

NIH ADVISORY COMMITTEE
TO THE DIRECTOR (ACD)
NEXT GENERATION
RESEARCHERS INITIATIVE
WORKING GROUP REPORT

December 2018

Table of Contents

Working Group Members	ii
Acknowledgements.....	iv
Executive Summary.....	v
ACD Next Generation Researchers Initiative Working Group Report	1
I. Understanding the Need.....	1
Stability of the biomedical workforce.....	1
Early-career scientists’ challenges	2
II. Review of NIH Policies and Activities	5
New Investigator/Early Stage Investigator policies	5
Centralized and IC-specific program approaches	5
Efforts to address workforce issues through resource management	6
Next Generation Researchers Initiative	7
III. Working Group Charge and Activities.....	8
Charge	8
Activities.....	8
IV. Recommendations.....	11
Theme 1: Modify the original NGRI policy.....	11
Theme 2: Develop methods to identify and support “at-risk” investigators and Early Stage Investigators.....	14
Theme 3: Promote sustainable training opportunities that incorporate diversity and inclusion	22
Theme 4: Monitor outcomes and optimize workforce stability through improved metrics and further research	29
Theme 5: Continue transparency efforts and engagement with scientists across career stages to inform policy decisions	31
Recommendations for the broader biomedical research community	34
V. Concluding Statements.....	35
VI. Appendix.....	1
A. Roster	A-1
B. Invited Speakers.....	B-1
C. External Stakeholder Correspondence Received.....	C-1
D. NIGMS Analysis of the Effect of the Early Established Investigator Policy	D-1
E. Summary of 2018 NGRI Approaches to Funding ESI & “At-risk” Investigators.....	E-1
F. References	F-1

Working Group Members

Co-chairs

Jose C. Florez, MD, PhD
Chief, Diabetes Unit, Massachusetts General Hospital; Professor, Harvard Medical School

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

Members

Christine Curran, PhD
Associate Professor, Northern Kentucky University

Amicia Elliott, PhD
Postdoctoral PRAT Fellow, National Institute of Mental Health/National Institute of Biomedical Imaging and Bioengineering, NIH

Gary Gibbons, MD
Director, National Heart, Lung, and Blood Institute, NIH

Linda Griffith, PhD
S.E.T.I. Professor of Biological & Mechanical Engineering; Director, Center for Gynepathology Research, Massachusetts Institute of Technology

Pamela Kreeger, PhD
Associate Professor, Vilas Associate, University of Wisconsin-Madison

Michael Lauer, MD
Deputy Director for Extramural Research, NIH

Michael Levitt, PhD
Professor, Stanford University

Jon Lorsch, PhD
Director, National Institute of General Medical Sciences, NIH

Stephani Page, PhD
Postdoctoral Research Associate, American Heart Association Fellow, Duke University School of Medicine

Timothy Reddy, PhD
Assistant Professor, Duke University

Juan Pablo Ruiz
NIH Oxford Scholar, National Heart, Lung, and Blood Institute, NIH

Elba E. Serrano, PhD
Regents Professor, New Mexico State University

Christina Stallings, PhD
Associate Professor, Washington University in St. Louis, School of Medicine

Bruce Weinberg, PhD
Professor, The Ohio State University

Executive Secretary

Nicole J. Garbarini, Ph.D.
Special Assistant to the NIH Principal Deputy Director, Immediate Office of the Director, NIH

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Executive Summary

The working group recommendations listed here reflect a balancing of needs – the need to balance the future of the biomedical research workforce with sustaining existing research programs; support a balanced workforce across all career stages; create clear and consistent policies across NIH that support the next generation of researchers, while also maintaining flexibility for ICs to address scientific areas/their mission with unique approaches. The working group recommendations address the importance of demonstrating a return on investment on taxpayer dollars that support biomedical research. This includes not only returns in the form of scientific advances, but also returns such as supporting a robust, dynamic, and diverse biomedical research workforce.

The working group recommendations for NIH are grouped into five themes. In addition, the working group made recommendations for the broader biomedical research community. As described throughout the report, the working group sought to outline the pros and cons of all recommendations discussed, and to identify majority and minority perspectives when the working group could not reach consensus. This report also provides recommendations on areas for further investigation that could not be fully addressed by the group but were identified as critical for improving the playing field for early stage and “at-risk” researchers.

Theme 1: Modify the original NGRI policy

- 1.1 Redefine ESI status to increase flexibility and support for individuals at the beginning stages of their career who have had no previous funding as a sole investigator from a major independent award**
- 1.2 Discontinue the “Early Established Investigator (EEI)” definition**
- 1.3 Introduce the definition of “at-risk” applicants, taking into account the duration of their investigative career**

Charged with evaluating the original NGRI policy proposed in August 2017, the working group considered the ESI and EEI definitions, and made recommendations to change the NGRI policy. While the group ultimately only opted to recommend a change to the ESI definition by adjusting consideration of multi-PI projects (see Recommendation 2.2), they agreed that the report should reflect the pros and cons of redefining the ESI status. Showing both sides of the coin, and the perspectives discussed during working group meetings, highlights the difficulty of a policy adjustment that would better support mid-career investigators without detracting from the support of ESIs. A key turning point in the working group’s understanding of the shortcomings of the EEI definition came from real and recent NIGMS data that modeled how applying the EEI definition would indeed rescue the targeted population as intended, but at the cost of losing grants by investigators who were very similar to those favored by the strict EEI definition. As an alternative to the EEI, the working group recommends special funding consideration for “at-risk” investigators -- applicants with meritoriously-scored applications who would not have major NIH research funding if the application under consideration is not awarded. In addition, an “at-risk” investigator would not have significant research support from other sources.

Theme 2: Develop methods to identify and support “at-risk” investigators and Early Stage Investigators

2.1 Expand pathways for funding ESIs through programs that do not require preliminary data

One of the main supporting arguments for increasing the use of the DP2 – a recommendation proposed by members of the research community and also included as a NASEM report recommendation – was to encourage independent lines of investigation, such that the applicant would not feel obligated to use the preliminary data from their postdoctoral training, but could branch out into a new line of research. The working group strongly supports the spirit of this argument, but recommends exploring other avenues to fulfill it through RPGs such as an alternative R01 pathway that does not require preliminary data, or reevaluating the R03 and R21 programs and increasing their budget size.

2.2 Preserve ESI status after first multi-PI award

A repeated theme in the working group discussions was that collaborations between senior or established PIs and less experienced investigators should be true partnerships that can also help launch an ESI’s independent research career. The current ESI multi-PI stipulation is that ESI status is lost in a multi-PI setting: the ESI’s MPI application does not benefit from that status when at least one of the other PIs is not an ESI, and if the application is awarded, the ESI loses their ESI status for a subsequent application. This current stipulation could be seen as penalizing the ESI for embarking on such a collaboration. Thus, the working group recommends preserving ESI status after the ESI’s first multi-PI award.

2.3 Separate review, comparison and scoring/percentiling of ESI applications, grouped during the initial discussion in Study Section

2.4 Prioritize funding for meritorious applications from ESI and at-risk investigators

2.5 Fund ESI investigators’ R01-equivalent applications for at least 5 years

The working group recommends that at a programmatic level, meritorious applications from both ESI and at-risk investigators be given additional consideration and prioritized for funding. The working group, while advocating for the at-risk definition, also felt like revealing the “at-risk” status to peer reviewers would disadvantage their applications. Thus, the working group specifically recommends batching ESI applications in review by grouping them for discussion in the beginning of the peer review meeting, and scoring and percentiling ESI investigator applications relative to each other. In addition, the working group supports measures that help early-career investigators achieve sustained research funding, relieving some of the challenges associated with starting an academic research career. The most significant measure is that all ESI investigator R01s should be at least 5 years in length.

2.6 Incentivize the inclusion of ESIs as project leaders in Program Project Grant applications

While the R01 has long been the main path by which NIH supports investigator-initiated research, there are many other program types which can still be used to support independent research careers. However, NIH also supports major investigator-initiated ideas through other approaches. Program project grants can build comprehensive and integrated research programs to fulfill the research

portfolio needs in support of ICs' missions. The working group thus recommends that NIH incentivize the inclusion of ESIs as project leaders in Program Project Grant applications, citing the NHLBI P01 funding opportunity announcement model.

2.7. Extend R15 awards, per the investigator's choice, to up to 5 years

2.8. Expand R15 use at all NIH ICs

The working group recommends enhancements to, and expansion of, the R15 Academic Research Enhancement Award (AREA) program in support of geographic diversity and diversity in the types of institutions that NIH supports.

2.9 Conduct, within one year, a detailed analysis of salary support derived from NIH grants by updating the 2007 study on this topic

With updated data, the NIH should model various "caps"/levels on the proportion of salary that can be drawn from NIH grants, and the effect this would have for PIs, Co-PIs, and Co-investigators. Particular emphasis should be directed to assess whether: overall positions would be lost; what level of additional resources salary caps would yield; and, to what extent any changes will differentially affect individuals at different stages of career development or in different career tracks (e.g. PhDs vs MDs).

Stakeholder consultation should be conducted with the goal of gradually introducing some level of salary cap limit (informed by the modeling exercise) over a 7-10 year implementation period.

Theme 3: Promote sustainable training opportunities that incorporate diversity and inclusion

3.1 Increase gradient of post-doctoral support levels after 5 years

The working group acknowledges and supports the spirit behind recommendations of postdoctoral fellowship "caps". The working group agrees that postdoctoral training periods should not be inordinately long, and that post-doctoral fellows should be training for an independent career, not prolonged low-cost labor. However, the working group also feels that such "postdoc tenure caps" may penalize postdoctoral fellows as they seek to transition to a faculty position, and thus detract from the broader aims of the Next Generation Researchers Initiative. Alternatively, the working group recommends a postdoctoral stipend scale which is significantly increased after the fifth year of postdoctoral work to reflect advanced experience, disincentivize consideration of postdoctoral fellows as inexpensive labor, and encourage transitions to permanent roles. The working group recommends a steep gradient during these later years so that the stipend is in line with compensation (including benefits) for staff scientists with comparable qualifications, for example, a 10% increase between years 5 and 6, and 7 and 8.

3.2 Ensure that all funding opportunity announcements for training, fellowship, and career awards reflect the requirement to promote diversity and inclusion in a sustainable way

The working group recommends that, for all F/K/T award programs, NIH examine the program and funding opportunity language used to describe a) what applicants should be addressing and b) what peer reviewers should be evaluating, to make sure the program supports the aim of enhancing

workforce diversity. In addition, the working group recommends that NIH support scientific review officers (SROs) in being proactive and making sure that study sections appropriately discuss and address the training environment and mentorship plan during the peer review meeting.

3.3 Require institutions to provide professional development and training plans for mentors and trainees listed on research grants, including actionable feedback from trainees and detailed language in annual and renewal progress reports

As aforementioned, the majority of trainees and fellows are supported on research project grants. The working group recommends that NIH require institutions to provide professional development and training plans for mentors and trainees listed on research grants, and receive actionable feedback from trainees with detailed language in annual and renewal progress reports. The working group recommends that program officers should intervene and remediate any signs of inadequate mentorship.

3.4 Implement ACD Working Group on Diversity recommendations

3.5 Analyze the effect of research topic choice on R01-equivalent funding outcomes

3.6 Expand access to the National Research Mentoring Network-type resources

The working group recommends that NIH implement recommendations proposed by the ACD Working Group on Diversity. The working group also recommends NIH further explore two avenues raised in ACD Diversity Working Group discussions: 1) analyzing the effect of research topic choice on research funding, particularly R01-equivalent funding outcomes, to assess how it may influence diversity among NIH-funded investigators; and, 2) expanding access to National Research Mentoring Network-type resources to support meaningful collaborations as a path for enhancing workforce diversity.

3.7 Ensure that POs interact equitably with all investigators, including ESI and at-risk investigators, and persons from underrepresented groups

3.8 Require broad and recurrent evidence-based training on unconscious bias for POs, SROs, and peer reviewers, and include this as a required component of RCR training for both mentors and trainees

The working group recommends that NIH take measures to ensure that program staff, who often receive questions and inquiries from the research community, are equitably responsive to all investigators. Such measures may include additional assessment of programmatic activities and interaction with potential applicants, or additional training. The working group also recommends that unconscious bias training is integrated in several venues in order to enhance diversity and inclusivity in the biomedical research workforce. This includes training for NIH extramural staff, in support of Recommendation 3.7, as well as training for members of the extramural community (peer reviewers, and mentors and trainees supported by NIH funding).

3.9 Require grantee organizations to provide assurances that they have effective, fair, and up-to-date policies to preserve a harassment-free environment

3.10 Require R13 (conference grant) applications to describe what best practices for a safe and harassment-free environment will be employed at conferences and professional meetings

Threats to a supportive and inclusive climate for trainees and faculty (particularly new faculty) include microaggressions and sexual harassment. The working group recommends that grantee organizations are required to provide assurances directly to NIH that they have effective, fair, and up-to-date policies to preserve a harassment-free environment. The working group also recommends that NIH support workforce diversity and inclusive environments at conferences supported by NIH funding.

Theme 4: Monitor outcomes and optimize workforce stability through improved metrics and further research

- 4.1 Create and establish a formal analysis plan for evaluating the impact of NGRI and early-career investigator programs, and for assessing disparities across ICs**
- 4.2 Support further research on assessments of workforce capacity**
- 4.3 Revise NIH project scoring criteria and funding decision criteria to emphasize the PI's previous 7 years of service and mentorship contributions**
- 4.4 Assess portfolio-wide and NIH-wide productivity and return on investment of taxpayer dollars**

The working group recommends continued examination of the NGRI policy and metrics of productivity and workforce capacity, in support of evaluation of the NGRI and workforce trends overall. The working group recommends that NIH meet these recommendations by engaging stakeholders both internal (such as stakeholders across NIH ICs) and external (such as researchers in the fields of economics and science policy) to advance ongoing efforts.

In addition, the working group expressed a need to consider the many types of scientific contributions beyond publications. The working group recommends that NIH revise its project scoring criteria so that, when evaluating the investigator's contributions to science, reviewers focus on the most recent years of research experience, as well as service and mentorship contributions (up to the 7 most recent years, when applicable). Programmatically, NIH should likewise make funding decisions that focus on the impact of a PI's recent contributions, including service and mentorship contributions.

Theme 5. Continue transparency efforts and engagement with scientists across career stages to inform policy decisions

- 5.1 Increase accessibility of NIH administrative data for both members of the biomedical research community and researchers investigating biomedical science**

The working group recommends two main categories of the type of data NIH should make accessible: 1) administrative data that can describe overall funding trends, and thereby serve to inform career path decision making, and 2) internal data which can be made more accessible for study by researchers investigating biomedical science. The working group also proposed additional metrics that when published and shown at an NIH-wide level and by IC, would be helpful to support the aims of the NGRI.

- 5.2 Expand channels by which the NIH solicits and receives public comments**

To complement Requests for Information (RFIs) which often require long and formal responses, the working group also recommends NIH engage in other modes of soliciting feedback, not just from professional organizations, but also from diverse perspectives beyond standing organizations, as well.

NIH should include paths for novel perspectives and new ideas to be heard, increase diversity of thought, and invite more voices to the table in a two-way dialogue to help inform and shape policy decisions and the public understanding of NIH's policy-making.

5.3 Create a standing working group to monitor and refine the policy recommendations for the Next Generation Researchers Initiative

5.4 Appoint scientists from across career stages and life experiences to NIH working groups and committees

The working group recommends continued input and consultation on the progress of the Next Generation Researchers Initiative. NIH can also further seek input from internal (NIH staff) stakeholders, and leverage existing internal trans-NIH working groups to help support the Next Generation Researchers Initiative. Notably, this is the first ACD working group with considerable representation by early-career investigators and Ph.D. candidate participation. This model of representation and involvement of people across career stages should be carried forth into future iterations of the NGRI working group, as well as other NIH working groups, both external and internal.

Recommendations for the broader biomedical research community

The working group specifically recommends that the broader biomedical research community, particularly NIH-funded organizations as the employers of members of the biomedical research workforce, take action in support of the next generation of researchers. Specifically, the working group recommends that the broader research community examine: 1) hiring and recruitment practices as a point of intervention, 2) salary support and bridge funding for early-career faculty and "at-risk" labs, 3) staff scientist recruitment, 4) impacts on term caps for postdoctoral research fellows, and 5) contributing to data-gathering and transparency.

ACD Next Generation Researchers Initiative Working Group Report

I. Understanding the Need

Stability of the biomedical workforce

In support of its mission, one of NIH's stated goals is "to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease". In addition, NIH identifies another primary goal as advancing scientific knowledge "to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research". A key aspect of both of these goals is stewardship of the biomedical workforce: funding training and career programs, conducting analyses of NIH support, and developing strategic programs and policies in support of biomedical research workforce stability and a strong and well-prepared next generation of researchers.

NIH has long understood that supporting the future biomedical workforce is essential to cutting-edge scientific advances and lasting impact on human health needs. One of the first programs to target support to new investigators was specifically created to "bridge the gap between the research trainee and the independent investigator" for the then-emerging interdisciplinary studies of pathophysiology in trauma and burn patients where a "manpower shortage still seriously inhibits the work to be done in this area."¹ Since then, NIH continued to evolve and refine its policies and programs.

Over the past decade, many groups have published data on the aging of the workforce, and on the age distribution of NIH-funded researchers. Since the late 1990s, the percentage of NIH-funded investigators over the age of 60—those earning research-project and other substantive NIH awards—has risen significantly compared with other age groups.

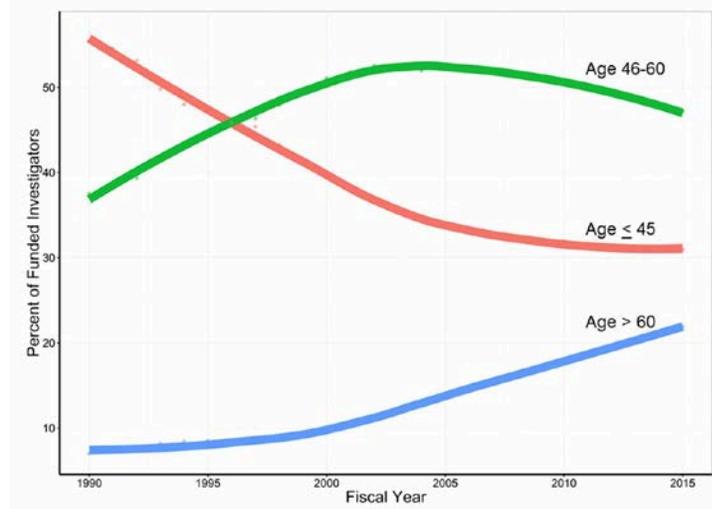


Figure 1: Percent of NIH funded investigators, by age, 1990-2015.

A 2017 PNAS paper describes how the scientific workforce in particular has aged rapidly in recent years, even relative to the aging of the workforce, due to a decline in retirement rate (post elimination of the mandatory retirement rate in 1993) and a steady-state distribution maintained by the baby boomer

generation. Modelling the long-run age distribution of the scientific workforce implies a further substantial increase in the age of the workforce in the years to come.²

While high impact scientific findings can take place throughout an individual's research career and the relationship between age and creativity is influenced by many factors³⁻⁵, there is a need to ensure an overall continuity and stability in the biomedical research workforce.

Such data have led to renewed efforts to address biomedical research stability. This includes a suite of actions in response to 2012 Advisory Committee to the Director (ACD) reports on the biomedical research workforce and workforce diversity, and a 2014 ACD report on the physician-scientist workforce⁶⁻⁸. Even with these changes, a continued confluence of circumstances have created a number of challenges for early-career scientists.

Early-career scientists' challenges

Many stakeholders in NIH-supported research have raised the need for NIH to take additional actions in support of early-career researchers, and much has been published about the various factors that have contributed to additional challenges for early-career researchers.

Since the NIH doubling ended, there has been an increase in the number of individuals seeking funding⁹ (Figure 2 and Figure 3, below). This has led to a hypercompetitive environment, with a core problem described simply as "too many researchers vying for too few research dollars".¹⁰ In addition, competition for academic tenure-track positions has increased for those seeking their first academic position.¹¹ NIH and others have brought attention to broader career options as another aspect of workforce reforms (for example, through the Common Fund program "Strengthening the Biomedical Research Workforce", and "Broadening Experiences in Scientific Training" awards).¹² However, there is a continued need to address the concerns of early-career researchers even after they receive their initial major independent award.

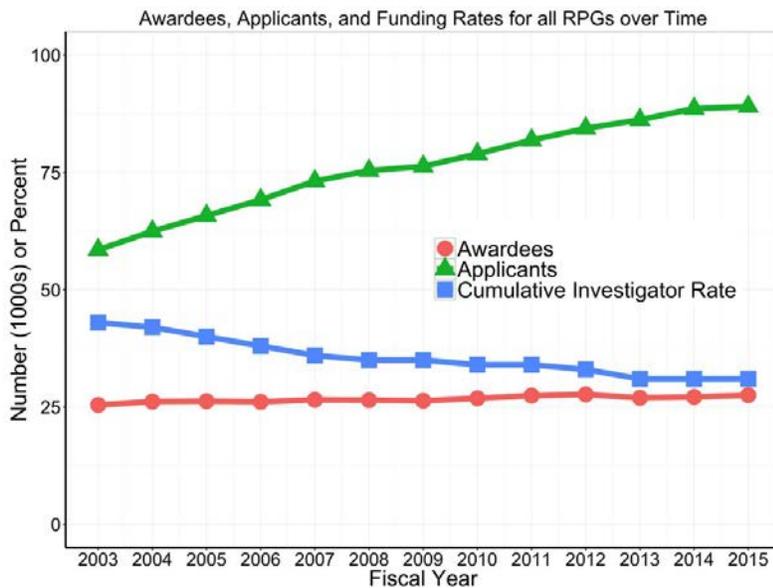


Figure 2: Trend in RPG "cumulative investigator rate" (unique applicants over 5-year window)

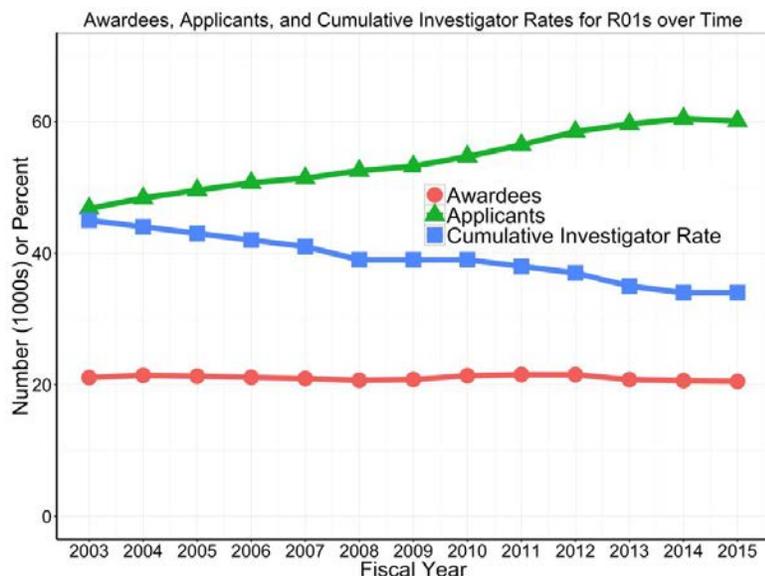


Figure 3: Trend in R01 "cumulative investigator rate" (unique applicants over 5-year window)

Increased attention is being directed toward a “lost generation” of scientific researchers who may have obtained some initial funding, but face increasing pressure in sustaining their new laboratory. These researchers have voiced concerns: a constant pursuit of grants leaving no time for science; needing to rely on senior scientists to advance; detrimental effect of extreme competition on producing well-done experiments.¹³ Several NIH groups have identified and investigated the rate at which investigators drop out from the NIH-supported workforce. Most individuals drop out after the end of their first R01 award.^{14–16} For example, an NIH Office of Extramural Research analysis examined the percent of all first-time R01-equivalent awardees who go on to receive at least one more second substantial award within 5 years. For those who received their first award in 1996, over 55% received at least one substantial award. For first-time awardees in 2011, that value fell to only 38%, even after accounting for ARRA funding (Figure 4).

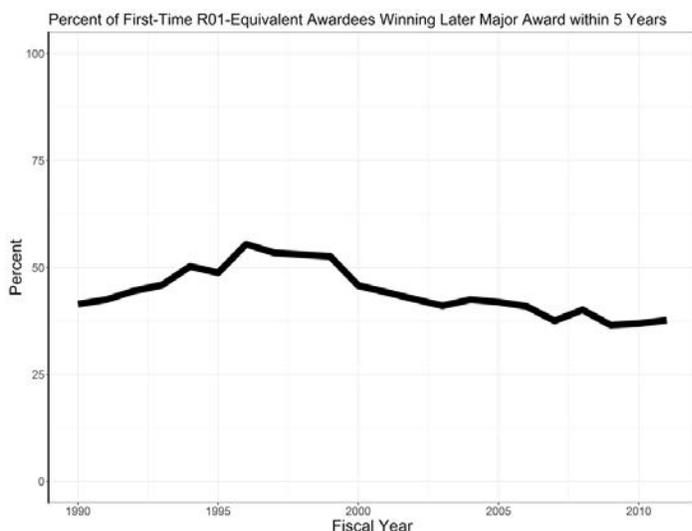


Figure 4 Percent of all first-time R01-equivalent awardees who go on to receive at least one more second substantial award within 5 years

Additionally, while there is a stable representation of NIH-funded investigators aged 24-40 years old, there has been a decline in the proportion of NIH-funded investigators aged 41-55 years old.¹⁷

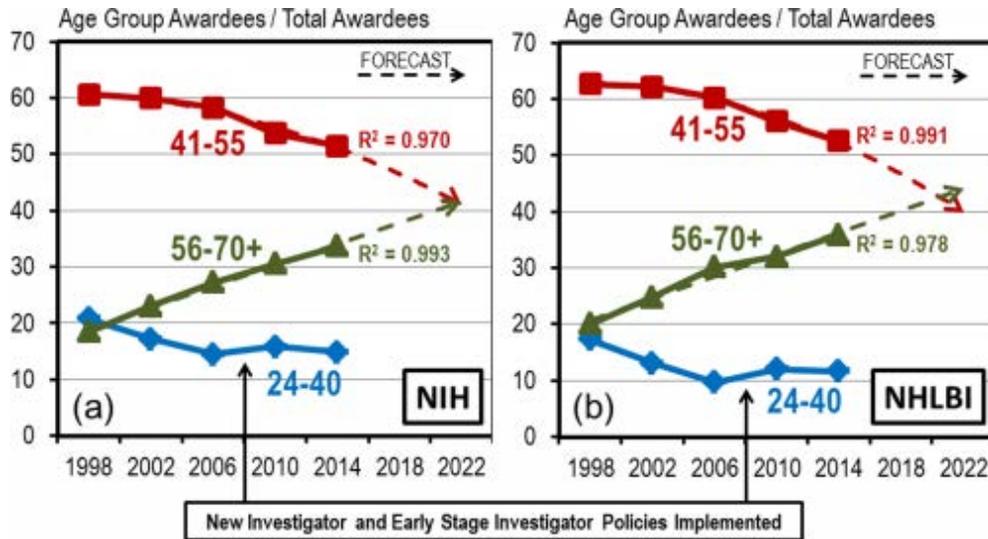


Figure 5 Using age as a proxy for career stage, these graphs show the NIH funded workforce representation of three groups: principal investigators (PIs) aged 24 – 40, 41-55 (the mid-career group), and 56 and above. Dotted line projections assume a stable trend in the composition of the workforce. from: Charette M, Oh Y, Maric-Bilkan C, Scott L, Wu C, Eblen M et al.

Some have pointed to the distribution of funding as one reason why, although the NIH budget has increased in recent years, early- and mid-career researchers continue to experience pressure to obtain funding. As shown in Figure 6, the distribution of research portfolio investment is concentrated and directed to a small fraction of investigators, overall.

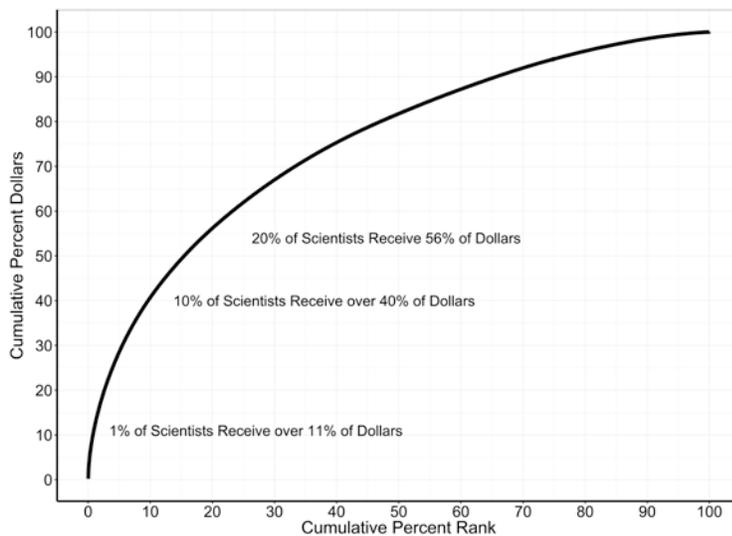


Figure 6 Distribution of funding among NIH-funded PIs. Data includes dollars from both competing and non-competing segments of a grant in a fiscal year. The chart data are at a person-level, where total dollar amount for a person (PI/MPI) was computed by aggregating dollar from all awards on which a person was a PI/MPI. Chart data includes RPGs and other activity codes that were assigned a non-zero Research Commitment Index value (e.g. T32, T35, T15, R24, R25, U54, P30, P20, P41 and P50).

NIH has also examined several efforts to identify the number of researchers that the system can sustain through previous modeling attempts in 2009, as part of the 2012 ACD biomedical research workforce report, and from reports in published literature.^{18,6,19}

II. Review of NIH Policies and Activities

NIH has had a long-standing interest in creating policies and programs that help create an entry into independence.²⁰

New Investigator/Early Stage Investigator policies

Policy changes to support new and early stage investigators were adopted in 2008, to increase the numbers and the percentages of competing R01-equivalent awards going to new investigators who had not-yet received a major independent award.

The New Investigator Policy stated that NIH institutes and centers should make funding decisions that ensure the success rates for New Investigators on new (type 1) R01-equivalent research grant applications should be comparable to the success rates on similar applications from established investigators.

The Early Stage Investigator (ESI) policy addresses the increasing average age of New Investigators. It stated that NIH institutes and centers will make funding decisions that ensure that at least half of the awarded New Investigators are Early Stage Investigators (ESIs): within 10 years of completing their terminal research degree or their medical residency.

NIH clustered R01-equivalent grant applications from New Investigators in peer review to allow peer reviewers to compare applications from PD/PIs with comparable levels of experience. Peer reviewers are instructed to focus more on the proposed approach than on the individual's past research history, and to expect less preliminary information than might be provided by an established investigator.

While the ESI policy had shown some effect, as aforementioned, representation of mid-career investigators in the NIH-supported workforce has declined, pointing to a need of complementary approaches to these prior policies.¹⁷ This led to creating the Next Generation Researchers Initiative, described below.

Centralized and IC-specific program approaches

In addition to NIH-wide policy approaches described above, NIH places a significant investment in programs to support transition to an independent research career through a variety of programs such as fellowships, career awards, and awards targeted for transitions to independent careers (e.g., K99-R00)^{21,22}. In addition, many ICs have specific programs to support early-career investigators. Some of these programs include: National Institute of Dental and Craniofacial Research (NIDCR) Sustaining Outstanding Achievement in Research (SOAR)²³, National Institute of Environmental Health Sciences (NIEHS) Outstanding New Environmental Scientist (ONES)²⁴, National Institute of Mental Health (NIMH) Biobehavioral Research Awards for Innovative New Scientists (BRAINS)²⁵.

Efforts to address workforce issues through resource management

NIH has also sought to address workforce stability through strategies to manage existing resources. Some means for this include:

- Special Council Review (SCR) implementation: In 2012, NIH implemented a policy to provide additional review to determine if additional funds should be provided to already well-supported investigators.²⁶ Advisory Council members provide additional consideration of new and renewal applications from well-supported investigators who currently receive \$1 million or more in direct costs of NIH funding to support Research Project Grants (RPGs).
- Request for Information on Sustainability of Biomedical Research: In April 2015, NIH solicited community input on the possible development of new policies and other strategies to improve the impact and sustainability of the NIH-funded biomedical research enterprise.²⁷⁻²⁹ This input informed the deliberations of an internal working group on developing policies for efficient and stable funding, such as the development of an index to describe grant support.³⁰
- Proposing the use of a Grant Support Index (GSI): One strategy considered was the NIH-wide monitoring of investigators' Grant Support Index (GSI), with the idea that over time, and in close consultation with the extramural research community, NIH would phase in a resetting of expectation for total support provided to any one investigator.³¹

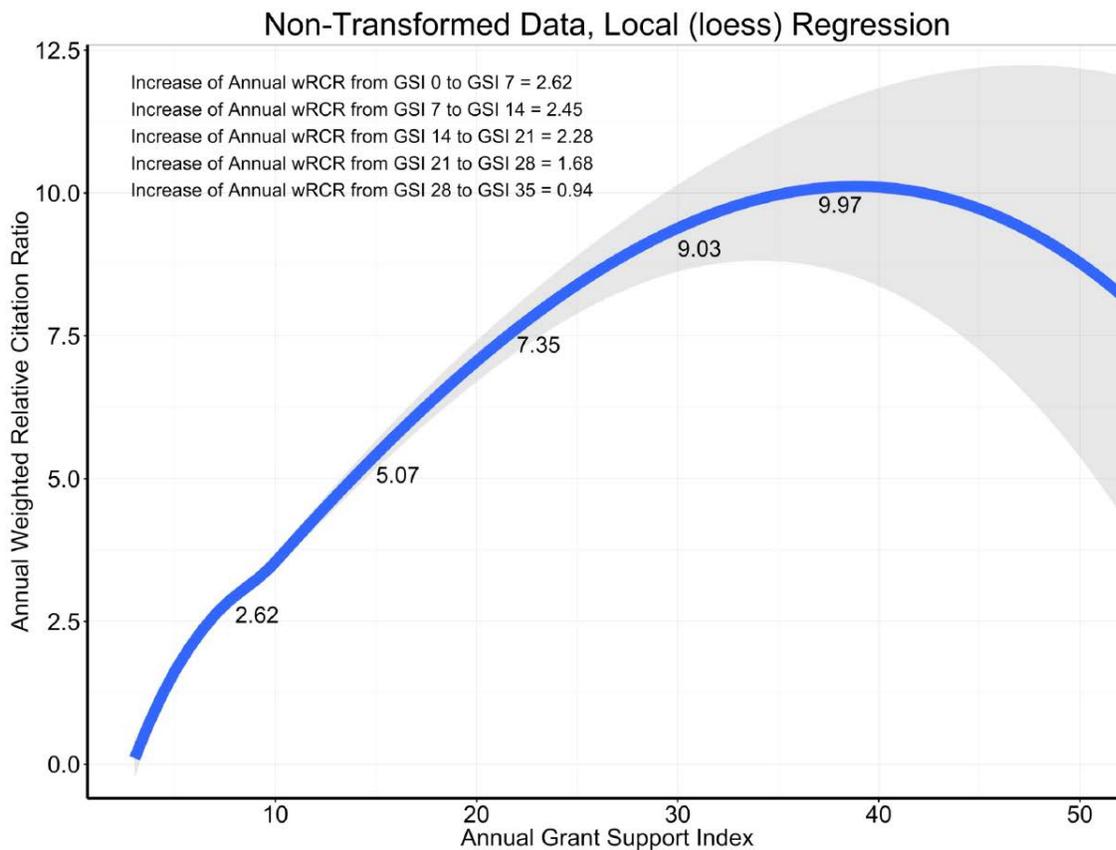


Figure 7 Association of grant support (as assessed by an index that assigns point values to activity codes to quantify research support) with productivity (as assessed by the weighted Relative Citation Ratio).

Next Generation Researchers Initiative

The 21st Century Cures Act, enacted December 13, 2016, includes a section entitled, “Investing in the Next Generation of Researchers” that requires the NIH Director to “Develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity”.³² NIH considered the Grant Support Index as a strategy to fulfill the aim of this charge.^{30,31,33} In response to stakeholder feedback^{34–39}, NIH proposed using a suite of multiple strategies under the umbrella of a new initiative, the Next Generation Researchers Initiative (also referred to as NGRI or “Next Gen”).

On August 31, 2017, NIH announced the Policy Supporting the Next Generation Researchers Initiative, which amended the Early Stage Investigator (ESI) definition; updated ESI policies; introduced a new policy for early established investigators (EEIs); and described how NIH would implement the policy and determine impact on the NIH portfolio.⁴⁰

Early concerns were voiced about this change in approach. For example, in an essay published in November 2017, Mark Peifer proposed that a source for the funds to support ESIs is needed, and such an initiative as it currently stood would jeopardize mid-career investigators who are doing high-quality work with only one R01.⁴¹

Interim approach

Based on preliminary work by the ACD working group and other stakeholder input, NIH announced flagging EEI status would not be used in application and review systems as previously planned. Instead, an interim strategy for Fiscal Year 2018, to consider “at-risk investigators,” would be used until deliberations of the ACD working group are complete, and as recommendations are implemented, as announced in an NIH Guide Notice⁴².

III. Working Group Charge and Activities

Charge

In August 2017, the NIH Director charged the Advisory Committee to the NIH Director (ACD) Working Group on the Next Generation Researchers Initiative to provide advice on the development, implementation, and analysis of the NGRI policy to increase the number of NIH-funded ESIs and EEIs and stabilize the career trajectory of scientists. Considerations were to include:

- Advising NIH leadership on the development of a trans-NIH Next Gen policy;
- Reviewing independent assessments to identify evidence-based metrics for research productivity, and determine the impact of NIH grant support on scientific progress;
- Providing advice and recommendations on approaches for developing or enhancing NIH funding mechanisms aimed at ESIs and EEIs;
- Proposing recommendations for tracking and assessing funding decisions for ESIs and EEIs with fundable scores to ensure the Next Gen initiative is effectively implemented in all areas of research;
- Assuring alignment of recommendations for the opportunities and needs of ESIs and EEIs with the work of other ACD and internal NIH WGs regarding the demographics of workforce, age, sex, ethnic/racial diversity, MDs vs. PhDs;
- Reviewing analyses to assess the impact of the Next Gen policy on the overall NIH scientific portfolio and workforce trends.

In addition, the working group was charged to engage individuals at every career stage, as well as research institutions and other stakeholders.

The working group was assembled as a standing working group of the ACD: Working group members are appointed by the NIH Director, and the working group is comprised of no more than 18 members, consisting of the following: two co-chairs (the NIH Principal Deputy Director and an external member); NIH Leadership (Deputy Directors, OD Office Heads, IC Directors); ACD members; full, associate, and assistant professors; postdoctoral researchers and/or graduate students; economist(s). At the NIH Director's discretion, members are appointed for a term not exceeding 4 years. Members may serve after the expiration of their terms until successors have been appointed. At the expiration of a member's term, the Director may reappoint the member for an additional term.

Recommendations on continued working group activities are included in IV. Recommendations, Theme 5.

Activities

Summary of meetings

After the August 2017 ACD meeting, the working group participants (see roster in Appendix item A) met for a total of 17 meetings (14 video/teleconferences, and three in-person meetings). Initial meetings involved reviews and discussion of relevant published papers, and presentations by NIH senior leaders

on NIH programs to support early-career researchers. The working group developed draft recommendations in Spring 2018, and presented the draft recommendations at the June 2018 ACD meeting. Further discussions and briefings by external groups informed the revisions of these recommendations. The draft recommendations and the working group report were refined at a November 2018 in-person meeting, in preparation for the final draft report delivery at the December 2018 meeting of the ACD. As further discussed in the recommendations section, while the group did not reach consensus on all topics, the group felt that describing the areas of discussion and debate in this report would be advantageous to future deliberations. In addition, the group did cite the need for further exploration of certain areas covered in the charge.

Literature and data reviewed

The working group compiled a library of papers and online data resources throughout the course of their meeting activities. The working group also requested data from the Office of Extramural Research to inform their discussions, including the data shared with the National Academies for the *Breaking Through*⁴³ report. Much of the literature referenced in this working group report formed the basis of initial working group meeting discussions in Fall 2017. A list of references and further resources is provided in the Appendix.

Briefings and information provided by NIH staff

The ACD working group requested information on different models of programs used by NIH Institutes and Centers (ICs) and the Office of the Director to support early-career researchers. Several staff briefings were provided at the first working group in person meeting (Appendix B, Invited Speakers). A narrative summary developed in March 2018 compiled information on how NIH ICs were approaching meeting fiscal year (FY) 2018 NGRI targets through various programs. This is provided in Appendix E.

Engagement of external groups

Many individuals and organizations outside of the NIH and the ACD NGRI working group have shown and continue to show an active interest in the NGRI. As such, and to provide even more input to inform the WG activities, several individuals were invited to brief the working group on their perspectives. A list of invited speakers is provided in Appendix B, Invited Speakers.

The working group also received input in the form of letters to the working group chairs from several scientific societies who either provided input on behalf of their members, or in one instance, issued their own request for information on the initial themes proposed at the June 2018 ACD meeting. This correspondence was shared with the working group members for consideration. These letters can be found in Appendix C, External Stakeholder Correspondence Received.

Consideration of National Academies working group activities

In parallel, the working group considered the comprehensive report and recommendations developed in response to Congressional mandate as per the Department of Health and Human Services Appropriations Act, 2016 (Public Law 114-113)⁴⁴ and section 489 of the PHS Act. This study and its resulting report, *Breaking Through*⁴³, conducted by the National Academy of Sciences and supported by funding from the National Institutes of Health and the Bloomberg Philanthropies, resulted in recommendations that span actions that could be undertaken by NIH, by Congress, and by research institutions. The working group reviewed and discussed report materials and recommendations after its April 12, 2018 publication, and hosted a briefing by the Committee on the Next Generation Initiative chair, President Ronald Daniels, and NAS Board of Higher Education and Workforce staff (Lida Beninson,

Study Director and Program Officer, and Thomas Rudin, Director (Appendix B). Several recommendations from the *Breaking Through* report also arose organically in parallel during ACD working group discussions. A few working group recommendations arose from discussion of the NAS committee recommendations, as well. The compilation of other reports on the biomedical research workforce, provided as an appendix in *Breaking Through*, was an especially informative resource for the working group.

IV. Recommendations

- **Theme 1: Modify the original NGRI policy**
- **Theme 2: Develop methods to identify and support “at-risk” investigators and Early Stage Investigators**
- **Theme 3: Promote sustainable training opportunities that incorporate diversity and inclusion**
- **Theme 4: Monitor outcomes and optimize workforce stability through improved metrics and further research**
- **Theme 5: Continue transparency efforts and engagement with scientists across career stages to inform policy decisions**
- **Recommendations for the broader biomedical research community**

Theme 1: Modify the original NGRI policy

1.1 Redefine ESI status to increase flexibility and support for individuals at the beginning stages of their career who have had no previous funding as a sole investigator from a major independent award

The working group had many discussions about the definition of ESI status, particularly in light of the working group charge and the working group’s clear consensus to shift away from the EEI definition. The ESI designation, and related policy, implemented in 2008⁴⁵, had shown some positive effects in support of the goal of funding more early-career researchers. However, the working group identified some major limitations and drawbacks to the definition. For example, the working group expressed much concern over the idea of ‘front-loading’ the workforce, only to have ESI awardees effectively ‘fall off the cliff’ once facing the renewal of their first R01. The drop-off and lack of retention of 1st time R01-awardees has been documented by several groups.^{14,15}

At the June 2018 ACD meeting, the working group reported on preliminary recommendations, which included a two-pronged approach to the ESI definition: 1) ESI status based on years since terminal degree or end of clinical training, but with an expanded time window from 10 years to 12-15 years; 2) ESI status ‘clock’ beginning at the date of first independent position, and setting the end of the period at approximately 6-7 years. The group continued to discuss the adjustment of the ESI window in subsequent meetings. Ultimately the majority of the group decided to retain the 10 year window with a contingency change for MPI status (see Recommendation 2.2 below). However, the group sought to capture the various adjustments proposed in this report.

ESI window extension

The debate for extending the ESI status window was the most difficult to reconcile. There were several main drivers for this recommendation. Data from NCI showed that, for their IC, 15 years would be a more appropriate window given the data showing a longer median time to first R01.^{46,47} Several members of the working group thought that it was important to include this recommendation to give active, actionable support to the cohort of scientists on the edge of losing ESI status, and in between early- and mid-career status. The driving reason for this support was that lengthening the ESI window could benefit early-career scientists who may have had to take longer in postdoctoral training for any reason.

However, several working group members saw potential adverse effects of lengthening the ESI window. The major reason cited is that it would likely cause a further forward shift to the median time to the first R01. Some working group members believed that this lengthened window would either consciously or subconsciously orient peer reviewers or faculty mentors to the idea that these individuals had “more time” to come back and write a stronger application. In addition, a longer window might encourage people to stay as postdocs longer, further shifting forward the median time to first R01.

As an alternative to lengthening the ESI window, some pointed to improved promotion of the ESI eligibility window extension process as a way to still help those who may have had to take longer in postdoctoral training. However, there was no clear consensus on if this process was sufficient, given that this would take work from the ESI to apply for the extension and justify the length of time needed. Going forward, the working group recommends collecting better data to inform this extension. (Note: in the later stages of working group discussion, an NIH policy was announced to alleviate administrative burden by granting a 1 year extension window to ESI extension applicants who cite ‘childbirth’ as the extension request [given that the majority of ESI extension requests are for this reason]⁴⁸. NIH could explore further efficiencies for ESI extension requests, as appropriate.)

The working group also recommends more strongly communicating what an ESI is to trainees so they can consider this definition in their decisions and career timeline. For example, trainees may choose to wait to graduate until a paper is done, rather than doing a mini-postdoc to finish it which would count towards a year of their ESI window.

Setting the ESI status clock at the date of first independent position

A minority of working group members supported the idea of having, in parallel to the automatic 10-15 year ESI window, a mechanism by which the applicant could themselves indicate the beginning of the ESI status ‘clock’ at the date of first independent position. This period of special consideration would then end at approximately 6-7 years after the first independent position. There are several private foundation programs which focus on awards targeting the newly appointed independent investigator. These include award programs managed by the Burroughs Wellcome Fund⁴⁹, Pew Charitable Trusts⁵⁰, and others⁵¹⁻⁵³.

Concerns raised about this were 1) lack of clarity as to what problem it sought to address, 2) how to operationalize the definition in a fair and standardized way, and 3) scaling up for the quantity of NIH programs. For example, with regard to operationalization, whereas date of degree could be verified against institutional data, the establishment of an independent position would use self-reported data. Another operational concern pointed to the variation of institutional appointment approaches, making it difficult for NIH to define what should qualify as an independent appointment. An alternative approach would be for NIH to let the individual self-determine the ESI “clock” start, without allowing the applicant room for changing the date at a later time; the potential for individuals trying to “game the system” using this approach, and how such a policy would further the goals of the NGRI, would need to be further discussed and considered.

Further ESI definition considerations

Another drawback identified by the working group was the binary nature of the ESI designation, particularly if the New Investigator definition would no longer be broadly used. One discussion theme that was often raised was how NIH could implement a “tiered”, “phased”, or “tapered” approach to defining ESIs. Such an approach would address aforementioned concerns about “falling off the ESI cliff”,

and further delaying the time to first R01 award for ESI applicants. This approach would potentially also support mid-career investigators. However, the mechanics of such an approach remained difficult to resolve, in terms of operationalizing this idea in a manner that would not cause confusion to applicants. The working group encourages further exploration of this idea through modelling of different paradigms of “tiered” or “phased” early-career advantages.

Summary

While the group ultimately only opted to recommend one change to the ESI definition, by adjusting consideration of multi-PI projects (see Recommendation 2.2), they agreed that reflecting the identified pros and cons of redefining the ESI status would highlight the difficulty of a policy adjustment that would better support mid-career investigators without detracting from the support of ESIs. Further consideration would be needed to examine policies to address: 1) the needs of those *currently* in the system, and 2) the needs of those *entering* the system.

1.2 Discontinue the “Early Established Investigator (EEI)” definition

The NGRI in its original iteration included a new category of consideration for additional support: the Early Established Investigator (EEI). An EEI was defined as a Program Director/Principal Investigator (PD/PI) who is within 10 years of receiving their first substantial, independent competing NIH R01-equivalent research award as an ESI. A meritorious NIH application with a designated PD/PI EEI would have been prioritized for funding if: 1) the EEI lost or is at risk for losing all NIH research support if not funded by competing awards this year, OR 2) the EEI is supported by only one active award.⁴⁰

The working group felt that tying special consideration of support to prior ESI status was too restrictive. Concerns were raised that targeting support towards a group of investigators that already received a major independent award, such as an R01, would also further hamper efforts to enhance diversity in the biomedical research workforce. A key turning point in the working group’s understanding of the shortcomings of the EEI definition, and the pivot to the at-risk model, was the NIGMS analysis of NIH data for the previous 3 years of funding (see Appendix Item D. NIGMS Analysis of the Effect of the Early Established Investigator Policy). This presentation demonstrated that applying the EEI definition would indeed rescue the targeted population as intended, but at the cost of losing grants by investigators who were very similar to those favored by the strict EEI definition (comparable priority scores and career stages, identical “at-risk” status, very narrowly outside of the EEI window). The data demonstrated that using the EEI definition would have no cumulative impact in supporting mid-career investigators, and essentially be a wash. The “at-risk” definition (described in Recommendation 1.3, below) expands the specialized funding consideration area to capture all investigators in this similar range. It also preempts the need to specify where funds will come from a priori by using a “class-based” approach (i.e. treating all well-funded investigators as a class rather considering individual contributions), a major concern raised in discussions of the GSI approach with the extramural community.

NIH independently chose to delay the original NGRI policy implementation with regard to using the EEI definition, pending working group deliberations, the report to the NIH Advisory Committee to the Director, and NIH consideration of the ACD recommendations and the National Academies recommendations.⁴²

1.3 Introduce the definition of “at-risk” applicants, taking into account the duration of their investigative career

As an alternative to the EEI, the working group recommends special funding consideration for “at-risk” investigators -- applicants with meritoriously-scored applications who would not have major NIH research funding if the application under consideration is not awarded. In addition, an “at-risk” investigator would not have significant research support from other sources.

A cited benefit of looking at using an “at-risk” definition as characterized above is that it would support both ESI applicants (with no history of prior, major independent research funding) and mid-career applicants (both New Investigators/those with no history of prior major independent research funding, and those who may have has a prior major award such as an R01, but are now at risk for losing funding).

Some in the working group noted the “at-risk” label might be viewed as a negative to applicants, and cause peer reviewers to judge applications differently if the PI is flagged as such. Therefore, the working group recommends that special funding consideration of these at-risk investigators be given at the programmatic level (program officer-level decisions) rather than as a part of peer review evaluations.

One aspect of this approach that the working group did consider is whether this “at-risk” consideration might be combined with additional parameters to better target mid-career investigators. The working group discussed the possibility of pairing the at-risk definition with a delimiter (e.g., a certain number of years from their first major independent research award) or by using a phased or tapered approach, tapering the size of the benefit proportional to the length of time of receiving major, independent NIH support. The working group did not reach consensus on specifics, and therefore recommends that ICs take into account the duration of the investigator’s career in decision-making.

Theme 2: Develop methods to identify and support “at-risk” investigators and Early Stage Investigators

2.1 Expand pathways for funding ESIs through programs that do not require preliminary data

The working group acknowledged that early-career investigators should be supported whether they chose to a) begin their research career path with a project that emerges out of their postdoctoral training period, or b) launch their research career with a research proposal that builds upon past training experiences *generally* but is unrelated to their postdoctoral work.

A key revelation emerged from discussions with representatives of Rescuing Biomedical Research (Appendix B. Invited Speakers) and from further deliberations about a consistent recommendation put forth by Rescuing Biomedical Research members⁵⁴⁻⁵⁶ -- to increase the DP2 program to support more Early Stage Investigators.

The working group did not coalesce around supporting such an increase in DP2s. The structure of the DP2 program is that it is specifically used to support high-risk, high-reward research. This is why it provides at the outset a large upfront award for supporting up to 5 years of research. The working group felt that while the DP2 program has a place to complement the NIH research portfolio with high-risk, high-reward projects, it should not be a major vehicle for promoting ESI support and sustaining a stable biomedical research workforce.

One of the main supporting arguments for increasing the use of the DP2 was to encourage independent lines of investigation, such that the applicant would not feel obligated to use the preliminary data from their postdoctoral training, but could branch out into a new line of research. The working group strongly supports the spirit of this argument, but recommends looking at other avenues to fulfill it. The R21 program is often cited as a path for exploratory research⁵⁷ but given the short length of these awards (up to 2 years in length) and low budget ceilings (no more than \$275,000 in direct costs and no more than \$200,000 in a single year), the working group does not feel the R21 is up to the task of fulfilling this need.

The working group recommends NIH expand pathways for funding ESIs through programs that do not require preliminary data. NIH will need to further investigate the balance of how much it should invest in these new programs, in terms of how to strategically support IC-specific missions. The working group also recommends that SROs reinforce that preliminary data is not a scorable criteria for such programs, to ensure they are evaluated appropriately.

In addition, the working group recommends that NIH reevaluate its R03 and R21 program size. The working group noted that the R03 budget is too small to be an effective route to encourage establishing an independent line of investigation – it should be increased to at least \$75,000 per year to support both personnel and supplies. The working group also recommended that the R21 would be better served to have a \$300,000 budget divided evenly between the two years, rather than a small budget for year one, and the additional module for year two. In addition, these programs should take inflation into consideration over the long-term; NIH could explore ways to build this in to the program language.

2.2 Preserve ESI status after first multi-PI award

The working group recommends that ESI status be preserved for individuals who participate in their first multi-PI award.

NIH's ESI policy established in 2008 and implemented in 2009⁴⁵ stipulated that ESI applicants would lose their ESI status for subsequent independent applications if they are a co-principal investigator (co-PI) with an established investigator on an awarded major independent research grant. (This is known as a "multi-PI" grant.) This ESI status stipulation was maintained in the establishment of the 2017 NGRI policy. For example, if an ESI applicant and an established applicant are awarded an R01 as co-PIs, the ESI applicant would not be able to apply for a subsequent R01 as an ESI. Or, in another example, if an ESI applicant and new investigator applicant are co-PIs and successfully compete for a major independent research grant, the ESI applicant would no longer maintain this status for their subsequent application.

The working group recognizes the many valuable aspects of collaborative research between an Early Stage Investigator and an established PI. In addition to the inherent value of team science approaches, the working group also noted that collaborations between senior PIs and more junior PIs are also advantageous in that they link together a diversity of perspectives from different generations to tackle scientific problem-solving. The current ESI multi-PI stipulation could be seen as penalizing the ESI in embarking on such a collaboration. NIH frequently advises that ESIs carefully weigh their decision to partner with established investigators^{58,59}, highlighting how ESI applicants are cautioned as to the consequences of such joint applications.

Indeed, as the number of multi-PI grants has been increasing, and the number of PIs per grant has also been increasing (Figure 8 and Figure 9, below) there is a steady downward trend in the percentage of

MPIs including an ESI (Table 1), suggesting that the disincentives for ESIs to join MPI projects has a notable effect.

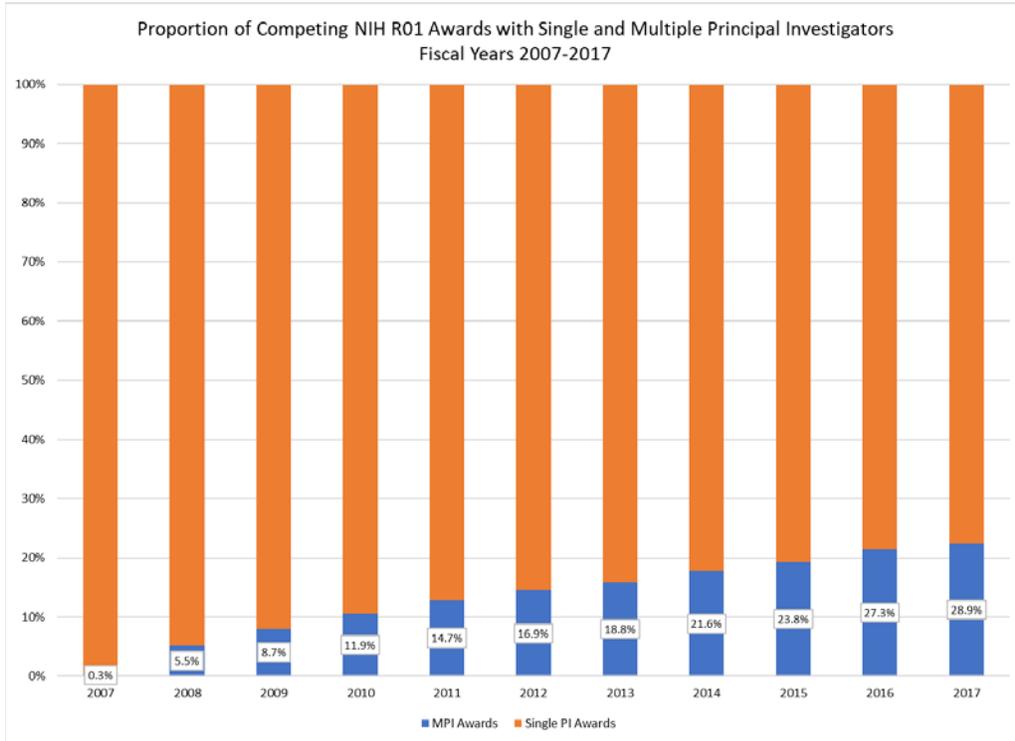


Figure 8 Proportion of Competing NIH R01 Awards with Single and Multiple Principal Investigators

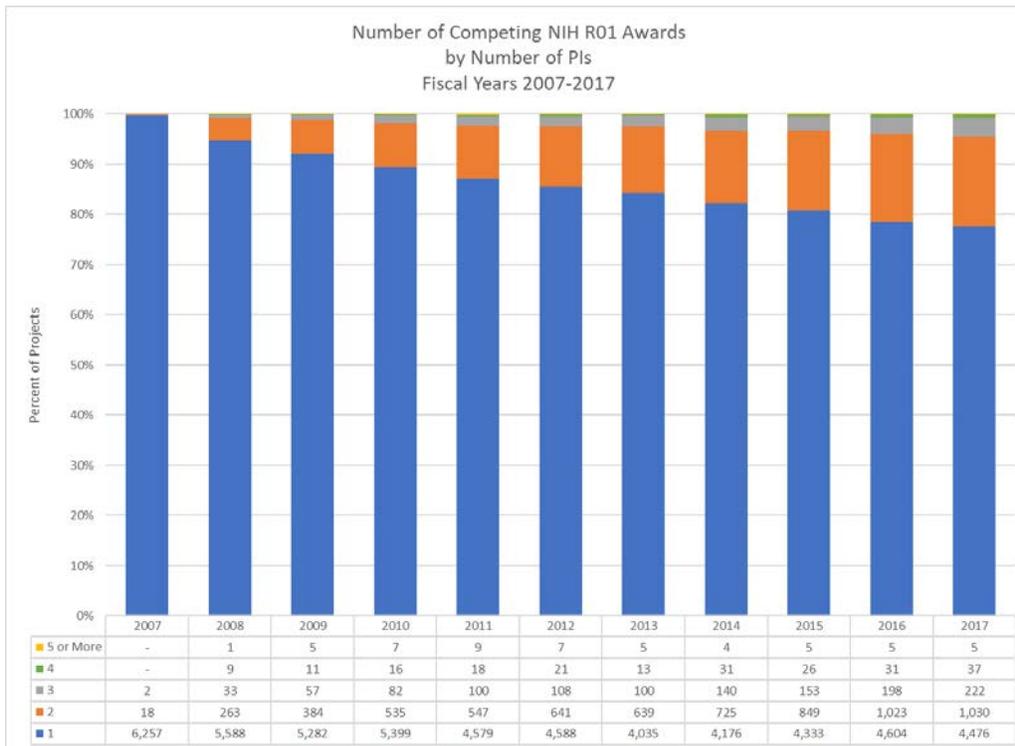


Figure 9 Number of Competing NIH R01 Awards by Number of PIs, FY2007-2017

Table 1

Fiscal Year	Activity	MPI Grants	Grants including ESI	% of MPI Grants with ESI
2009	R01-Equivalent	454	119	26.2%
2010	R01-Equivalent	643	120	18.7%
2011	R01-Equivalent	671	130	19.4%
2012	R01-Equivalent	772	121	15.7%
2013	R01-Equivalent	758	115	15.2%
2014	R01-Equivalent	909	160	17.6%
2015	R01-Equivalent	1,037	136	13.1%
2016	R01-Equivalent	1,286	164	12.8%
2009	P Grants	8	2	25.0%
2010	P Grants	20	4	20.0%
2011	P Grants	29	4	13.8%
2012	P Grants	24	3	12.5%
2013	P Grants	23	0	0.0%
2014	P Grants	17	1	5.9%
2015	P Grants	36	1	2.8%
2016	P Grants	39	1	2.6%

A repeated theme in working group discussion was the need for collaborations between senior or established PIs and less-experienced investigators to be true collaborations. True collaborations involve multi-directional exchanges of advice and ideas, rather than the less-experienced investigator simply following the project ideas and plans of the established PI with little opportunity for input or growth into an independent researcher. The working group also recommends that NIH seek ways to support meaningful collaborations between experienced and less-experienced investigators. While research project grants cannot request information on mentorship and training, the working group recommends exploring avenues in support of this goal.

2.3 Separate review, comparison and scoring/percentiling of ESI applications, grouped during the initial discussion in Study Section

Peer review is a critical intervention point for NIH to take action to support the next generation of research investigators. Early-career researchers must compete against established investigators that have preliminary data and existing resources. The working group believes that interventions in the peer review process are a key aspect of NGRI reforms, and recommends that ESI applications are reviewed and/or scored separately from the applications of established investigators. Several programs targeted

for ESI support provide the advantage that incoming applications are reviewed as a cohort in their own study section (for example, the NIH Director’s New Innovator (DP2) Awards and the NIGMS ESI MIRA).

However, on the large scale of R01 applications across all of NIH’s ICs, this model would be impractical in that it would cause enormous strain on the peer review system by almost doubling the number of study sections needed. An alternative is to batch ESI applications in review by grouping them for discussion in the beginning of the peer review meeting. Additionally, scoring and percentiling of ESI investigator applications should be done relative to each other, and not scored and percentiled together with established investigator applications.

(For an explanation how peer review scores and percentiles are calculated, see NIH Extramural Nexus posts on this topic.^{60,61})

2.4 Prioritize funding for meritorious applications from ESI and at-risk investigators

The working group recommends generally that – in addition to the specific advantages laid out in the other recommendations in this section – that at a programmatic level, meritorious applications from ESI and at-risk investigators be given additional consideration and prioritized for funding.

2.5 Fund ESI investigators’ R01-equivalent applications for at least 5 years

Sustained funding is a key issue for early-career investigators, and investigators with their first major research award. New PIs face many challenges including managing the start-up of their laboratory, recruiting staff, launching a competitive research project, and participating in departmental or professional society activities in tandem support of contributing to their research community and progressing to a tenured position. Seeking a renewal of a first R01, or a second award to help carry the lab forward, adds additional pressures to early-career and mid-career PIs who are already competing against well-funded, long-tenured investigators.

The working group supports measures that help early-career investigators achieve sustained research funding, relieving some of the challenges associated with starting an academic research career. The most significant measure recommended is that all ESI investigator R01s should be at least 5 years in length.

Other measures to support sustained research funding were also discussed, and the following actions were recommended by the working group:

- Widespread adoption of an ESI R35 program, such as the NIGMS Maximizing Investigators Research Award (MIRA)⁶²
 - o The working group members noted that the early data from the ESI MIRA program shows promising results for supporting early-career investigators.⁶³
 - o The working group members specifically recommend that every IC adopts an R35-type or similar program targeted for ESIs.
- Following outcomes of the “5+2” approach that the National Cancer Institute (NCI) has recently launched as a pilot ^{46,47}, as another model of sustained research funding for early-career investigators.
 - o At their November 2017 advisory council (National Cancer Advisory Board), NCI announced its plan to give special consideration to not only ESIs but also applicants within 5 years of the end of their ESI period (effectively a 15 year period of special

consideration after the terminal research degree). Such investigators awarded under this scheme would receive additional mentoring from NCI, and their progress would be re-reviewed at year three or four of their R01 for a two-year extension

- The working group debated and did not come to consensus on the concept of a lengthened ESI status window, as described in Recommendation 1.1. However, the working group supported the spirit of the “5+2” concept and was eager for further NIH-wide consideration and evaluation of such an approach.

2.6 Incentivize the inclusion of ESIs as project leaders in Program Project Grant applications

While the R01 has long been the main path by which NIH supports investigator-initiated research, there are many other program types which can still be used to support independent research careers. NIH supports major investigator-initiated ideas through other approaches than R01 awards. Program project grants can build comprehensive and integrated research programs to fulfill research portfolio needs in support of ICs’ missions.

The working group recommends that NIH incentivize the inclusion of ESIs as project leaders in Program Project Grant applications. The primary example that the working group reviewed and supported is a new program policy launched by the National Heart, Lung, and Blood Institute (NHLBI) that incentivizes Early Stage Investigator participation on P01 application.⁶⁴ For NHLBI P01 applicants, higher budgets may be requested for applications that include at least four projects (one of which has an Early Stage Investigator as Project Leader). The application must include the ESI as a project lead in a significant role and describe how the ESI lead will be supported in a manner that will enhance their career development scientifically and professionally. Importantly, in assessment of the P01 application as a whole, the expectation of demonstrated ability to lead an R01, or R01-equivalent, grant does not apply to ESI project leaders, and the ESI project leader’s ESI status remains intact should the P01 be awarded.

The working group suggests NIH also explore how other funding mechanisms and activity codes beyond the R01 can be used to support independent research careers.

A further, related recommendation, described in “Recommendations for the broader biomedical research community”, describes how universities can support early-career investigators through cultural change in the tenure review process, and by looking beyond R01 grants as a symbol of success or future potential.

2.7 Extend R15 awards, per the investigator’s choice, to up to 5 years

The working group recommends enhancements to the R15 Academic Research Enhancement Award (AREA) program in support of geographic diversity and better support for the types of institutions that NIH supports. One way to alleviate burden for R15 applicants – without increasing the amount of awards – is to allow this funding to be spread out over a five year project period, not a three year maximum, as is current policy⁶⁵. This is a simple way to alleviate the pressures of seeking sustained funding. The working group recommends that the project period length be per the investigator’s choice up to 5 years of support.

2.8 Expand R15 use at all NIH ICs

Citing again the need to better support geographic diversity and diversity of the types of institutions supported by NIH funding, the working group recommends all NIH ICs fund R15s. These awards support

small-scale research projects at educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation’s research scientists, but that have not been major recipients of NIH support.⁶⁵

Year	Applications	Awards	Success Rate	Funding
2008	759	213	28.1%	\$44,395,633
2009	805	178	22.1%	\$37,299,776
2010	992	185	18.6%	\$52,352,418
2011	1,454	216	14.9%	\$77,504,120
2012	1,408	208	14.8%	\$78,318,428
2013	1,568	197	12.6%	\$76,426,450
2014	1,633	232	14.2%	\$88,405,266
2015	1,700	288	16.9%	\$110,021,380
2016	1,652	282	17.1%	\$117,886,166
2017	1,680	258	15.4%	\$108,204,555

Table 2 NIH Funding to R15 Programs: Data does not include ARRA funding.

2.9 Conduct, within one year, a detailed analysis of salary support derived from NIH grants by updating the 2007 study on this topic

The working group recommends that within one year NIH conduct a detailed analysis of salary support derived from NIH grants by updating the 2007 study on this topic. With updated data available, NIH should model how PIs, co-PIs, and co-investigators would be affected by different “cap” levels on the proportion of salary that can be drawn from NIH grants. Particular emphasis should be directed to assess: whether overall positions would be lost; what level of additional resources various salary caps would yield; and, to what extent any changes will differentially affect individuals at different stages of career development or in different career tracks (e.g., PhDs vs MDs). Stakeholder consultation should be conducted with the goal of gradually introducing some level of salary cap limit (informed by the modeling exercise) over a 7 to 10 year period.

Increasing reliance on “soft money” positions – where PIs must primarily support their salary from NIH grants and other outside funding sources – was raised as a major concern because it disproportionately disadvantages early-career scientists.

A recommendation on this topic was raised in previous science policy recommendations. It was included in the 2012 Biomedical Research Workforce ACD Report, specifically as, “*The working group*

recommends that NIH consider a long-term approach (over a 20 year period) to gradually reduce the percentage of funds from all NIH sources that can be used for faculty salary support.”⁶⁶

Even as far back as 1960, a U.S. Presidential scientific committee stated concerns with over-reliance on federal funds for faculty salaries and effect on workforce dynamics: *“We recognize that many university scientists are strongly opposed to the use of Federal funds for senior faculty salaries. Obviously we do not share their belief but we do agree with them on one important point—the need for avoiding situations in which a professor becomes partly or wholly responsible for raising his own salary. If a university makes permanent professorial appointments in reliance upon particular Federal project support, and rejects any residual responsibility for financing the appointment if Federal funds should fail, a most unsatisfactory sort of “second-class citizenry” is created, and we are firmly against this sort of thing.”⁶⁶*

The working group as a whole agrees with the general principle of grantee organizations increasing institutional (i.e. “hard money”) salary support for early-career investigators, and to increase their contributions toward bridge funding for established but “at-risk” investigators. NIH cannot dictate where a PI’s salary comes from, but it can limit the percent of NIH funds that will go towards the salary cap (for the last fiscal year, this was set to the Executive Level II-\$189,600). The group considered a number of potential “cap” levels to be gradually introduced over a 5 to 10 year period of time, with some working group members strongly advocating for the recommendation to enact a specific cap. However, several members of the working group voiced strong concerns about having an incomplete understanding of the effect of this recommendation on investigators depending on their degree, department/division/school, type of research (clinical vs. basic science), and institution type.

Specific concerns raised include:

- There are now more PhD scientists working in clinical departments than in basic science departments in schools of medicine or academic medical centers. However, positions of this type are typically predicated on a substantial proportion of salary that is derived from federal funding. If the percent of salary that can be derived from NIH grants were decreased, the number of such positions may be reduced. Thus, such a requirement could disproportionately negatively affect PhDs/basic scientists in clinical departments. A resultant reduction of the number of PhD scientists employed at academic medical centers could have downstream consequences on translational investigation and basic/clinical collaborations, as well as a drastic reduction in faculty positions available for new trainees.
- For many MDs, early-career and late-career/established investigators alike, schools of medicine or academic medical centers could insist that any salary short-fall created by a cap on the percent of salary that can be derived from NIH grants would be redressed through an increase in clinical practice. This could disproportionately affect young clinician-scientists by degrading the time available to write grants or conduct research, thus lengthening the time needed to launch their careers.
- Such a recommendation would disproportionately affect smaller institutions with insufficient size and operating budgets to absorb the impact, potentially eroding geographic diversity among NIH-funded research institutions.

The last available data on this point, from 2007, revealed that NIH-wide, less than 35% of PIs/Co-PIs receive more than 60% of their salary support from NIH. A 2009 AAMC study reports that for full-time

research faculty without MD degrees, about 50% of their salary comes from sponsored research, and a 2013 report states non-MD researchers on average received 49% of salary from sponsored research.

Gathering medical faculty salary data is further complicated by the different breakdowns used across institutions in reporting, such as calculating percentages based on “regular pay” (base pay) versus gross pay (which includes negotiated additional pay for clinical care and research by funded from mixed sources (e.g., clinical revenues, contracts, and grants)).

Thus, a detailed analysis of salary support derived from NIH grants would better inform NIH and its stakeholders regarding approaches for gradually introducing some level of salary cap limit (informed by the modeling exercise) over a 7 to 10 year period.

Theme 3: Promote sustainable training opportunities that incorporate diversity and inclusion

As per 21st Century Cures, the Next Generation Researchers Initiative calls on NIH to “*develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity*”.³²

The recommendations in this section capture the working group’s discussion and recommendations for enhancing training, mentorship, and workforce diversity in a meaningful and sustainable way. In considering diversity of the workforce, the working group not only discussed gender and racial and ethnic diversity, but also diversity in terms of the representation of researchers in different stages of their career, diversity of geographic representation, diversity of scientific disciplines, and diversity in the types of institutions that NIH supports. As discussed in the section “Recommendations for the broader biomedical research community,” the working group also discussed actions recommended for the broader research community to help support inclusive and diverse research environments.

With regard to training and mentorship, the working group’s initial focus was primarily on the transition point into the first faculty position, and those newly appointed to academic research positions. In later meetings, an additional major point of discussion was how to better support postdoctoral fellows as trainees. The NASEM *Breaking Through* report provided a number of recommendations that seek to address postdoctoral fellows’ contributions to the biomedical workforce, and how postdoctoral fellowship practices may contribute to an imbalanced workforce and the hypercompetitive environment for early-career researchers. The working group discussed these recommendations as well, and overall supported the spirit of many of them, though in many cases proposed alternate paths for NIH to pursue, as further described below.

3.1 Increase gradient of post-doctoral support levels after 5 years

Two of the major recommendations of the NASEM *Breaking Through* report involved caps on postdoctoral fellowship training periods – capping postdoctoral fellow support on an R01 to 3 years, and

capping total postdoctoral training to 5 years. There was not a majority support for the idea of a cap, however. The working group acknowledges and supports the *spirit* behind limiting postdoc tenures. The working group agrees that postdoctoral training periods should not be inordinately long, and they should be training for an independent career, not prolonged low-cost labor. In addition, the working group supports the idea of encouraging earlier independence or transition to employee-level staff scientist-type positions. However, the working group also feels that such postdoc tenure caps’ penalize postdoctoral fellows, and thus detract from the broader aims of the Next Generation Researchers Initiative. While two working group members agreed with a cap, they stated that the 3 year suggestion in the NASEM report is unfeasibly short.

Alternatively, the working group recommends a postdoctoral stipend scale which is significantly increased beginning on the 6th year of postdoctoral work, to reflect their advanced experience, to disincentivize consideration of postdoctoral fellows as inexpensive labor, and to encourage transitions to permanent roles. Stipends should also be adjusted for inflation. The working group recommends a steep gradient during these later years so that the stipend is in line with compensation (including benefits) for staff scientists with comparable qualifications, for example, a 10% increase between years 5 and 6, and 7 and 8.

3.2 Ensure that all funding opportunity announcements for training, fellowship, and career awards reflect the requirement to promote diversity and inclusion in a sustainable way

Though the majority of trainees and fellows are supported on research project grants (Figure 10 and Figure 11 below) ^{67,68}, the criteria for evaluating training programs (“T” awards), fellowship programs (“F” awards) and career programs (“K” awards) make them an effective space for enhancing diversity.

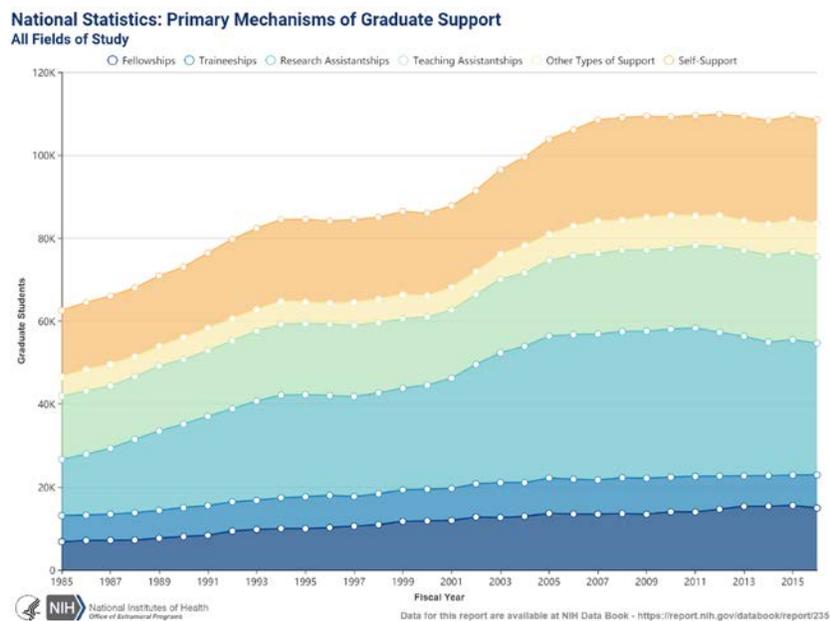


Figure 10 National Statistics: Primary Mechanisms of Graduate Support, All Fields of Study (Biomedical Sciences, Behavioral and Social Sciences, Clinical Sciences)

National Statistics: Primary Source of Support for Postdoctorates
All Fields of Study

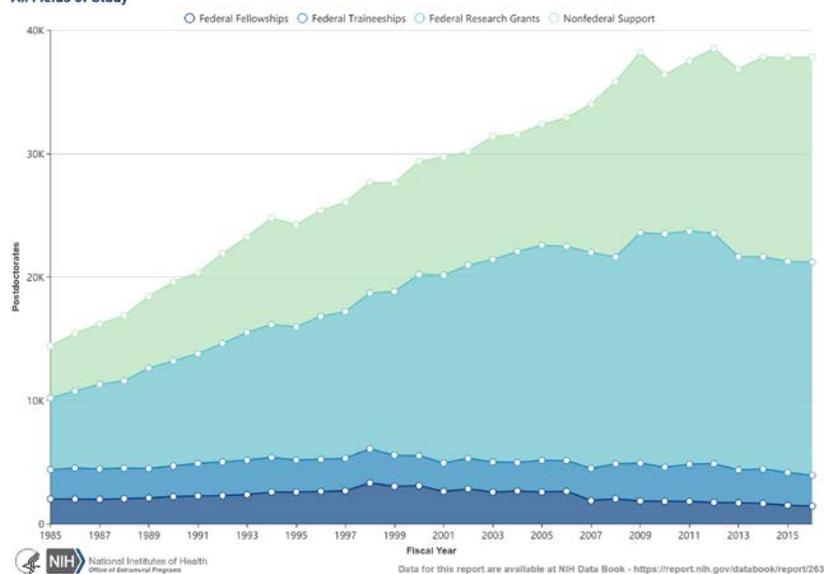


Figure 11 National Statistics: Primary Source of Support for Postdoctorates, All Fields of Study (Biomedical Sciences, Behavioral and Social Sciences, Clinical Sciences)

All of these programs include consideration of the training environment and/or mentorship plans as a scored component in peer review⁶⁹. The working group recommends that for all F/K/T award programs that NIH examine the program and funding opportunity language used to describe a) what applicants should be addressing and b) what peer reviewers should be evaluating, to make sure it supports the aim of enhancing workforce diversity. In addition, the working group recommends NIH support scientific review officers (SROs) in being proactive to make sure that study sections appropriately discuss and address the training environment and mentorship plan during the peer review meeting.

3.3 Require institutions to provide professional development and training plans for mentors and trainees listed on research grants, including actionable feedback from trainees and detailed language in annual and renewal progress reports

As aforementioned, the majority of trainees and fellows are supported on research project grants. Therefore, the working group recommends that NIH require institutions to provide professional development and training plans for mentors and trainees listed on research grants, and receive actionable feedback from trainees and detailed language in annual and renewal progress reports. The working group recommends that program officers should intervene and remediate any signs of inadequate mentorship.

Another suggestion made by some working group members was having applicants address, in the Just-in-Time form, their plans to manage multiple grants to maximize productivity across all research projects, and to ensure proper oversight and mentoring of trainees supported on all grants. This could give Councils and program officers critical information beyond the impact score when deciding how to allocate their resources.

One example reviewed by the working group was the National Science Foundation application language on postdoctoral researcher mentoring plans, which states that, “Each proposal that requests funding to support postdoctoral researchers must include, as a supplementary document, a description of the mentoring activities that will be provided for such individuals. Examples of mentoring activities include, but are not limited to: career counseling; training in preparation of grant proposals, publications and presentations; guidance on ways to improve teaching and mentoring skills; guidance on how to effectively collaborate with researchers from diverse backgrounds and disciplinary areas; and training in responsible professional practices. The proposed mentoring activities will be evaluated as part of the merit review process under the Foundation's broader impacts merit review criterion.”.⁷⁰

The requirement for NSF proposals to include a postdoc mentoring plan was mandated by Congress in 2007^{71,72}, with some in the scientific community raising concerns about this requirement.^{73,74} NIH should also take into consideration the scientific community concerns raised in response to the NSF requirement.

3.4 Implement ACD Working Group on Diversity recommendations

The NIH Advisory Committee to the Director has a standing working group focused on diversity in biomedical research (ACD Working Group on Diversity or ACD Diversity WG)⁸. At the first in-person meeting, the NextGen working group was briefed on the ACD Diversity WG’s activities and their efforts to improve diversity of the next generation of scientists. The working group recommends NIH build and expand upon analyses that the ACD Diversity WG has developed and has proposed for future research. For example, increasing transparency across NIH ICs and assessing diversity by funding mechanism would support both working groups’ understanding of how to support individuals already in the NIH “pipeline”, and how different scientific areas compare in terms of diversity among funded PIs. Several of the then preliminary recommendations were presented and further explained by the ACD Diversity WG at the June 2018 ACD meeting^{75,76}.

3.5 Analyze the effect of research topic choice on R01-equivalent funding outcomes

The working group recommends that NIH analyze the effect of research topic choice on R01 funding outcomes. The suggestion to pursue this type of analysis was presented at the June 9, 2016 meeting of the ACD.⁷⁷ This presentation described that, regardless of race of the applicant, certain topics are less likely to be funded NIH-wide. Preliminary data indicates that African American/Black (AA/B) scientists prefer these topics but produce far fewer applications overall than do white scientists, and AA/B scientists are less likely to be funded even in these topics. The working group recommends NIH further pursue analyses that look at the effect of research topic choice on research funding, particularly R01-equivalent funding outcomes, to see how this affects diversity among NIH-supported PIs and the biomedical research workforce.

3.6 Expand access to the National Research Mentoring Network-type resources

The working group recommends that NIH expand access to National Research Mentoring Network-type resources to support meaningful collaborations as a path for enhancing workforce diversity. Established programs such as the NIH Building Infrastructure Leading to Diversity (BUILD) and National Research Mentoring Network (NMRN) programs^{78,79} could be evaluated to determine best practices and models

which may be adopted more broadly across NIH, and integrated into other programs or types of research support.

3.7 Ensure that POs interact equitably with all investigators, including ESI and at-risk investigators, and persons from underrepresented groups

One aspect of pursuing NIH funding involves interactions between the applicant and NIH staff. For example, following the peer review of their application, NIH applicants are advised to seek guidance from an NIH program officer as to whether to submit a new or resubmission application⁸⁰. While well-funded senior investigators have experience in communicating with NIH staff, and may have existing familiarity with NIH staff members, early-career investigators and those who have never been funded before likely do not. This may influence how likely early-career investigators are to achieve funding.

The working group recommends that NIH take measures to ensure that program staff, who often receive questions and inquiries from the research community, are equitably responsive to all investigators. Such measures may include additional assessment of programmatic activities and interaction with potential applicants, or additional training.

3.8 Require broad and recurrent evidence-based training on unconscious bias for POs, SROs, and peer reviewers, and include this as a required component of RCR training for both mentors and trainees

The working group recommends that unconscious bias training be integrated in several venues in order to enhance diversity and inclusivity in the biomedical research workforce. This would include:

1.) Incorporation of unconscious bias training in peer reviewer orientation: The peer review system as a whole is a strong asset to the biomedical research enterprise, in that it convenes external subject matter experts to assess scientific merit, and provides a forum for discussion to inform NIH's funding decisions. Nevertheless, NIH should continually evaluate and reassess whether the peer review process is meeting the NIH-wide priority of supporting the next generation of researchers, and how to improve the process.

The working group recommends that NIH should specifically incorporate unconscious bias training into its existing onboarding for peer reviewers. The working group believes reaching peer reviewers is important, as this is a critical intervention point for supporting a strong and diverse research workforce. At the same time, the working group is also conscious of administrative burden, and adding additional requirements for those serving as peer reviewers. Incorporating unconscious bias training in the existing reviewer orientation would also be further supported by training for scientific review officers who manage peer review meetings. NIH's stated core values of peer review include the values of fairness and impartiality⁸¹. Unconscious bias training supports these values, and as appropriate NIH should reinforce the linkage of peer review integrity with impartiality and fairness, as it pertains to a robust and diverse workforce.

2.) Unconscious bias training for all program officers: As described in Recommendation 3.7, the relationship between an applicant and NIH program staff can be a key point of intervention to prevent "old boys' network" type relationships. Unconscious bias training would again support both early-career researchers and workforce diversity, through equitable access to information about NIH research priorities or funding opportunities.

3.) Unconscious bias training for mentors and trainees, potentially as part of Responsible Conduct of Research training: Acknowledging that today's trainees and early-career researchers also hold an important role for supporting diversity in generations of researchers to come, the working group recommends that NIH provide avenues for unconscious bias training of trainees. One potential venue is through pairing such a training requirement with existing requirements, such as responsible conduct of research (RCR) training. RCR training is currently mandated for trainees on an NIH institutional research training grant, individual fellowship, career development award (institutional or individual), research education grant, dissertation research grant, and other grant programs that have a significant training component.⁸²

Unconscious bias training needs to be of sufficient quality and periodicity to be effective. The working group recommends that NIH thoughtfully consider and seek input on which recommended models and what frequencies of unconscious bias training are best suited for each of the different audiences described above.

3.9 Require grantee organizations to provide assurances that they have effective, fair, and up-to-date policies to preserve a harassment-free environment

Threats to a supportive and inclusive climate for trainees and faculty (particularly new faculty) include microaggressions and sexual harassment. A recent National Academies report, *Sexual Harassment of Women: Climate, Culture, and Consequences in Academic Sciences, Engineering, and Medicine*⁸³, describes the interplay between diversity and civil working environments:

Diverse, inclusive, and respectful academic environments are environments where careers flourish, but sexual harassment does not. Such environments have a culture that values diversity, inclusion, and respect, but they also need to have a climate that demonstrates that these values are put into action. Diverse and inclusive environments are ones where cultural values around gender and racial equity align with a climate where policies and practices do not disadvantage groups of people, and thereby making them incompatible with sexually harassing behavior. Similarly, a respectful environment is one where civility and respectful work behavior are not just valued but also evaluated and rewarded, and this is reflected in policies and procedures.

NIH already requires notification for any reason that affects the ability of the employee(s) to continue as PI or other senior key personnel on an NIH award (for example, if the institution takes an administrative or disciplinary action against its employee(s) such as limiting access to the institution's facilities or resources or modifying employment or leave status during an investigation of alleged sexual misconduct).^{84,85} The working group recommends that grantee organizations be required to provide assurances directly to NIH that they have effective, fair, and up-to-date policies to preserve a harassment-free environment. NIH's own staff policies and procedures for Preventing and Addressing Harassment and Inappropriate Conduct and policy statement on Personal Relationships in the Workplace^{86,87} are examples of the types of policies which institutions could adopt and assure as part of this requirement. Such a requirement would allow NIH to request, as a term and condition of NIH awards, the assurance that its grantee institutions have policies that support a harassment-free environment for all members of the NIH-supported research workforce.

3.10 Require R13 (conference grant) applications to describe what best practices for a safe and harassment-free environment will be employed at conferences and professional meetings

In addition to Recommendation 3.9, the working group also recommends that NIH support workforce diversity and inclusive environments at conferences supported by NIH funding. As of 2016, NIH revised its conference grant funding opportunity announcements to clearly state the expectation that organizers of NIH-supported conferences will take steps to maintain a safe and respectful environment for all attendees by providing an environment free from discrimination and harassment. The working group recommends strengthening this expectation by specifically asking R13 applicants about their plan to enact these steps, thus making these steps a term and condition of award. The working group recommends that NIH require R13 applicants describe in their application what best practices for a safe and harassment-free environment will be employed at the NIH-supported conference or professional

meeting. NIH should seek input on best practices and share them broadly by making a web page or other public resource for conference organizers, as well.

Related considerations

In addition to the postdoctoral fellowship caps described earlier in this section, the NASEM NGRI report recommended quintupling F/K awards to support postdocs. The working group did not coalesce around these paired recommendations for several reasons: 1) a forced timeline for applying for an F/K would add additional burden and further penalize postdocs seeking transition to independent research careers, 2) institutional training grants could better support geographic diversity, capacity building, and cultural change rather than solely focusing on awards such as F/Ks which support only a single individual, 3) F/Ks support only a single individual and may not cover the individual's entire project (thus they are still relying on additional RPG funding from the lab) and 4) this quintupling would decrease the pool of funding for RPGs, which in turn would most likely cause additional hypercompetitive strain on early- to mid-career researchers and magnifying the funnel effect.

Given strong concerns over unintended negative consequences for both trainees and early-/mid-career investigators, the working group recommends that NIH pursue other positive rewards, combined with an independent feedback mechanism. NIH could pursue measures which speak to changing the culture of how postdocs are viewed, and which incentivizes PIs who are good mentors. Such proposals which were raised for further consideration of feasibility include:

- ways to reward a PI for good mentoring, such as through continuous submission privileges, or a payline/scoring advantage for the **next** fellow in their lab applying for fellowship support (this would reward both the PI and the subsequent postdoc)
- exploring methods to change how PIs are assessed in peer review if their mentees go into science related careers outside academia (mentee track record is considered in tenure review, and is not considered the same way across the board)
- having predoctoral and postdoctoral trainees submit independent feedback about their former mentor, such as through an independent upload into eRA Commons, to ensure their feedback is heard apart from their PI's personal assessment of their own mentorship track record

Theme 4: Monitor outcomes and optimize workforce stability through improved metrics and further research

4.1 Create and establish a formal analysis plan for evaluating the impact of NGRI and early-career investigator programs, and for assessing disparities across ICs

The working group recommends that NIH creates a formal analysis plan for evaluating the impact of the NGRI. NIH should evaluate how the policy impacts ESIs and "at-risk" investigators across ICs, as well as on an IC-specific basis. Looking at ESI and "at-risk" investigator numbers for each IC will help assess disparities across ICs and different scientific areas, and inform when special IC-specific programs may warranted to provide support to ESIs and "at-risk" investigators in specific fields. By monitoring the policy in a centralized fashion, NIH can also better coordinate meeting ESI and "at-risk" investigator targets and appropriately allocate resources to support these investigators (for example, if an individual is competing for funding at different ICs in the same fiscal year).

In addition, the working group recommends NIH provide a central, and most importantly, clear description of the ESI and “at-risk” definitions, as well as any exceptions which might apply, and links to the process to requesting a change or extension in status as appropriate. These definitions and steps, as well as IC implementation plans, should be written clearly and publicly posted, so that trainees can find this information and follow this guidance.

4.2 Support further research on assessments of workforce capacity

The working group recommends that NIH support further research into understanding the carrying capacity of the NIH supported workforce. One example is through support of science of science policy, and joining efforts such as the National Science Foundation’s SciScip program⁸⁸. Another approach suggested is targeted support through research programs and research project grants that will assess biomedical research workforce capacity.

4.3 Revise NIH project scoring criteria and funding decision criteria to emphasize the PI’s previous 7 years of service and mentorship contributions

The working group recommends that NIH revise its project scoring criteria so that, when evaluating the investigator’s contributions to science, reviewers focus on the most recent years of research experience, as well as service and mentorship contributions (up to the 7 most recent years, when applicable). In addition, the working group recommends that NIH make funding decisions that focus on the impact of a PI’s recent contributions, including service and mentorship contributions.

In working group discussions, members expressed the need to consider many types of scientific contributions and productivity, beyond publications. Such contributions could include mentoring, patents/commercial ventures, or service to the institution or the community. Working group members strongly cautioned against application changes which would add additional sections and potentially further tax ESIs and add administrative burden. The format of the biosketch was revised in 2015 to allow flexibility in explaining accomplishments, particularly for early-career and new investigators. The biosketch now not only allows inclusion of journal publications, but also outputs such as datasets⁸⁹, and most recently, preprints⁹⁰. Thus, one way this recommendation could be enacted in the peer review process is simply through application instruction changes, and revisions to NIH scoring criteria, while using the existing biosketch format.

4.4 Assess portfolio-wide and NIH-wide productivity and return on investment of taxpayer dollars

The working group recommends that NIH assess portfolio-wide and NIH-wide productivity and return on investment of taxpayer dollars. The working group recommends that NIH meet this aim by engaging stakeholders both internal (such as stakeholders across NIH ICs) and external (such as researchers in the fields of economics and science policy) to advance ongoing efforts.

The working group supports the pursuit of validated, comprehensive, and holistic metrics which can be used to evaluate productivity. One major concern raised by some in the extramural community regarding the Grant Support Index was that it did not take into account variations in individual productivity as well as other measures of productivity relevant to the research enterprise (e.g. mentoring, patents, commercial ventures, institutional service, citizenship in the wider community) not captured by a publication index. These stakeholders argued that other approaches should be used to capture and assess research productivity and a PI’s effort relative to their level of NIH funding.³⁴

Following many discussions on this topic, the working group agreed that there are multiple levels of assessing research productivity: a micro-level (assessment of an individual’s productivity relative to their NIH funding) and a macro-level (assessment of outputs resulting from all NIH research funding, or from a portfolio of funded projects.) Metrics used to assess individual productivity should be considered distinctly from those that assess portfolio-level productivity.

Theme 5: Continue transparency efforts and engagement with scientists across career stages to inform policy decisions

A continued theme throughout working group discussions was the importance of engaging the external community throughout the policy development process. The working group conversations highlighted several distinct ways that NIH could continue to enhance its efforts to increase transparency into the policy decision-making process, and engage scientists across career stages.

5.1 Increase accessibility of NIH administrative data for both members of the biomedical research community and researchers investigating biomedical science

The working group supports efforts to increase making NIH-wide data public and transparent, such as through the NIH Data Book and blogs from NIH leadership (e.g., Dr. Lauer’s *Open Mike* blog). The working group recommends continuing and expanding these efforts.

The working group recommends two main categories of the type of data NIH should make accessible:

- 1) administrative data that can describe overall funding trends, and thereby serve to inform career path decision making
- 2) internal data which can be made more accessible for study

NIH has consistently published end-of-year reports on the success rates and funding rates for experienced PIs vs first-time PIs, but does not publish this information for ESIs (Figure 12).^{91,92}

R01-Equivalent Investigators, New (Type 1): Funding Rates, by Career Stage of Investigator

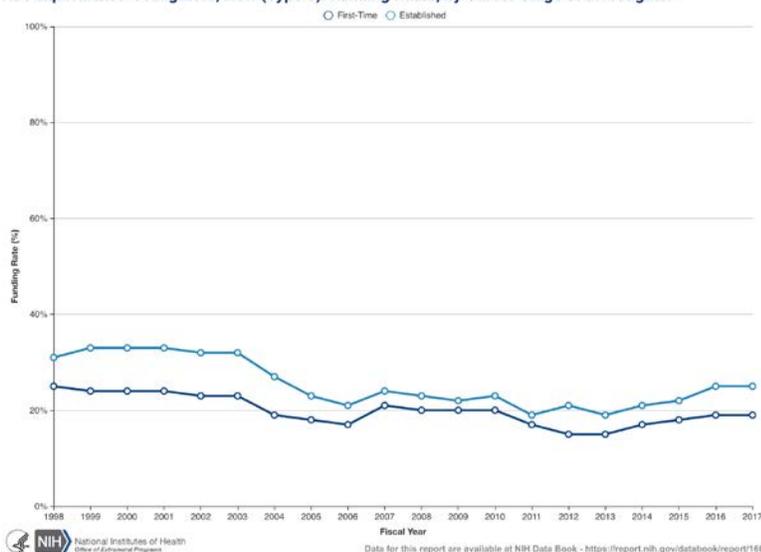


Figure 12 R01-equivalent investigators, New (Type 1): Funding rates for first-time PIs and established PIs

Stakeholders have cited the need for data availability as key to help guide the next generation of researchers.^{93,94} The working group strongly supports empowering career decision making through availability of NIH data, as well as research institutions making available their data on training programs (See “Recommendations for the broader biomedical research community”). Additionally, the working group recommends that NIH increase accessibility of internal data for researchers studying the biomedical research workforce, to support Recommendations 4.2 and 4.4, above.

Through the course of the working group meetings, the working group proposed additional metrics that would be helpful to support the aims of the NGRI, and to assess its efficacy. IC-specific breakdowns of the data would also help address disparities across ICs/scientific fields.

Specific trans-NIH and IC-specific metrics that the working group recommends monitoring and making public on a yearly basis are:

- Success rates and funding rates of ESIs
- Success rates and funding rates of “at-risk” investigators
- Average length of postdoctoral training periods for NIH-supported postdoctoral fellows
- The number of trainees supported by NIH
- Cumulative Award Rates for ESIs and “at-risk” investigators, as shown in Figure 13 and Figure 14, below

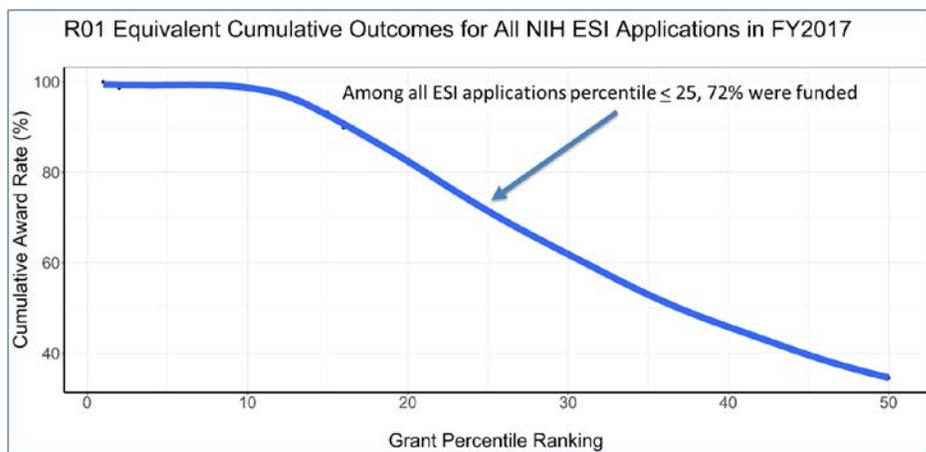


Figure 13 R01-equivalent cumulative outcomes for all NIH ESI applications in 2017

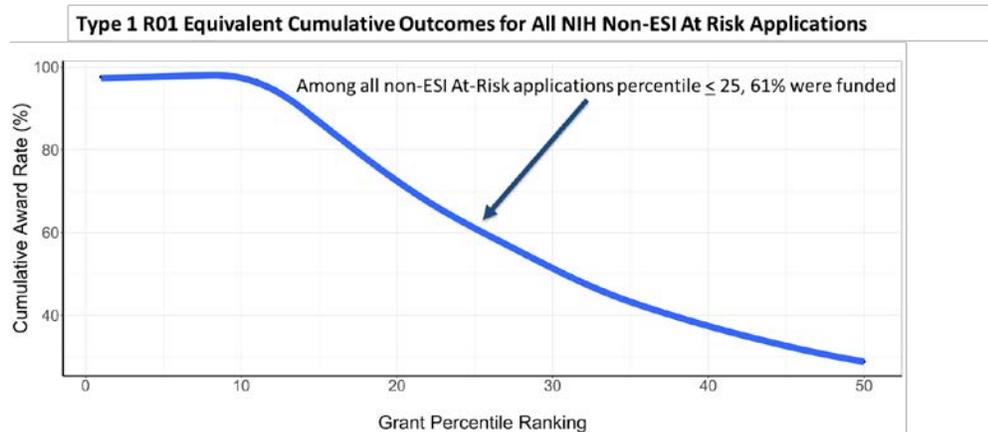


Figure 14 Type 1 R01-Equivalent Cumulative Outcomes for All NIH Non-ESI At-Risk Applications, FY2017

5.2 Expand channels by which the NIH solicits and receives public comments

The working group recommends that NIH expand the channels by which it solicits and receives public comments. When appropriate, NIH should invite public comment via well-publicized requests for information (RFIs), open for a comment time period that allows sufficiently detailed responses. Given that RFIs often require long and formal responses, the working group also recommends NIH engage in other modes of soliciting feedback.

The working group encourages NIH to be responsive to the public's comments on the data and analyses it publishes. When soliciting community input, NIH should provide transparency into the comments received, and the factors influencing ultimate policy decisions.

There are several external groups which are stakeholders in the Next Generation Researchers Initiative. The working group encourages ongoing engagement with organizations such as the National Postdoctoral Association to provide input into NIH policy decisions. The working group also recommends NIH continue to seek diverse perspectives beyond these standing organizations, as well. There is of course a need to invite input from subject matter experts and long-standing spokespersons focused on biomedical research workforce policy. This however should be complemented by other approaches, and NIH should include paths for novel perspectives and new ideas to be heard as well. Identifying and including working group members from various career stages will help meet this aim, increase diversity of thought, and invite more voices to the table in a two-way dialogue to help inform and shape policy decisions and the public understanding of NIH's policy-making.

5.3 Create a standing working group to monitor and refine the policy recommendations for the Next Generation Researchers Initiative

The ACD Next Gen working group was established as a standing ACD working group with rotating membership that includes representatives both internal and external to the NIH (See Section III., Working Group Charge and Activities). This group could be leveraged for the continued monitoring, evaluating, and refining of metrics and to assess the efficacy of the Next Generation Researchers Initiative. NIH can also further seek input from internal (NIH staff) stakeholders, and leverage existing internal trans-NIH working groups to help support the Next Generation Researchers Initiative.

5.4 Appoint scientists from across career stages and life experiences to NIH working groups and committees

This is the first ACD working group with notable representation from early-career investigators, and Ph.D. candidate participation. The discussions were substantially enriched by the presence of such diverse perspectives. While consensus on specific concrete suggestions may have been more laborious to achieve, there was a remarkable agreement on fundamental principles and a more thorough vetting of innovative proposals. Since the initiation of this working group, other newly formed working groups, such as the ACD High Risk, High Reward Working Group, have also followed suit with inclusion of early-career and mid-career investigators and Ph.D. candidate representatives. The working group supports NIH's efforts in including additional perspectives and diverse viewpoints in its working group deliberations. This model could be carried forth into other NIH working groups, both external (e.g., advisory groups and workshops on specific scientific areas) and internal (i.e., trans-NIH committees should be assembled to include a diversity of perspectives, including NIH staff representatives from various career stages, from varied career paths as appropriate, and with varying levels of seniority and/or tenure.)

Recommendations for the broader biomedical research community

The working group felt strongly that this report should acknowledge the constraints the working group encountered and where opinions on specific topics differed. Supporting the next generation of researchers will take contributions and changes not only from NIH, but also from universities and research institutions as they are employers and recruiters of research scientists, faculty, postdoctoral fellows, and graduate students. The working group discussed and considered many possible methods to address NGRI aims even when the authority for certain actions was outside NIH's scope. This section highlights specific recommendations, needs, and challenges for the broader biomedical research community.

Hiring and recruitment by research organizations as a point of intervention

As employers and recruiters, research institutions and universities have a major role in strengthening the biomedical research workforce. The working group recommends research organizations examine hiring and recruitment practices to better support a diverse and strong future biomedical research workforce.

Support of early-career faculty

The working group discussed how paying 75-100% of a salary off of grants is particularly hard for early stage and at-risk investigators, and how this overloading of salary sources may not accurately reflect the individual's actual distribution of effort. In addition to the recommendation for NIH described in Theme 2, Recommendation 2.9, the working group recommends that research organizations also explore ways to support these individuals' salaries as they are establishing their labs, in ways that do not solely rely on NIH funding, and instead are supplemented with other means (e.g., endowment).

Staff scientist recruitment

The working group discussed the role of staff scientists in the extramural research workforce. In the NIH intramural program, NIH employs staff scientists, whereas extramural principal investigators are reliant on postdoctoral fellows. Research points to this being an economics decision. Universities with the most

postdoctoral scholars have the most cost-efficient systems and the greatest success in bringing in grant funding. Hiring staff scientists requires longer-term commitments, and staff scientists are paid more than postdoctoral fellows.⁹⁵

The working group recommends that research organizations explore ways to create and support staff scientist positions, and incentivize the recruitment and hiring of staff scientists. Grant funding can be used to support staff scientists, so examining the incentives at every level (university administration, department heads, faculty, etc.) is key to understanding how to overcome existing practices and potentially enact this approach. Also key is exploring examples from institutions that support staff scientists through non-federal funding, such as philanthropy and endowments. For example, the Broad Institute supports staff scientists on significant philanthropic funding, especially in cores, and there is a great fluidity in positions to allow staff scientists to transition readily to other positions within the organization and to rise to positions of leadership. It would be worthwhile to determine if this model would translate to other types of research institutions.

Term caps for postdoctoral researchers

In discussing the NASEM recommendations related to capping the length of postdoctoral tenure (see Theme 3), several working group members raised the point that some universities where they had trained set institutional caps on postdoc tenure. It is unknown how widespread this practice is, and further understanding how it affects postdocs and their training experience would be helpful. In further exploring this topic, the working group recommends seeing if there is a difference between how public and private institutions address postdoctoral fellow tenure caps, and also extend this to determining what percent of public and private universities also place institutional limits on the length of graduate students' training time.

Contributions to data-gathering and transparency

The working group's Recommendation 5.1 describes the importance of data-driven decision making about career paths. The working group supports initial efforts by universities to collect and add transparency to their own workforce data, such as that by university members of the Coalition of Life Sciences.⁹⁶ The working group recommends all NIH-supported organizations make this data available as well. Students and recent Ph.D. graduates will benefit from access to this data as they consider where to pursue graduate studies or postdoctoral training.

V. Concluding Statements

In closing, the working group reiterates the continued need to evaluate the Next Generation Researchers Initiative. In creating policies to support the future biomedical workforce, not one size fits all – for example, scientific fields are different, have specialized needs, and will continue to evolve with time. Similarly, NIH's understanding of future workforce needs, and approach to policy, should likewise evolve. A notable focus of working group deliberations was that while its members all come from different fields and represent different perspectives, in supporting the biomedical research workforce of the future they are pro-sustainability, pro-non-harassment, and pro-diversification in every conceivable way. Consideration of these issues of diversity and harassment as essential part of workforce policy is a key evolution from previous reports on the biomedical workforce and early-career investigators.

As policies are evaluated and adjusted, accountability and transparency are also paramount. This will help trainees in a particular way, and the working group encourages trainees to shop around for the right institution, mentor, and training environment, while considering scientific interests. The working group calls upon NIH-funded organizations to have agency in supporting the goals of the Next Generation Researchers Initiative. These recommendations embody a person-based view of research, and not just a research-based view of research, centered on the consideration of the scientists contributing to society through biomedical research.

VI. Appendix

A. Roster

Co-chairs

Jose C. Florez, MD, PhD
Chief, Diabetes Unit, Massachusetts General Hospital; Professor, Harvard Medical School

Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH

Members

Christine Curran, PhD
Associate Professor, Northern Kentucky University

Amicia Elliott, PhD
Postdoctoral PRAT Fellow, National Institute of Mental Health/National Institute of Biomedical Imaging and Bioengineering, NIH

Gary Gibbons, MD
Director, National Heart, Lung, and Blood Institute, NIH

Linda Griffith, PhD
S.E.T.I. Professor of Biological & Mechanical Engineering; Director, Center for Gynecopathology Research, Massachusetts Institute of Technology

Pamela Kreeger, PhD
Associate Professor, Vilas Associate, University of Wisconsin-Madison

Michael Lauer, MD
Deputy Director for Extramural Research, NIH

Michael Levitt, PhD
Professor, Stanford University

Jon Lorsch, PhD
Director, National Institute of General Medical Sciences, NIH

Stephani Page, PhD
Postdoctoral Research Associate, American Heart Association Fellow, Duke University School of Medicine

Timothy Reddy, PhD
Assistant Professor, Duke University

Juan Pablo Ruiz
NIH Oxford Scholar, National Heart, Lung, and Blood Institute, NIH

Elba E. Serrano, PhD
Regents Professor, New Mexico State University

Christina Stallings, PhD
Associate Professor, Washington University in St. Louis, School of Medicine

Bruce Weinberg, PhD
Professor, The Ohio State University

Executive Secretary

Nicole J. Garbarini, Ph.D.
Special Assistant to the NIH Principal Deputy Director, Immediate Office of the Director, NIH

B. Invited Speakers

James Anderson, MD, PhD, Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH

Shelli Avenevoli, PhD, Deputy Director, National Institute of Mental Health, NIH

Mark Peifer, PhD, Michael Hooker Distinguished Professor of Biology, University of North Carolina at Chapel Hill

Hannah Valentine, MD, Chief Officer of Scientific Workforce Diversity, NIH

National Academies briefing

Lida Beninson, PhD, Program Officer, Board on Higher Education and Workforce (BHEW), National Academies of Sciences, Engineering, and Medicine (NASEM)

Ronald J. Daniels, JD, LL.M., President, Johns Hopkins University, and Chair, Committee on the Next Generation Researchers Initiative, BHEW, NASEM

Tom Rudin, MPA, MSW, Director, BHEW, NASEM

Rescuing Biomedical Research briefing

Bruce Alberts, PhD, Steering Committee, Rescuing Biomedical Research; Chancellor's Leadership Chair in Biochemistry and Biophysics and Education, University of California, San Francisco

Kafui Dzirasa, MD, PhD, Steering Committee, Rescuing Biomedical Research; Assistant Professor, Duke University Medical Center (*note: Dr. Dzirasa also was a member of the Committee on the Next Generation Researchers Initiative*)

Shirley Tilghman, PhD, Chair, Rescuing Biomedical Research; President of the University, Emeritus, Professor of Molecular Biology and Public Affairs, Princeton University

Harold Varmus, MD, Steering Committee, Rescuing Biomedical Research; Lewis Thomas University Professor and Senior Advisor to the Dean and Provost, Weill Cornell Medical College

C. External Stakeholder Correspondence Received



an international forum for cell biology

8120 woodmont avenue, suite 750 • bethesda, maryland 20814-2762, usa
tel: 301-347-9300 • fax: 301-347-9310 • email: ascbinfo@ascb.org • website: www.ascb.org

March 8, 2018

Lawrence A. Tabak, DDS, PhD
Jose Florez, MD, PhD
Co-Chairs
Next Generation Researchers Initiative Working Group
Immediate Office of the Director
One Center Drive, Room 126
Bethesda, Maryland 20892-0147

Dear Dr. Tabak and Dr. Florez:

In May, 2017, the NIH announced a proposal for a new Grant Support Index (GSI) program to limit the total amount of NIH-supported research to an individual principal investigator (PI). The proposed limit was intended to maximize the productivity of NIH funds by addressing possible issues such as bandwidth and diminishing returns, as well as try to reverse the trend of declining grant funding awarded to early- and mid-career investigators. The imbalance in grant funding is most notable in a chart by the NIH that shows over the last 25 years the increasing percentage of NIH investigators over the age of 60, while the percentage of mid- and early-stage NIH investigators is decreasing within the same period. After a month long discussion and request for feedback, the NIH made the decision to abandon the GSI program and instead implement the Next Generation Researchers Initiative (NGRI). This program would not limit total NIH support for any one investigator, but instead aimed to provide targeted funds toward investigators who were perceived to be most at risk – those with 10 years or less of NIH Research Project grant support. The source of funds for the NGRI was not immediately clear.

The ASCB is a professional society encompassing thousands of basic biomedical researchers in all 50 states and at all career levels. As such, our community is greatly concerned by the troubling trends and imbalance in the NIH-supported biomedical research workforce. Many productive early and mid-career investigators among our membership are struggling to retain or regain funding for their labs. Since about 70% of NIH-funded researchers only have one grant, even most currently funded PIs are only one grant away from losing their research program. This troubling statistic clearly indicates the stability of our biomedical workforce is at great risk. Clearly, maintaining the status quo at NIH is not acceptable, and we therefore urge the NIH not to abandon the discussion that started with the GSI and continue to collect feedback around these issues. We hope that the current NGRI Working Group is one example of a continuing commitment to this goal.

As the NIH NGRI Working Group continues its work, the ASCB believes that there are

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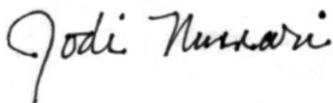
Editor-in-Chief

basic principles that should guide its work.

- 1) **Avoid Unintended Consequences:** Any final proposal for NGRI must take into consideration impacts outside the scope of the proposal. Data gathered by the NIH reveals that mid-career researchers are equally or more at risk than early-career PIs. It is important that efforts to support one career stage not result in inadvertent stresses at other places in the career pipeline. A rigid limit on the career status of those funded by NGRI could, for example, potentially exacerbate the funding difficulties of mid-career PIs. It is also important that if funding is part of the final proposal, the funds used lead to an increase in the number of productive labs funded, rather than simply re-arranging which labs have no funding. Therefore, it is critical that the source of funds for the NGRI is identified.
- 2) **Don't Reinvent the Wheel:** The NIH consists of 27 individual research institutes and centers, with a wide-range of experience on how to fund research. We urge the Working Group to take advantage of this experience and benefit from the successes and failures within the NIH I/Cs, taking full advantage of the successful programs already underway. We particularly recommend to the Working Group the 20 year old policy by the NIGMS regarding support for research in well-funded laboratories.
- 3) **Policy should be NIH-wide:** Since so many NIH researchers receive funds from multiple institutes, we believe any recommendation by the Working Group must apply across the NIH.
- 4) **Transparency:** To receive the support of the community that will be critical for ultimate success of any policy, the ASCB urges the Working Group to be as transparent as possible in explaining the goals of the policy and to make data widely available to the community.
- 5) **Going beyond just the NGRI discussion,** the ASCB wishes to put forward other suggestions for consideration that might address some of the current imbalance issues.
 - a. Consider a grant review system similar to that used by the European Research Council, in which investigators are only competing against those at similar stages in their careers. The separate review of Early Career from other investigators in the new NIGMS MIRA Program provides another example.
 - b. Limit the number of people any one PI can support with NIH funding, thereby limiting laboratory size. This would require a nuanced approach that takes into account factors that contribute to the variable costs of doing research.
 - c. Use a variable percentile cut off for funding grants depending on the size of the group. Specifically, funders could use a lower percentile cut off for each incremental grant. For example, they might fund every lab with no other grant up to the 30th percentile. This will take care of junior investigators trying to break into the system and will keep more labs from closing. Then require a 20th percentile score for the second grant and the 10th percentile score for the third grant (obviously on a sliding scale rather than in big steps).

As the Working Group continues its work the ASCB stands ready to share our views with you in more detail. We also thank you for the seriousness with which you are approaching this important topic.

Sincerely,



Jodi Nunnari, PhD
ASCB President



Erika C. Shugart, PhD
ASCB Chief Executive Officer

Next Generation Researchers Initiative – ASBMB Policy Recommendations

The American Society for Biochemistry and Molecular Biology (ASBMB) strongly supports the goals of the Next Generation Researchers Initiative (NGRI) and actions by the NIH to ensure the long-term viability and sustainability of the biomedical research enterprise. We have identified 5 policy areas of importance to our membership, which we submit for consideration by the NGRI Working Group. The policy recommendations below are meant to serve as guides; specific numbers associated with them should be adjusted based upon an analysis of the relevant data.

1. Establish a Program to Fund Early Stage Investigators (ESIs)

Definition

Recommendation: An investigator, without an R01-equivalent federal grant, who is within their first 6 years of an independent faculty position.

Rationale: This defines the ESI based on the time of their first hiring as an independent investigator, thereby equalizing potential differences in time spent in post-doctoral fellowship and eliminating disincentives to extend PhD training.

Funding Threshold

Recommendation: We concur with the [report on Open Mike](#) (June 16, 2017) that targets funding ESIs with R01-equivalent applications that score in the top 25th percentile.

Rationale: This gives ESIs an advantage over established investigators, thus decreasing the ESI funding gap.

Submission Windows

Recommendation: Implement a Continuous Submission policy (NOT-OD-17-042) to ESIs for R01-equivalent applications.

Rationale: This permits ESIs increased turn around for grant submission, review and potential funding as has been successfully accomplished in other special cases (for example, HIV-related applications/reviews are accelerated by a full cycle).

2. Establish a Program to Retain At-Risk Established Investigators

Definition

Recommendation: An investigator who has lost all R01-equivalent research support within the last 3 years or is at risk of losing all R01-equivalent research support if they are not funded by competing awards this year.

Rationale: Retaining successful established investigators in the scientific work force maximizes prior grant dollar investment. Establishing funding stability would contribute to the desirability of this career path to the next generation.

Funding Threshold

Recommendation: Institutes should consider determining a modified payline for at-risk investigators.

Rationale: This should give at-risk established investigators a small advantage over other established investigators, thus retaining highly trained and successful academic scientists in the workforce.

Submission Windows

Recommendation: Implement a Continuous Submission policy (NOT-OD-17-042) to at-risk established investigators for R01-equivalent applications.

Rationale: This permits at-risk established investigators increased turn around for grant submission, review and potential funding as has been successfully accomplished in other special cases (for example, HIV-related applications/reviews are accelerated by a full cycle).

3. Establish a Cross-NIH Sliding Scale for the Funding of Multiple Awards

Definition

Recommendation: A principal investigator with 2 funded R01-equivalent grants will be required to meet an increasingly higher threshold for the funding of each subsequent new proposal. NIH should also take into account how to appropriately weigh the contribution of investigators in multi-PI grants or subcontracts so as not to discourage team-based science.

Rationale: This mechanism will free up funds to support ESIs and at-risk established investigators, and will ensure that meritorious scientific research can still be funded while taking into account the report ([Lorsch, 2015](#)) of a productivity plateau for increasing levels of funding.

Setting New Funding Thresholds

Recommendation: The funding threshold for an investigator's first 2 R01-equivalent research awards will remain unchanged. Funding of each additional R01-equivalent research award will occur at increasingly higher thresholds with each subsequent proposal. We recommend that the funding threshold for each subsequent grant be reduced by 1/3 of that of the previously funded proposal.

Rationale: A stepped reduction in funding threshold does not preclude the funding of meritorious research. Rather, it spreads the funding among a larger number of investigators proposing equally meritorious research. Basing thresholds on the number of grants held by an investigator, as opposed to setting a dollar limit, takes into account the different costs that are incurred in different research areas.

Training Grant and Administrative Core Exception

Recommendation: Training grant awards and the administrative core portion of program project grants shall not count as R01-equivalent research awards for the purpose of determining funding thresholds, as these activities are a service for training the next generation and to the broader research enterprise.

Rationale: Investigators should not be punished for service-related funding that brings little to no research funding to the investigator's laboratory.

4. Set Salary Support Limit

Recommendation: NIH should consider placing limits on the overall percentage of salary support available to every investigator who receives NIH funding, in addition to the current salary limitation guidelines (NOT-OD-18-137). In so doing, the ability to fund meritorious research can be extended while advancing the intended partnership with academic and research institutions. The absence of publicly available data on salary support precludes recommendation of a definitive overall percentage cutoff.

Rationale: A salary support limit may free up funds and will help codify the partnership between institutions and the NIH in conducting biomedical research.

5. Establish a Program to Promote Re-entry

Definition

Recommendation: An established investigator with an independent faculty position who has lost all NIH grant support for more than 3 years.

Rationale: This program would retain highly-trained scientists in the workforce and permit realization of lost potential from the volatility of the biological research funding climate.

Funding Mechanism

Recommendation: Relax eligibility circumstances for PA-15-321, Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers to include faculty with long-term loss of R01-equivalent funding. The new or refined mechanism should provide both salary support and research support to promote successful re-entry.

Rationale: A mentored research experience may be critical for re-entry of some faculty-level scientists following a funding hiatus.

Thank you for taking our policy recommendations into consideration. If you have any questions or concerns about any of our recommendations please do not hesitate to contact Benjamin Corb, director of public affairs, at bcorb@asbmb.org.

Next Generation Working Group
Public Affairs Advisory Committee
American Society for Biochemistry and Molecular Biology
April 2018

Dear colleagues on the NIH ACD Next Generation Researchers Initiative Working Group:

As the Next Generation Researchers Initiative (NGRI) Working Group of the Public Affairs and Advisory Committee (PAAC) of the American Society of Biochemistry and Molecular Biology (ASBMB), we would like to follow up [our April 25 letter](#) with comments on the report issued at the 116th meeting of the ACD (June 14-15, 2018). We hope to continue our fruitful dialog with the NIH as you identify and propose policies to ensure the sustainability of the biomedical research enterprise. In particular, we wish to provide feedback regarding proposed policies for the next generation of scientists and for at-risk investigators with the common goal of supporting the future of biomedical research in the United States. Below we present our responses to several portions of the [ACD NGRI Working Group report](#).

The ESI status clock

Major theme 1, Slide 15: We were pleased that the ACD Working Group has considered altering the previous eligibility criteria for early stage investigator (ESI) designation, a move that we support. However, of the two proposed options for the status clock, we favor the second, as it better accounts for variability in training paths, including non-traditional paths and paths in different disciplines within biomedical research. The first definition using a 12-15 year window may be too short for investigators in multidisciplinary fields requiring multiple postdoctoral training appointments and, at the same time, may be too long for investigators in fields where shorter postdoctoral fellowships are sufficient. We favor using time from the start of the investigator's first independent position as the anchor date, requiring institutions to certify eligibility for designations as is common practice for scholar awards. This approach is successfully utilized for awards from the Pew Charitable Trust, the Camille and Henry Dreyfus Foundation, the Cottrell Scholars Collaborative, and the National Science Foundation CAREER program to support investigators who are in a similar career stage as NIH ESIs.

ESIs and multi-PI grants

Major theme 1, Slide 16: We agree that shifting the focus to meritorious at-risk investigators is critical. We also agree that the approach to have ESIs maintain their ESI status while receiving support from multi-PI grants is helpful to their scientific development and pursuit of an independent research program. However, before changes are made in study section format, we would like to see data that indicate that clustering of ESIs and at-risk investigators together during review leads to a fairer review process.

Methods to identify and support ESIs and at-risk investigators

Major theme 2, Slide 17: We agree it is important to develop grant mechanisms to support ESIs and at-risk investigators. We encourage NIH to expand their current efforts. While awards such as the DP2 and DP5 are valuable mechanisms for supporting outstanding ESIs, the limited number of awards made by these programs limits impact. We applaud the goals of the more widely used NIGMS MIRA R35 and encourage NIH to more broadly implement similar programs.

Meaningful and sustainable diversity

Major theme 3, Slide 18: We firmly agree that a diverse and inclusive scientific workforce is crucial for the future of life sciences in the U.S. The NIH should expand programs which aim to diversify the pool of NIH reviewers and grantees. We would like to see increased monitoring and reporting by NIH of outcomes on progress toward a diverse and inclusive scientific workforce.

Distribution of investigators

Major theme 4, Slide 20: We agree that the question of how many investigators and their research programs can be stably supported by NIH is an important question. Arriving at an answer may permit redistribution of some NIH funds to ESIs and at-risk investigators. However, the ACD must be careful not to arrive at an answer that would inadvertently influence career choices among early career scientists who might be easily discouraged by negativity or by a form of stereotype threat. Furthermore, as the biomedical research enterprise is an exceedingly complex endeavor with a diverse array of stakeholders, great care must be taken when generating a ‘carrying capacity’. We appreciate and support the working group’s goal that recommendations stemming from ‘carrying capacity’ modeling allow for both evaluation and course correction. We also advocate that these recommendations be paired upfront with suggested evaluation metrics and timelines to be used by NIH instead of requiring the NIH to simultaneously implement recommendations and develop evaluation metrics *de novo*.

We thank you for being open to our suggestions and recommendations, and look forward to our continued partnership in developing a stronger and sustainable scientific enterprise. Please do not hesitate to contact Benjamin Corb, director of public affairs at bcorb@asbmb.org, if you have questions or comments regarding our letter.

Next Generation Working Group
Public Affairs Advisory Committee
American Society for Biochemistry and Molecular Biology
October 2018

To: NIH ACD Next Generation Researchers Initiative Working Group

CC: NIH Division of Biomedical of Research Workforce and Office of Intramural Training and Education

The Federation of American Societies for Experimental Biology (FASEB) recently submitted feedback (**see attached**) to the National Academies' Committee on the Next Generation Initiative on its report, *The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through*. The Federation is appreciative of the thoughtfulness and hard work that went into developing *Breaking Through*, and agrees with many of the recommendations. Throughout our discussions, however, we did identify a number of concerns stemming from some of the proposals that warrant consideration by training stakeholders. FASEB hopes that our input will be of value as the Next Generation Researchers Initiative Working Group deliberates measures to increase the number and stability of NIH-funded early career researchers.

Please let me know if you have any questions, or if FASEB can be of assistance in any way.

Best,
Libby Barksdale

Elizabeth Barksdale, PhD
Senior Science Policy Analyst
Federation of American Societies for Experimental Biology
9650 Rockville Pike, Bethesda, MD 20814
Tel: 301.634.7328
Email: ebarksdale@faseb.org
Web: www.faseb.org





FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

301.634.7000
www.faseb.org

9650 Rockville Pike
Bethesda, MD 20814

Committee on the Next Generation Researchers Initiative
Board on Higher Education and Workforce
The National Academies of Sciences, Engineering, and Medicine

August 8, 2018

Comments submitted via email to LBeninson@nas.edu

Dear Dr. Daniels:

The Federation of American Societies for Experimental Biology (FASEB), a coalition of 30 scientific societies collectively representing over 130,000 biological and biomedical researchers, applauds the efforts of the National Academies of Science, Engineering, and Medicine's Committee on the Next Generation Initiative in producing the report, *The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through*. Helping postdoctoral researchers transition to and succeed in independent research positions is something the biomedical research community has struggled with for decades; the Committee's proposals for addressing myriad aspects of this problem both revisit and creatively depart from previous recommendations. After consideration and discussion of *Breaking Through* and potential consequences of its recommendations, FASEB identified a handful of concerns, questions, and suggestions for the Committee—indeed, all training stakeholders—to consider.

Limits on Postdoctoral Training and Support

Two of the most controversial recommendations, from FASEB's point of view, concern time limits for postdoctoral training. Although we understand the need to address the glut of postdocs and the increasing number of years many individuals spend in the position, the Federation questions whether the proposed limits on time in training and length of support on certain funding mechanisms would achieve the intended outcome of delivering more early career scientists into independent research positions.

Recommendations 4.3 and 4.4 advocate a three-year cap on salary support for postdocs from research project grants (RPGs) funded by the National Institutes of Health (NIH) and a five year limit on postdoctoral training, respectively. FASEB agrees with the underlying assumptions that obtaining independent funding is an important skill and career milestone for postdoctoral researchers on the path to independence, which should be encouraged, and that toiling for years in a position with low pay and uncertain career prospects does not benefit postdocs as researchers or as contributing members of society. However, there are a number of considerations to take into account before moving ahead with these suggestions.

First, RPG support is one of the only funding mechanisms open to foreign postdocs, as they are not eligible for NIH fellowship (F) and career development (K) awards, institutional training grants, or for many grants from private foundations or professional societies. It would be imperative that NIH implement Recommendation 4.2—to open eligibility for F and K awards to non-U.S. citizens—**before**

acting to curb RPG support. Second, many young researchers use their time as postdocs to learn new techniques or even switch fields. They should not be penalized for this learning period, which could take a year or more, during which time they are likely to be supported on a RPG and not producing much in the way of manuscript-quality research. Third, some research inherently takes longer (e.g., mouse vs. flies, or any animal model vs. computer modeling). If a postdoc starting a new position needs to create a new mouse line as part of her research project, it could easily be two years before she has any preliminary results, let alone enough to submit a fellowship application. Fourth, postdocs at small and/or under-resourced institutions could be especially hard-hit by these time limits because research activities there may already proceed at a slower rate than at well-resourced institutions, and such institutions may not have sufficient infrastructure to support institutional training grants. Finally, until institutions across the country standardize the definition for postdoctoral positions, specifically the terminology, expectations, and other parameters pertaining to these positions, it will be difficult to track compliance with caps on funding and time spent in the position.

We appreciate the Committee's caveat that pilot studies on the duration and impacts of limits on RPG support and total time in training should precede the creation and phasing in of new policies. We suggest that NIH also solicit feedback from postdocs themselves before considering any caps. In addition, NIH may want to consider other funding agencies' approaches to supporting postdoctoral researchers. Postdocs at the Department of Energy's (DOE) national laboratories, for example, must complete a formal application process for posted positions, which are limited to three years. However, postdocs can extend the position for one year, or apply for a second, three-year position, with the approval of the Department provided that they justify the necessity of the extra time for gaining additional knowledge and skills.

The "Postdoc Tax"

Included in Recommendation 4.1, that stakeholders should support postdocs' transition to independence by providing a high-quality training experience, was the provision that research institutions should levy a fee of \$1,000/year/postdoc supported on RPGs. This fee, which the Committee advises making an itemized direct cost on NIH research grants, would be used to implement and support institutional training programs and activities for both postdocs and mentors.

FASEB supports the idea of securing funds to ensure high-quality mentoring and resources for career and professional development. However, we do not think it is essential to dictate the source of those funds. In addition to grant set-asides, these activities could be supported by external sources, additional grants, or even institutional endowments.

We are concerned that requiring funds to come directly from principle investigators' (PI) grants connotes a punishment, one that could affect PIs' support for and participation in the training activities proposed. Moreover, the Committee states in the report that "The amount of \$1,000 is not so large that it will disrupt the RPG budgets...". Because NIH has not indexed the cap for modular research grant applications to inflation, grant dollars do not go as far today as they used to. The average RPG award was smaller in 2017 than in 2003 (in 1995 dollars; see FASEB's [NIH Research Funding Trends](#)). As PIs

grapple with how to manage increased equipment, reagent, and personnel costs in combination with decreased institutional support on effectively shrinking grant budgets, this extra fee could become a disproportionately large burden.

Increasing the Duration of Research Grants for Early-Stage Investigators

One of the provisions under Recommendation 5.1—to strengthen the research funding landscape for the next generation of investigators—is that NIH should ensure that all R01 research project grants awarded to early-stage investigators (ESIs) provide at least five years of support. FASEB agrees that affording ESIs sufficient time to establish their research programs and generate bodies of work that will enable them to secure additional funding is important for stabilizing their careers. It is possible, though, that increasing the duration of R01s to five or more years could have unintended consequences for ESI applicants lacking experience writing long-term research plans. This is a very specific skill and differs from the experience ESIs may have gained when applying for early career awards with shorter project periods (e.g., the K99/R00 or F32, which typically provide three years of support). Should the recommendation for longer periods of support for ESIs be adopted—and there is certainly merit in the proposal—it should be tied to a requirement for training in grant writing prior to applying for a R01. This training could occur as part of the career and professional development resources alluded to in Recommendation 4.1 (see above), through mentoring from an established investigator, as an offering by a professional society, or another mechanism. Additionally, NIH and other funding agencies may have to significantly restructure their grant review and award processes to accommodate the goal of providing extended funding to ESIs, and such changes should only be implemented after pilot studies to identify the most promising approaches.

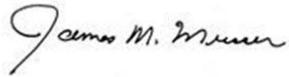
The Role of Staff Scientists

FASEB was pleased to see the Committee build on the suggestion from its [Sustaining Discovery](#) report that “the research community should employ more staff scientists.” We support the idea, from *Breaking Through* Recommendation 5.3, that NIH and research institutions should work in concert to increase the number of staff scientists and make the position a viable career option with attractive compensation and growth opportunities. However, there are some “first steps” that need to be addressed. Importantly, there needs to be an agreed upon definition of “staff scientist,” including roles and responsibilities, source(s) of funding, and career progression. Without these parameters in place, we are concerned that the second part of Recommendation 4.4, that postdocs who want to remain in a lab longer than five years be transitioned to employment as staff scientists, could result in the creation of a de facto “Senior Postdoc” position and actually inhibit postdocs’ chances of achieving independence.

In addition, we advise that core scientists be included in Recommendation 5.3 as a career option worth pursuing. FASEB’s [Maximizing Shared Research Resources](#) report shows that research cores and core scientists help maximize research efficiencies and outcomes with the support they provide in areas such as experimental design and technological training. Some postdocs may find the core scientist position more fulfilling than that of staff scientist, given the collaborative and technology-heavy nature of the role.

In conclusion, FASEB thanks the Committee on the Next Generation Initiative for its thoughtful and provocative report. *Breaking Through* has already spurred extensive discussions within the Federation, and more are sure to come. Please do not hesitate to reach out if FASEB can be of help as you explain and refine your recommendations through discussions with the greater biomedical research community.

Sincerely,

A handwritten signature in black ink that reads "James M. Musser". The signature is written in a cursive, flowing style.

James M. Musser, MD, PhD
FASEB President

D. NIGMS Analysis of the Effect of the Early Established Investigator Policy

Modeling Potential Implications of the Next Generation Researchers Initiative

Office of Program Planning, Analysis, and Evaluation

National Institute of General Medical Sciences

November 6, 2017

Current NGRI Policy

- Prioritizes funding for two groups of investigators
 - Early Stage Investigators (ESI) – *Existing category of investigator*
 - Investigators who have yet to successfully receive a competing major research project award, and are within 10 years of terminal research degree / residency
 - Early Established Investigators (EEI) – *New category of investigator*
 - Established investigators who received a competing award as an ESI within the last 10 years
 - EEIs prioritized if the competing award leads to fewer than 3 active major research project awards.
- NIH-wide target: additional ESI and EEI awards (200 of each) for 2017

Potential Implications of Current NGRI Policy

- In a budget-neutral environment, prioritization of additional ESI / EEI applicants requires a tradeoff.
 - Option 1: Skip R01-equivalent Applications from non ESI/EEIs
 - Applicants in deprioritized groups may lose all NIH funding.
 - Option 2: Reduce Award Sizes to Accommodate Additional Grants
 - Existing awardees would have fewer resources to complete research.
 - Option 3: Re-budget Other Mechanisms to Award more R01-Equivalents
 - Requires lower investment in other RPGs, Centers, etc.
- New Investigators who miss ESI eligibility by 1-2 years are considered non-EEI for the next 10 years.

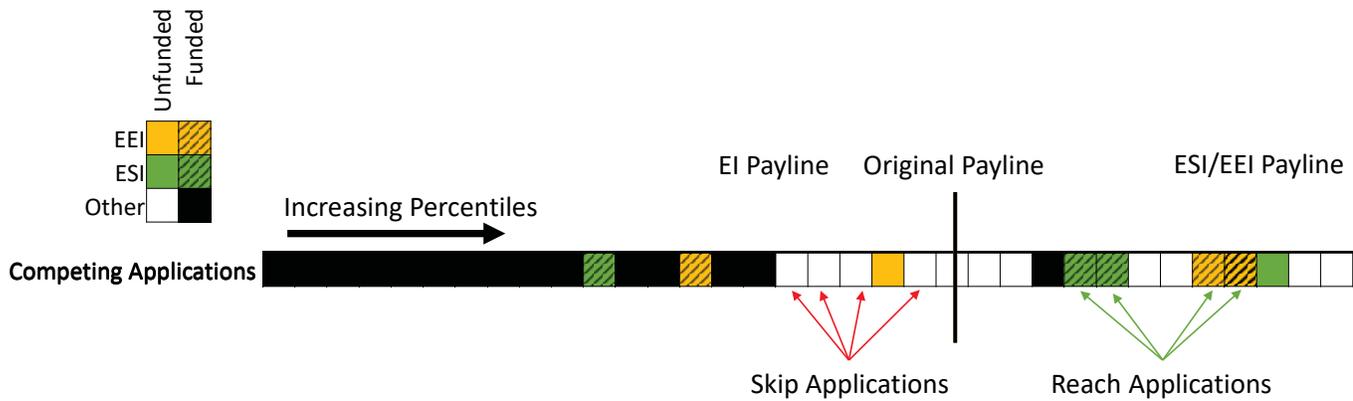
3

Modeling Implications of NGRI Policy

- Datasets
 - Competing R01-equivalent applications, FY 2014 to 2016 (for modeling)
 - All major research project awards, FY 2014 to 2016 (to describe investigator pool)
- Model Used – Option 1 (Reach / Skip Tradeoff)
 - Budget Neutrality
 - All additional awards must be offset by cost reductions, in the form of funded applications being unfunded.
 - Payline Behavior
 - Skips below payline and reaches above payline are left unaffected
 - Programmatic/administrative decision led to outcome, no changes made.
 - Reductions from Requested Budgets
 - Historical data used to create estimate of likely award size
 - ESI / EEI targets
 - Based on application distributions by IC

4

The Model – Example (Payline)

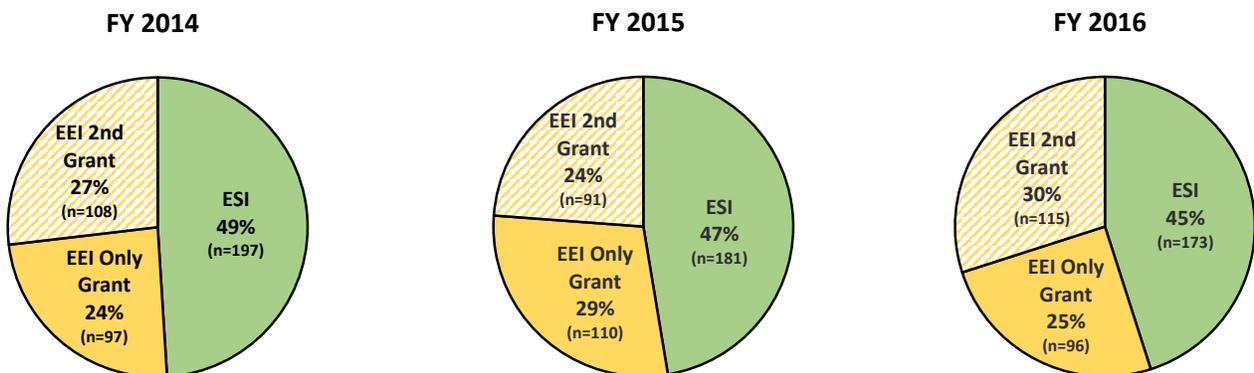


Reaching for 2 new ESI and 2 new EEI awards requires skipping 4 other awards

5

Modeling Results – Policy as Stated

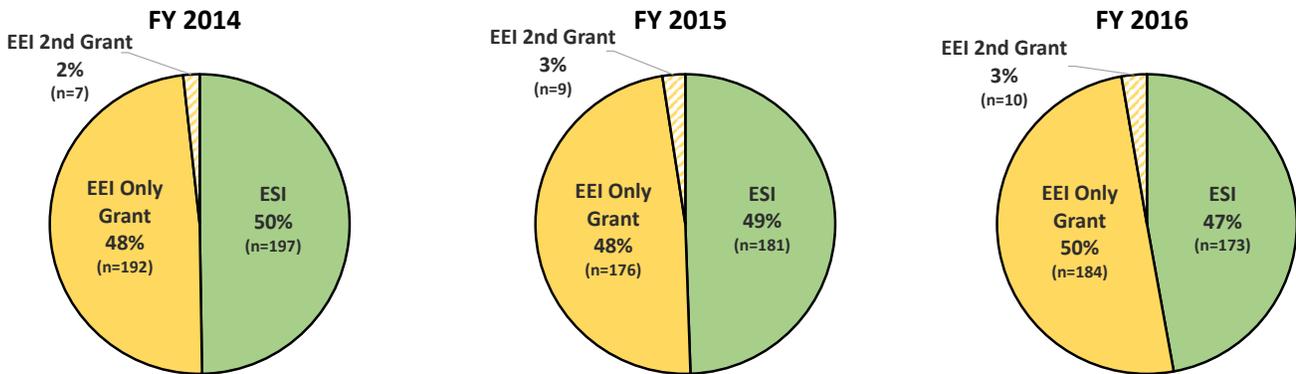
- Not all ICs could meet ESI targets.
 - Small ICs lacked applications, ICs already reaching for ESIs lacked additional meritorious applications
- 45-55% of EEI reaches funded an investigator's second project that year.



6

Modeling Results – Avoid 2nd Grant Reaches

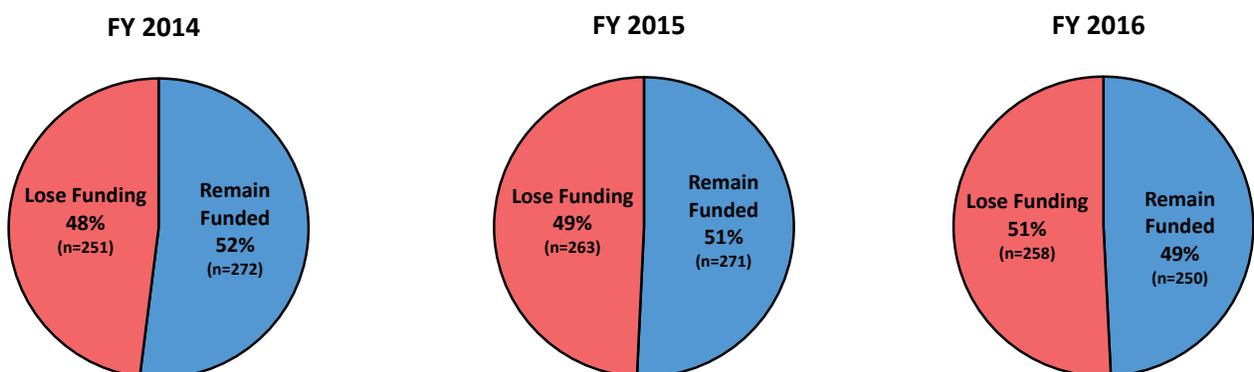
- Change to model – focus on supporting EEIs with no other grants
- Few EEI reaches funded an investigator’s second project that year.
 - All cases are due to MPI projects with at least one unfunded applicant



7

Modeling Results – Skip Applications

- More investigators were affected by skips than reaches in all years.
- Nearly half of skipped investigators lost NIH funding in each year.



8

Conclusions under Initial Model

- Negligible change in investigator pool from policy simulation.
 - 250-400 investigators gained (ESIs and EEI with only grant funded by policy).
 - Approximately 250 investigators lost (Non-ESI/EEI skipped by policy).
- Grants primarily reallocated among investigators with 0-1 awards.
 - Nearly half of skipped investigators held only one grant
- Alternatives?

9

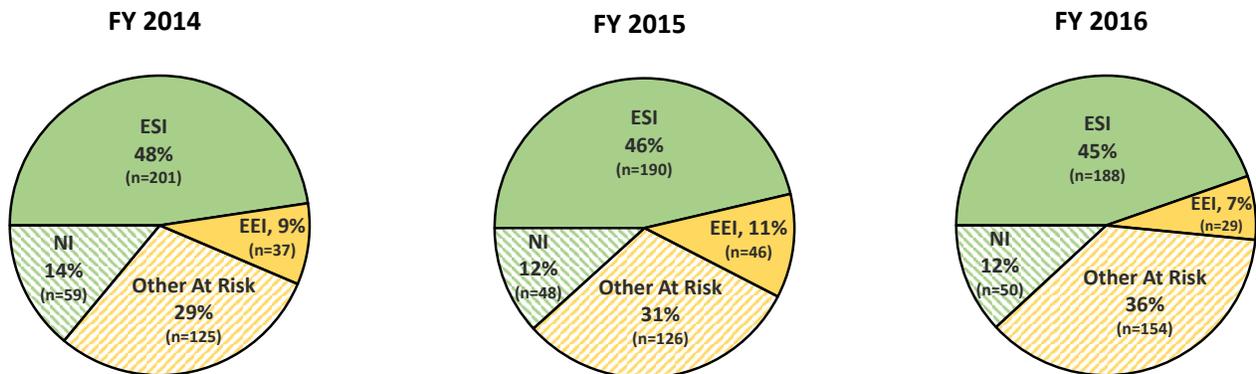
Alternative Model

- Identical analysis performed, prioritize all investigators with 0 grants or renewing existing grant
 - Restricts skips of “at risk” investigators
- Minimal changes to grant counts
 - Similar number of skips and reaches
 - Similar budget outlays
- Changes occur to EEI and skipped investigator populations

10

Alternative Model – Reach Applications

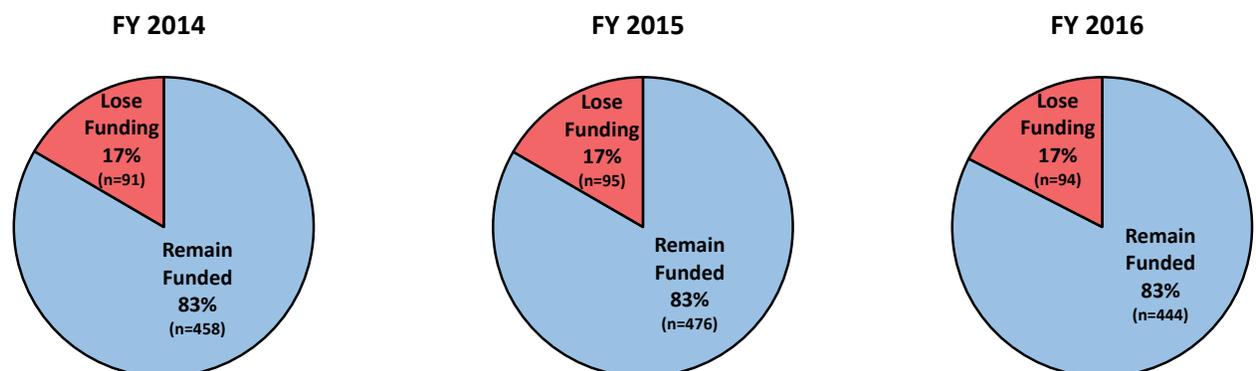
- Similar overall number of investigators reached
- Most “At Risk” reaches go to Non-EEIs



11

Alternative Model – Skip Applications

- More investigators were affected by skips than reaches in all years.
- Fewer investigators lose all funding than previous models
 - All investigators who lost funding were MPIs on an award with another investigator who did not lose funding



12

E. Summary of 2018 NGRI Approaches to Funding ESI & “At-risk” Investigators

ICs were asked to describe their planned strategy in 2018 in response to the NGRI. They were asked to describe whether they were:

1. extending their payline to ESIs, NIs, and/or established investigators close to the payline who are at risk of losing all funding.
2. using standard NIH definitions for ESI or NI.
3. using R56 awards to those at risk of losing all funding (or to those without prior major NIH awards)
4. using or developing an ESI R35 program, and how many projected awards in FY18?
5. Using specific strategies to ensure funding availability, such as:
 - a. Setting aside funds specifically for FY18 ESI awards XX% greater than dollars awarded in FY17
 - b. Reducing awards to selected established investigators with more than 3(?) significant awards
 - c. Standard administrative cuts to all awards
 - d. Other

Responses to question #1 reflected a notable heterogeneity of approaches to fund ESI, NI, and “at-risk” investigators. This is somewhat expected given the existing heterogeneity of approaches to funding grants (for example, not all ICs set paylines, and as per previously shared data, ICs use select pay in varying degrees, etc.). Of the ICs that do set paylines, the majority report modifying their payline to fund additional ESIs, to varying degrees. Six ICs report funding all ESIs up to the 20th-25th percentile. The remainder of the ICs that report using paylines describe expanding the payline by a specific amount, to create a zone of opportunity for reaching and funding additional ESIs.

Several ICs noted that a strict approach to funding all Early Stage Investigators within the 25th percentile was unsustainable due to major and deleterious effects on existing research programs.

Of the ICs that do not set paylines, a variety of approaches are used. The most common approach is to look for ESI/NI/“at-risk” applications with meritorious scores and proposed research that closely aligns with IC strategic plans/scientific priorities. One IC reported dedicating a specific amount of funding per fiscal year with which to fund ESIs.

While not specifically asked about other factors taken into consideration for select pay, some ICs provided descriptions of the factors they use, which include: availability of other funding sources, applications that address knowledge gaps or emerging opportunities/innovation, underrepresented groups, geographic location of institution.

While not specifically asked about success rate targets, several ICs described how they aim to fund equivalent success rates for established investigators and ESIs or NIs, as per past NIH fiscal policies.

In **question #2**, ICs were asked if they were using different ESI or NI definitions than those established by NIH. The majority of ICs are using the NIH definitions. Some notable variations are:

- An approach to extend the definition of ESI from 10 to 15 years from terminal degree or clinical training, and is exploring the possibility of programs to effectively give ESI status to applicants to 15 years from terminal degree or clinical training. NCI's extensive analysis of its early-career investigators over time determined that many early-career investigators are missing the 10 year cut off due to an almost doubling of time from degree to first R01 since FY 1990. While the median time from terminal degree to first submitted R01 application was 6 years in FY 1990, in FY 2016 it was 11 years. Further analysis of the data indicated that the bulk of this delay is due to an increase in time from degree to first application, with only a small increase in time from application to award.
- Including some investigators in their ESI count who just missed having ESI status, due to the timing of their awards versus the expiration of their ESI status. Similarly, for EEs who are being evaluated as to when their current funding will expire, consideration should be given not only to the status of funding for the current FY of support, but for the following FY as well.
- Special consideration extended to NI/ESI applications but not to applications from experienced investigators who include NI/ESI investigators as multiple PIs causing them to lose their NI/ESI status.
- Giving ESI status to applicants who are no longer technically ESIs if they are within their 37-month resubmission window for their ESI application. Technically they convert to NIs using the NIH definition, but the IC still gives them ESI preference.

In question #3, ICs were also asked if they use R56 awards for those at risk of losing all funding, with or without current or prior NIH funding. They were also asked if they provide R56 to ESI/NIs. 4 ICs do not use R56 at all – these are smaller or newer ICs, or ICs with unique needs. Of the ICs that use R56 awards, 2 ICs specifically stated that they aim to fund ESIs with R56 awards. Others use the R56 to fund a combination of ESIs, new investigators, investigators seeking to renew their grant but who received a score just outside the IC payline, and investigators with one award who are at risk of losing all funding.

For **question #4**, only 2 ICs report having an ESI-specific R35 program. One IC reports using the R35 specifically for mid-career investigators. One IC is piloting an ESI-specific R37 MERIT award.

For **question #5**, 2 ICs report formally setting aside funds for ESIs, however, based on responses it is not clear if this is set up as a pool of funding from which to fund ESIs, or the 'set aside' is in the form of a specific program (e.g., a target number of awards for an ESI-specific program). No IC reported following a policy that restricts established investigators from having more than 3 awards. The closest example of such a policy is one IC reporting that 'in most cases' they plan to restrict IC support to no more than 2 RPGs per PI, and another IC reporting that they will apply this strategy 'if needed'. Many respondents used this question to report that they are continuing to follow the NIH special council review policy for additional funding to well funded (>\$1M in direct costs) investigators. In response to the question about standard cuts, the IC responses were not specific as to whether their standard administrative cuts were to be used for funding ESI/"at-risk" investigators. This is reflected by several ICs responding that they are applying the continuing resolution policy of issuing non-competing continuation awards up to 90% of previously committed levels, or responses in which the IC affirms having a 'standard administrative reduction'. Three ICs did describe how standard budget cuts/project length cuts applied to established investigators were reduced or not applied to ESIs.

Many other approaches and strategies were reported in this section, and referenced in other areas of the IC responses as well. ICs included descriptions of specific early-career award programs using a variety of mechanisms, often programmatically aligned to their ICs mission (as per past materials, these were presented to the working group in November 2017, and provided to the working group in background documents.) Strategies/approaches that are variations beyond early-career-specific awards include:

- incentives for including ESI PIs as subproject leads on P01s
- focused meetings for investigators who are pre-R01 level that provide mentor contacts as well as information on programs for them
- IC does not reduce budgets on ESI's R01s or R21s that fall within the payline
- seeking co-funding from the ORWH, OBSSR, OAR, IDeA programs for ESIs and all investigators at risk of losing all NIH funding
- supplements to ESIs who re compete successfully for their type 2
- promoting innovation and novel high-risk projects by EEs
- generally providing ESIs support for their full requested level of four or five years (vs only three or four years for established investigators)

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