created two challenges to elicit proposals on New Methods to Detect Bias in Peer Review and Strategies to Strengthen Fairness and Impartiality in Peer Review. CSR chose winners in September 2014, but has not yet posted the results of these challenges.¹²²

7-3. NIH should pilot different forms of validated implicit bias/diversity awareness training for NIH scientific review officers and program officers to determine the most efficacious approaches.

Working Group on Diversity in the Biomedical Research Workforce (2012)

The NIH SWD group developed implicit bias education modules for presentations and workshops (see section 2-6). The Chief Officer for Scientific Workforce Diversity has indicated

¹¹⁹ https://acd.od.nih.gov/prsub.htm

¹²⁰ https://www.nih.gov/news-events/nih-proposes-critical-initiatives-sustain-future-us-biomedical-research

¹²¹ https://nexus.od.nih.gov/all/2014/05/29/new-efforts-to-maximize-fairness-in-nih-peer-review/

¹²² https://nexus.od.nih.gov/all/2014/05/29/new-efforts-to-maximize-fairness-in-nih-peer-review/

that approximately 300 investigators have received this training as of 2017,¹²³ though it is unclear what roles those investigators held in the grant review process. In addition, CSR created two challenges to maximize fairness in peer review of grant applications (see section 7-2).

¹²³ <u>https://diversity.nih.gov/blog/2017-04-19-re-thinking-first-impressions</u>