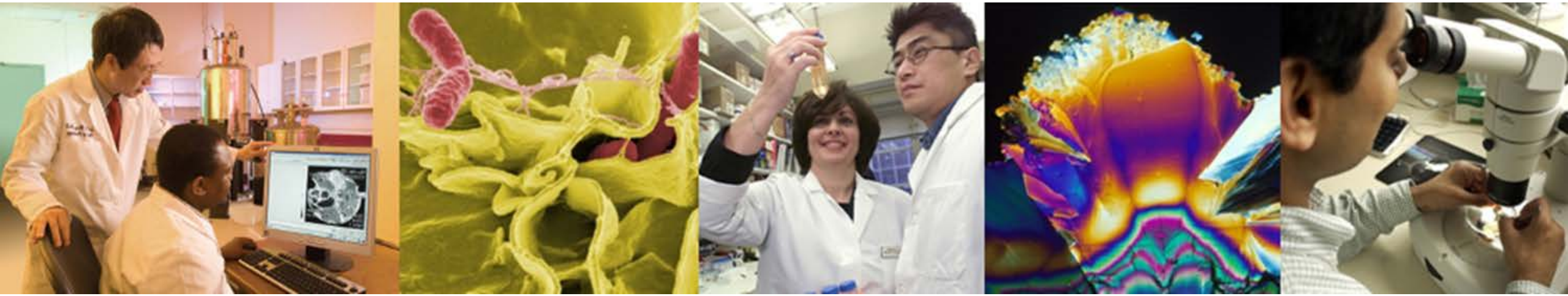
Next Generation Researchers Initiative: Report from ACD Working Group

116th Meeting of the Advisory Committee to the Director
June 14-15, 2018



Jose C. Florez, M.D., Ph.D.
Chief, Diabetes Unit; Investigator, Center for Genomic Medicine, Massachusetts General Hospital;
Professor, Harvard Medical School; Institute Member, Broad Institute
Co-chair, NIH ACD Working Group on the Next Generation Researchers Initiative

Outline of Today's Presentation

- Background
  - Review of original charge
  - Update on NGRI policy
- Working Group Activity Update
- Draft Recommendations
- Next Steps

21st Century Cures Act

- Section entitled, “Investing in the Next Generation of Researchers,” established the Next Generation of Researchers Initiative within the Office of the NIH Director.
- This initiative is intended to promote and provide opportunities for new researchers and earlier research independence.
- In particular, subsection (b) requires the 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*
- And subsection (c) requires the Director to *Carry out other activities…as appropriate, to promote the development of the next generation of researchers and earlier research independence.*

Review of the original charge to the working group

- Assist the NIH ACD on the development of a trans-NIH Next Gen policy;
- Review independent assessments to identify evidence-based metrics for research productivity, and determine the impact of NIH grant support on scientific progress;
- Provide advice and recommendations on approaches for developing or enhancing NIH funding mechanisms aimed at supporting ESIs and EEIs;
- Propose recommendations for tracking and assessing funding decisions for applications with fundable scores that involve ESIs and EEIs, to ensure the Next Gen is effectively implemented in all areas of research;
- Align 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;
- Review analyses to assess the impact of the Next Gen policy on the overall NIH scientific portfolio and workforce trends.

Update on NGRI policy for FY 2018

- For FY2018, NIH will continue to monitor:
  - How many more ESIs were funded compared to the prior year
  - How many meritorious “at risk” investigators receive support

- As the ACD and other stakeholders voiced concern about the EEI definition, NIH will continue to pause the use of the “Early Established Investigator” flag in its application and review systems until WG activities are complete and the ACD has had the opportunity to review and make its recommendations to the NIH Director

- NIH instead will look at both ESI and ‘at risk’ investigator targets in FY2018

- An ‘At Risk’ Investigator is defined as an investigator who has not received funding on any major award/source of independent NIH funding in fiscal year 2018 or whose NIH funding will end in fiscal year 2018 (includes New Investigators)

WORKING GROUP ACTIVITY UPDATES

Meetings convened

- Two teleconferences and one very productive in-person meeting in April
  - We discussed in-depth the themes that have emerged through our previous meetings
- Discussion and sharing of ideas and materials continued over our listserv, in addition to these meetings

Literature and data reviewed

- The working group ‘library’ and information we reviewed included:
- Copious amounts of data generated by the NIH Office of Extramural Research – Statistical Reporting Branch
  - This data was provided to the National Academies as well, and used heavily in their report
- Presentations of data from >5 NIH ICs and Common Fund (on their early career programs) and the ACD Diversity Working Group
- Research literature…

Literature and data reviewed

- AAMC RAND Research Metrics RAND_RR1606
- Callaway_Young Scientists Novel Age Nature 2015
- Danielle Li Sampat Azoulay Science NIH patents 2017 final version
- Eblan Fabsitz Wagner Social Network CV Research Evaluation 2012
- Fortin Currie Big Science PLOS ONE
- Hutchins et al. 2016
- Ioannidis JAMA PQRST 2014
- Katz. On the biomedical elite- inequality and stasis in scientific knowledge production
- Lofgren Jacob R01 funding 2011
- Research Evaluation Marginal Returns 2016 concentration of funding
- Santangelo_Mol. Biol. Cell-2017--1401-8
- Sinatra Baribasi Impact Age Science 2016
- Sinatra Prediction Science 2017
- Way-Larremore-PNAS-2017
- Williams_CureNetworks Cell 2015 Cures Galaxy Networks Cell Pico

- Alberts et al. 2014
- Ginther Kahn Nature Biotechnology Postdocs 2017
- Kimble et al. 2015
- New Innovator Award Outcomes Evaluation 2007-2009_508
- Wahls 2018 elife-34965-v1
- Valantine Lund Gammie systems apporach diversity CBE 2016
- Blau & Weinberg 2017
- Charette et al. 2016
- Katz. On the biomedical elite- inequality and stasis in scientific knowledge production
- Levitt & Levitt 2017
- Pool-Schaffer-Size and characteristics of the biomedical research-FASEBJ
- Research Evaluation Marginal Returns 2016 concentration of funding
- Sinatra Baribasi Impact Age Science 2016

- … and more
- Also referenced NIH Data Book, National Postdoctoral Statistics (RePORT.NIH.gov)

Listening to those who have sent us ideas and comments

- While we cannot list all names/organizations here…

ascb
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

OFFICERS
JODI NUNNARI
President
PIETRO DE CAMI
Past President
ANDREW MURRA
President-Elect
KERRY BLOOM
Secretary
GARY J. GORBSK
Treasurer
ERIKA C. SHUGA
Chief Executive Offi
COUNCIL
ANGELIKA AMON
MIKE EHLERS
BOB GOLDSTEIN
JOHN K. HAYNES
REBECCA HEALD
ERIKA L.F. HOLZB
JANET IWASA
GEORGE LANGFO
WALLACE F. MAR
ANNE SPANG
JULIE THERIOT
ORA A. WEISZ
COMMITTEE CH
ALYSSA LESKO
Co-Chair
COURTNEY SCHR
Co-Chair
Committee for Postd
ERIN DOLAN
Co-Chair

MBoC | PERSPECTIVE

The argument for diversifying the NIH grant portfolio

Mark Poifer*
Department of Biology, Curriculum in Genetics and Molecular Biology, and Lineberger Comprehensive Cancer Cente
University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

ABSTRACT The United States has been a leader in biomedical science for decades, in large

ASBMB
American Society for Biochemistry and Molecular Biology

American Society for
Biochemistry and Molecular Biology
11200 Rockville Pike, Suite 302
Rockville, Maryland
20852-3110

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

The National Academies of SCIENCES ENGINEERING MEDICINE

About | Ordering Information | New Releases | Browse by Division | Browse by Topic

The Next Generation of Biomedical and Behavioral Sciences Researchers
Breaking Through

Major Themes Discussed

- There is an urgent need to protect junior investigators for the future of the research workforce
- There is an equally urgent need to stabilize the career trajectories of successful and productive mid-career investigators
- Diversity must be enhanced and actively pursued
- Introduction of the “investigator at risk” category
  - Motivated by analyses showing that previous ESI/EEI definitions did not produce the desired effects
  - Emphasizes the stabilization of the workforce
  - Does not undermine merit within the window under consideration
  - Preempts the need to narrowly target the source of funds

Major Themes Discussed (cont.)

- We must understand and mitigate unintended consequences of any policy changes
  - Proposed policies must be rigorously vetted and evidence-based
  - There must be robust mechanisms for ongoing monitoring and re-evaluation of policies
  - Recommendations must recognize the autonomy of Institutes and Centers
- Focus on the investigator in addition to the project
- Productivity metrics, where appropriate, must holistically consider an individual's contributions to science

DRAFT RECOMMENDATIONS TO THE NIH ACD

Major themes so far

1. Modify the Original NGRI Definitions and Policy
2. Develop Methods to Identify and Support “At-Risk” Investigators and Early Stage Investigators
3. Enhance ESI Diversity in a Meaningful and Sustainable Way
4. Optimize Workforce Stability by More Clearly Defining the Target Distribution of Investigators Across Career Stages
5. Assess Productivity Through a Multifaceted Approach

1. Modify the Original NGRI Definitions and Policy

- Expand the definition of ESI status to increase flexibility and support for individuals at the beginning stages of their career who have had no previous funding from a major independent award
  - 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
    - Could benefit early career scientists who may have had to take longer in postdoctoral training for any reason
      - NCI models show that, for their IC, 15 years may be a more appropriate window

  OR

  - ESI status 'clock' begins at the date of first independent position, and setting the end of the period at approximately 6-7 years
    - Would use Institutional self-reported data to set ESI clock
      - May be difficult to operationalize in a fair and standardized way due to variation in Institutional appointment approaches

Modify the Original NGRI Definitions and Policy (cont.)

- Hinging the Early Established Investigator (EEI) definition to prior ESI status is too restrictive
  - Shift the focus to supporting highly meritorious, “at risk”, investigators
- Revise the approach to multi-PI applications
  - ESIs should not lose their ESI status when included on a multi-PI application
    - Need to further consider how to prevent *nominal* inclusion of ESIs alongside established investigators
    - Need to further consider how to include ESIs in *meaningful* collaborations
- Continue to stratify peer review to ensure that applicants in similar career stages are evaluated together, in the same way
  - Consider the effects of ESI and at-risk investigators clustered for discussion at the beginning of study section meeting, when the panel is most engaged

2. Develop Methods to Identify and Support ESIs and “At-Risk” Investigators

- Explore how to support ESIs and “at risk” investigators in funding mechanisms beyond the R01
  - Since Center and Program Project grants are a significant mainstay of some IC portfolios, explore opportunities to involve more junior investigators in a meaningful way, that better positions them towards a stable career trajectory
    - NIGMS IDeA program Centers of Biomedical Research Excellence (COBREs) are an example of center-based grants focusing on mentoring ESIs to funding independence
  - What can we learn from the:
    - NIH Director's Early Independence Awards (DP5)
    - NIH Director’s New Innovator Award (DP2) Program
    - NIGMs Maximizing Investigators’ Research Award (MIRA))
    - High-Priority, Short-Term Project (bridge) Award (R56)
    - NCI “5+2” ESI-MERIT (R37)
    - NHLBI program incentives for including one subproject lead as an ESI

3. Enhance Diversity in a Meaningful and Sustainable Way

- Supporting ESI and ‘at risk’ investigators with meritorious research proposals should enhance and sustain the diversity and inclusivity of the workforce
- POs should actively reach out to all investigators, including ESI and at-risk investigators
- Support for broad training on unconscious bias
  - Incorporation of unconscious bias training in peer reviewer orientation
  - Unconscious bias training for all program officers
  - Unconscious bias training for trainees, potentially as part of Responsible Conduct of Research training
  - Training needs to be of sufficient quality and periodicity to be effective

Enhance ESI Diversity in a Meaningful and Sustainable Way (cont.)

- Enhancing diversity & inclusivity at the faculty level must be a priority for sustaining a robust workforce

- Training, fellowship, and career awards are an effective space for integrating the importance of enhancing diversity as part of application review process
  - Training environment and/or mentorship plans can be considered as part of these applications
    - NIGMS new T32 FOA (PAR-17-341) - *"Are diversity and inclusion promoted at all levels of the research training environment (trainees, staff, faculty, and leadership)?"*

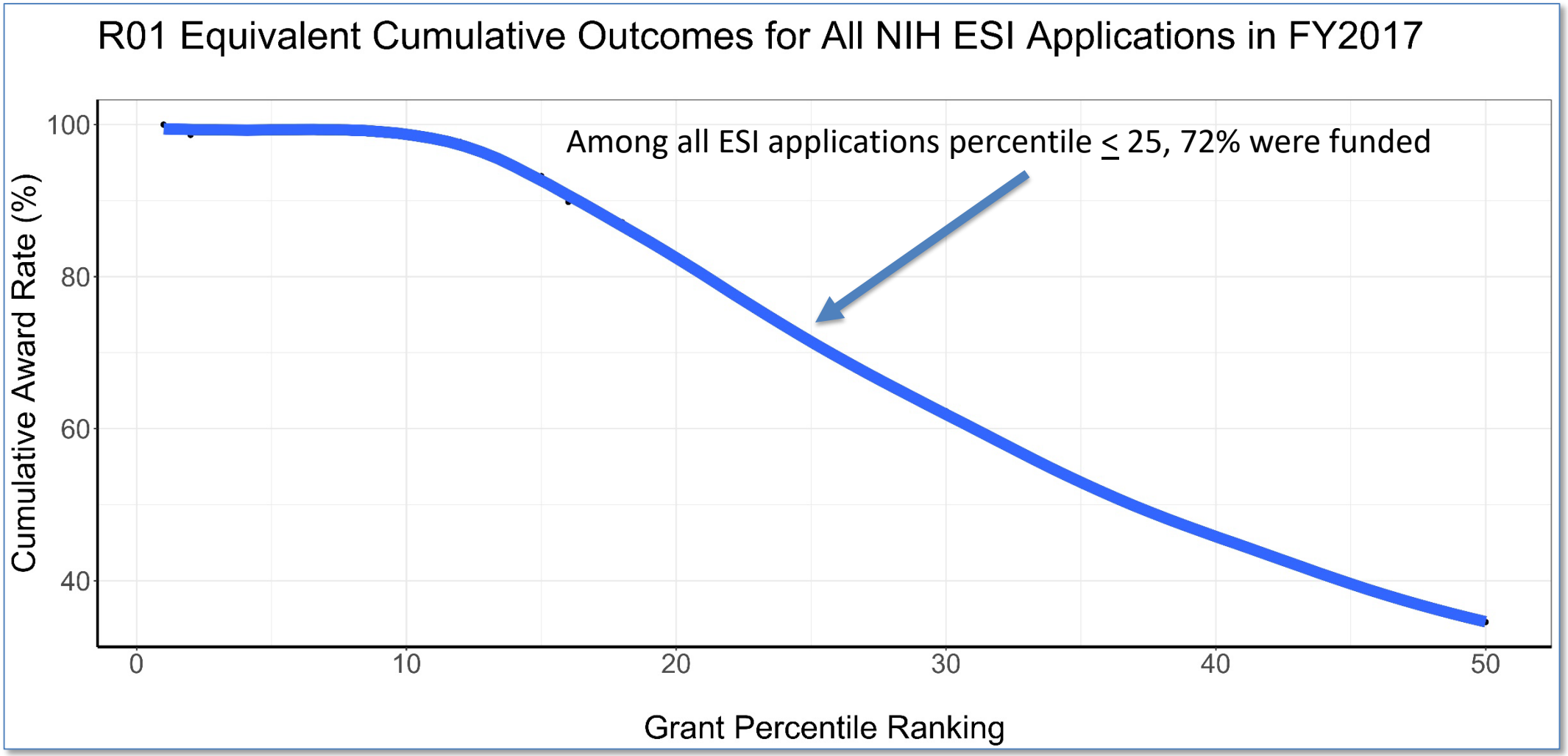
4. Optimize Workforce Stability by More Clearly Defining the Target Distribution of Investigators Across Career Stages

- The WG agreed this is an important question, but one that we do not yet have a solution for
  - Need to model the "carrying capacity" of the NIH system
    - This also could inform expectations of early career scientists
- Any recommendations to address the matter:
  - Should neither drastically reduce the number of investigators coming into the NIH-supported awardee pool nor add a large number of researchers whose careers cannot be sustained
  - Must allow for evaluation and course correction
  - Must yield a stable workforce

Optimize Workforce Stability by More Clearly Defining the Target Distribution of Investigators Across Career Stages (cont.)

- Regardless of approach, Other measures to examine the question of workforce stability could include:
  - similar trajectories (of funding) for ESIs, ‘at risk’, and established investigator

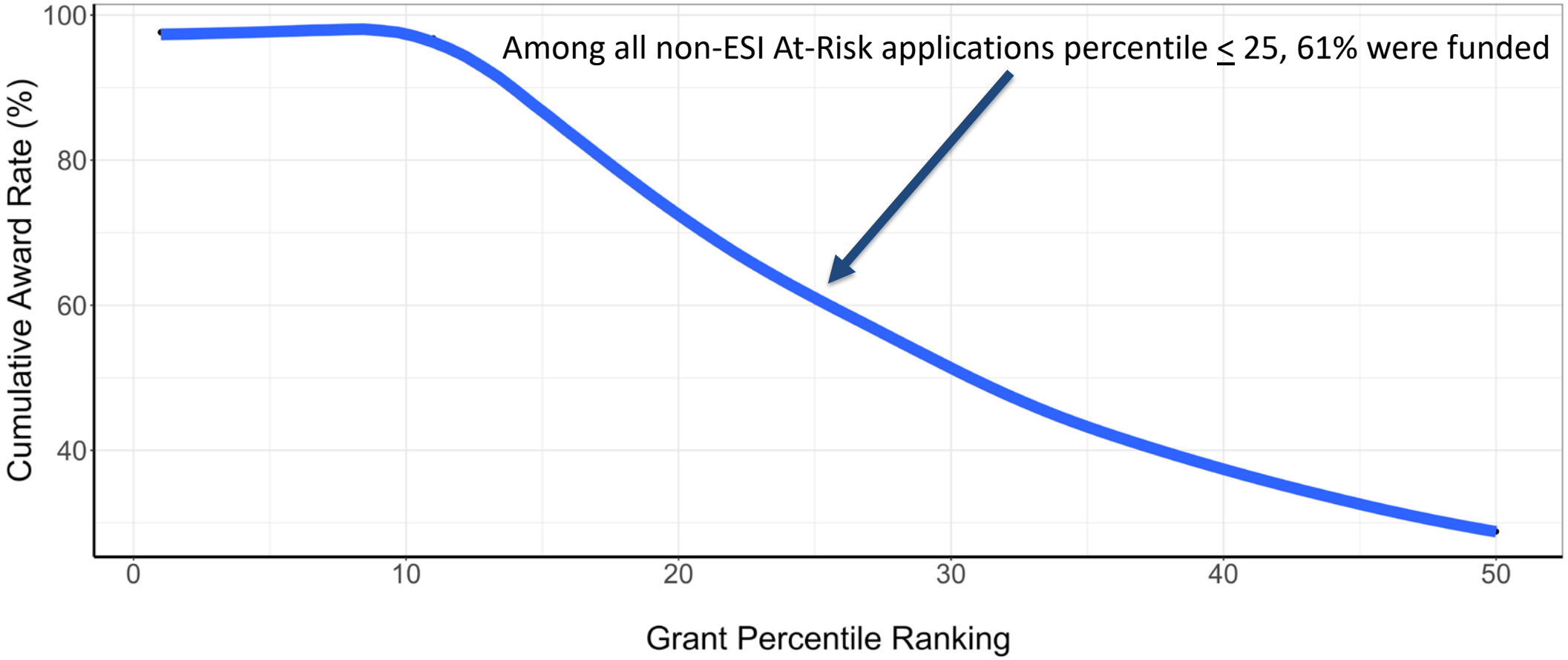
Another Way to Look at Funding of ESI Applications



- Recommendation: look at the same calculation for ‘at risk’ investigators as well

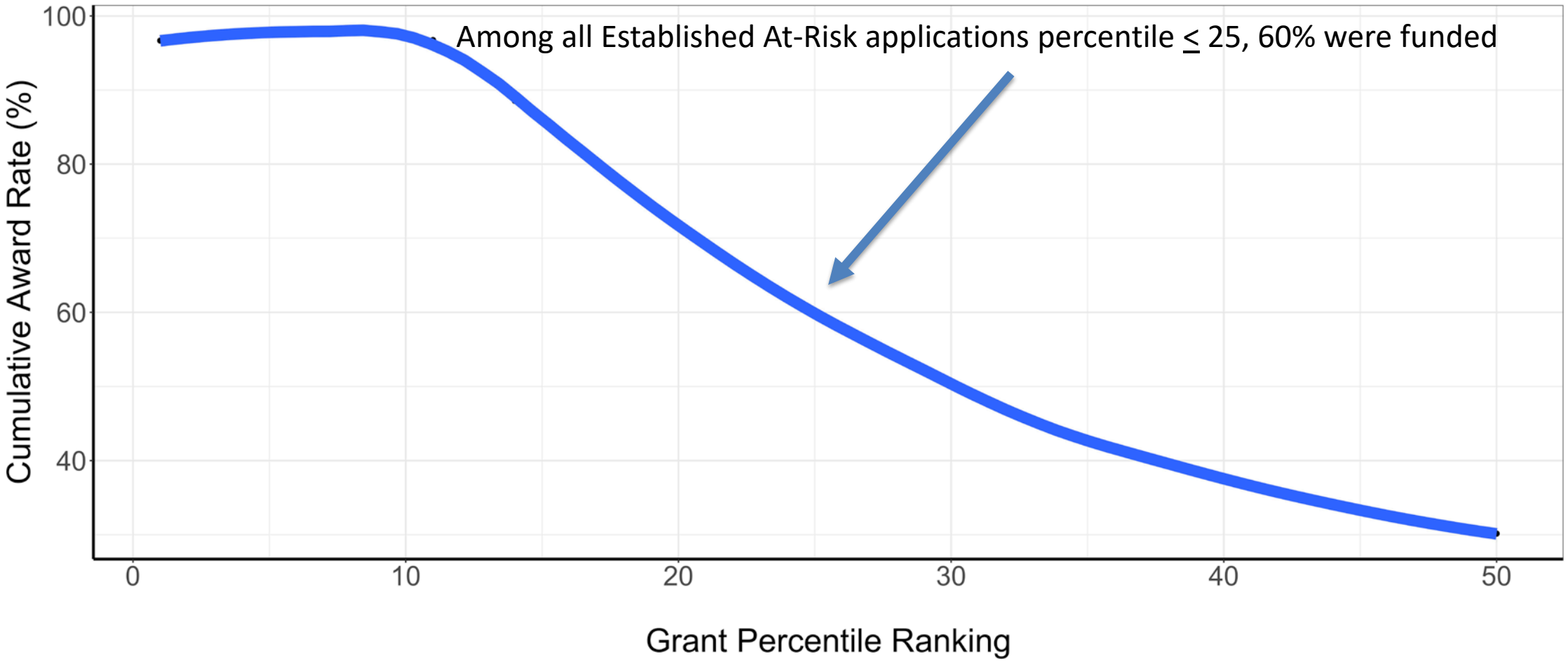
Non-ESI 'at risk' applications: (Includes Non-ESI New Investigators)

Type 1 R01 Equivalent Cumulative Outcomes for All NIH Non-ESI At Risk Applications



‘At risk’ applications from Established Investigators

Type 1 R01 Equivalent Cumulative Outcomes for All NIH Established At Risk Applications



Optimize Workforce Stability by More Clearly Defining the Target Distribution of Investigators Across Career Stages (cont.)

- Regardless of approach, Other measures to examine the question of workforce stability could include:
  - similar trajectories (of funding) for ESIs, ‘at risk’, and established investigator
- All efforts should be monitored to ensure that extending the ESI eligibility window does not lead to unintended consequences, such as increases in the average age at which people are funded on a first R01
  - Requires a central mechanism for tracking ESIs and ‘at risk’ investigators across NIH’s ICs

5. Assess Productivity Through a Multifaceted Approach

- Need for a continuous and thoughtful assessment of productivity
- Additional question under general discussion: what are holistic, multifaceted approaches to assessing an individual's contributions to science, that can be used when making decisions among the many equally highly meritorious applications identified through the peer review process?
- Potential for changing bio sketch instruction:
  - Asking applicants to address <u>recent</u> contributions to science in existing biosketch format

NEXT STEPS

Next steps

- Further meetings to develop draft recommendations with a target final report at the December 2018 ACD meeting
- Consideration of input from additional stakeholders
- Consideration of NASEM NGRI report recommendations under NIH's purview

NASEM NGRI Report

Several recommendations under NIH purview along the same lines as WG thinking

- ☑ ESIs on MPI grants should not lose ESI status
- ☑ Optimizing peer review for early stage and 'at risk' researchers
- ☑ Emphasizing recent contributions to science in biosketch
- ☑ ESI and 'at risk' investigator R01s should be at least 5 years
- ☑ Develop a central mechanism for evaluating impacts on ESIs and 'at risk' investigators across NIH's ICs

- ACD NGRI WG will discuss/consider other NASEM recommendations under NIH's purview
- They include:
  - Limiting postdoctoral training to 5 years
  - Limiting postdoctoral support on R01s to only 3 years
  - Increasing use of F and K awards

NASEM NGRI Report

Several recommendations under NIH purview along the same lines as WG thinking

- ☑ ESIs on MPI grants should not lose ESI status
- ☑ Optimizing peer review for early stage and 'at risk' researchers
- ☑ Emphasizing recent contributions to science in biosketch
- ☑ ESI and 'at risk' investigator R01s should be at least 5 years
- ☑ Develop a central mechanism for evaluating impacts on ESIs and 'at risk' investigators across NIH's ICs

NASEM report also includes many interesting recommendations beyond NIH purview

- Council-based model to examine the workforce
- Change in SBIR program for entrepreneurship development among next-generation scientists
- Change in NRSA eligibility to allow both foreign and domestic postdocs

Future discussion to also include

- Maintaining policy of ESI success rate parity with established investigators? Or encouraging ESI or ‘at risk’ success rates greater than those of established investigators?

- Building upon ACD Diversity Working Group analyses
  - NGRI WG interest in scientific topic-based analyses emerging from this group

- Concerns about trainee requirements to do research they cannot publish

Next steps

- Further meetings to develop draft recommendations with a target final report at the December 2018 ACD meeting
- Consideration of NASEM NGRI report recommendations under NIH's purview
- The NGRI WG has set a goal of developing recommendations for ACD review that will be sustainable, not just across ICs, types of institutions, and fields of research, but across time

The Next Generation Researchers Initiative Working Group

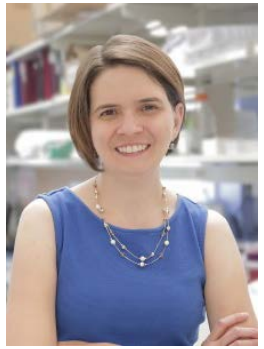
Christine Curran, PhD
Associate Professor
Northern Kentucky University

Amicia Elliott, PhD
Postdoctoral PRAT Fellow
NIMH/NIBIB, NIH

Jose C. Florez, MD, PhD,
Chief, Diabetes Unit
MGH
Professor, HMS

Gary Gibbons, MD
Director
NHBLI, NIH

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



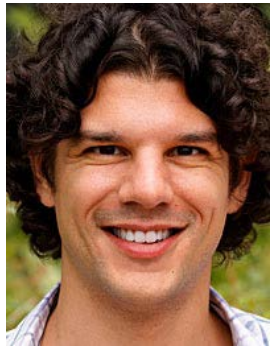
Pamela Kreeger, PhD
Associate Professor
Vilas Associate
University of Wisconsin

Michael Lauer, MD
Deputy Director
for Extramural Research, NIH

Michael Levitt, PhD
Professor
Stanford University

Jon Lorsch, PhD
Director
NIGMS, NIH

Stephani Page, PhD
Postdoctoral Research Associate, AHA Fellow, Duke University School of Medicine



Timothy Reddy, PhD
Assistant Professor
Duke University

Juan Pablo Ruiz
NIH Oxford Scholar
NHLBI, NIH

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

Christina Stallings, PhD
Assistant Professor
Washington University

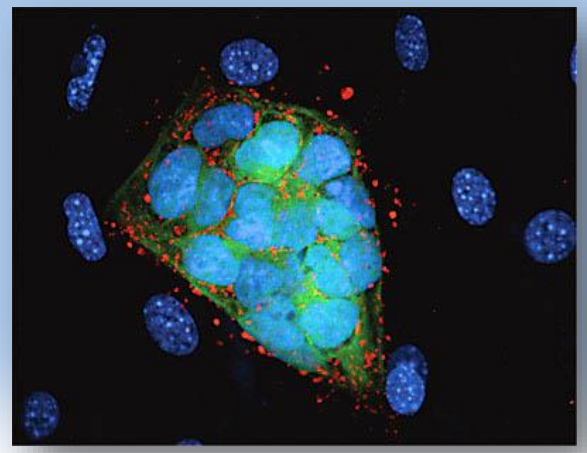
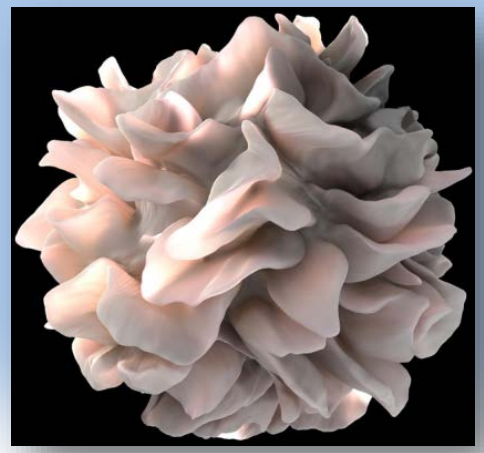
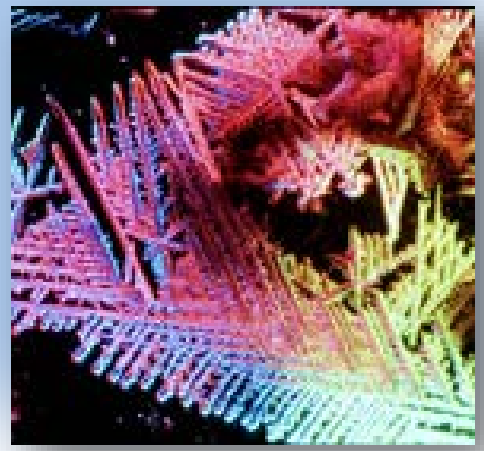
Lawrence Tabak, DDS, PhD
Principal Deputy Director, NIH

Bruce Weinberg, PhD
Professor
The Ohio State University




NIH…

Turning Discovery Into Health

APPENDIX SLIDES

Program-based awards like the ESI Maximizing Investigators' Research Award (ESI-MIRA R35)

- One NIGMS research grant per PI – R35
- Bigger and longer (5 years) than current R01 averages
- Can request up to $250,000 direct costs per year
- Not tied to specific aims
- Review based on track record and overall research ideas
  - Includes consideration of service & contributions to workforce development
- At renewal, budgets can be modulated based on review rather than using all-or-none funding decisions
- Separate panels and modified review considerations for early-stage investigators
- Maximizing Investigators' Research Award for Early Stage Investigators, PAR-17-190

High-Priority, Short-Term Project (Bridge) Award (R56)

- The High Priority, Short-Term Project Award, R56 grant will fund, for one or two years, high-priority new or competing renewal R01 applications with priority scores or percentiles that fall just outside the funding limits of participating NIH Institutes and Centers (IC).

- Investigators may not apply for R56 grants.

- https://grants.nih.gov/grants/funding/r56.htm

NCI Early Stage Investigator MERIT

- NCI has proposed a “5+2” MERIT (R37) award with up to 7 years of support in two segments
- ESIs get 5-year awards with the possibility of an additional 2 years of funding if they demonstrate good progress

NCI Method to Extend Research in Time (MERIT) Award for Early Stage Investigators (R37)

Notice Number: NOT-CA-18-037

Key Dates

Release Date: January 23, 2018

Related Announcements

None

Issued by

National Cancer Institute (NCI)

Purpose

Through this Notice, the NCI announces its use of the Method to Extend Research in Time (MERIT)(R37) Award to provide longer term grant support to Early Stage Investigators (ESIs). By providing such an opportunity for longer term support to ESIs, the NCI intends to give them flexibility and opportunity for creativity and innovation and additional time to successfully launch their careers and to become more established before having to submit renewal applications

NHLBI program incentives for including one subproject lead that is an Early Stage Investigator (ESI)

NHLBI Program Project Applications (P01 - Clinical Trial Optional)

P01 Research Program Projects

- Higher budget limit for P01s that include an ESI-led project
- Overall project budget must include a minimum of $250,000 per year in direct costs for the ESI-led project
- The ESI-Led Project must include a statement from the Overall PD(s)/PI(s) describing how participation provides a good leadership skills development environment and how the ESI Project Leader's scientific and professional career development will be enhanced through participation in the Program.
- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, outstanding investigator, provide assurance that the research facilities, resources, and training opportunities, including faculty capable of productive collaboration with the candidate, will be available for the candidate's planned career development and research programs, and include a statement that the candidate is eligible to apply as the PD/PI for an independent research grant.