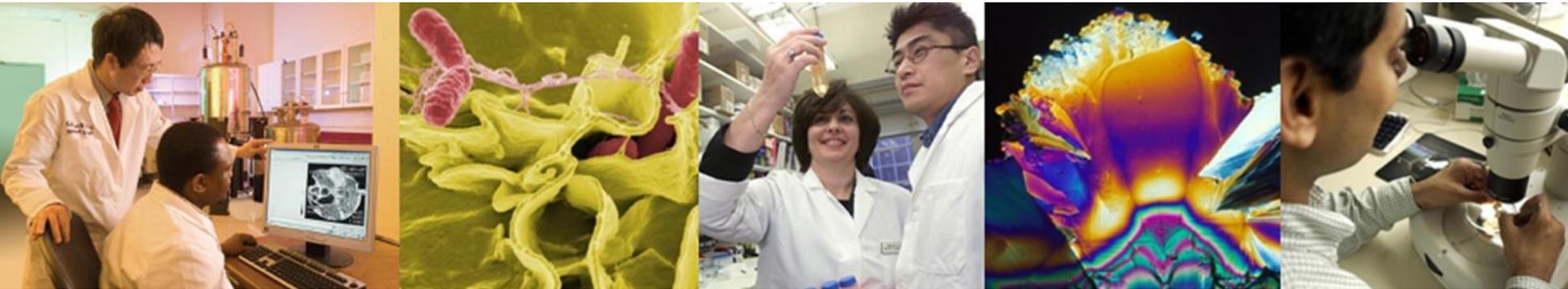


# Next Generation Researchers Initiative: Report from ACD Working Group

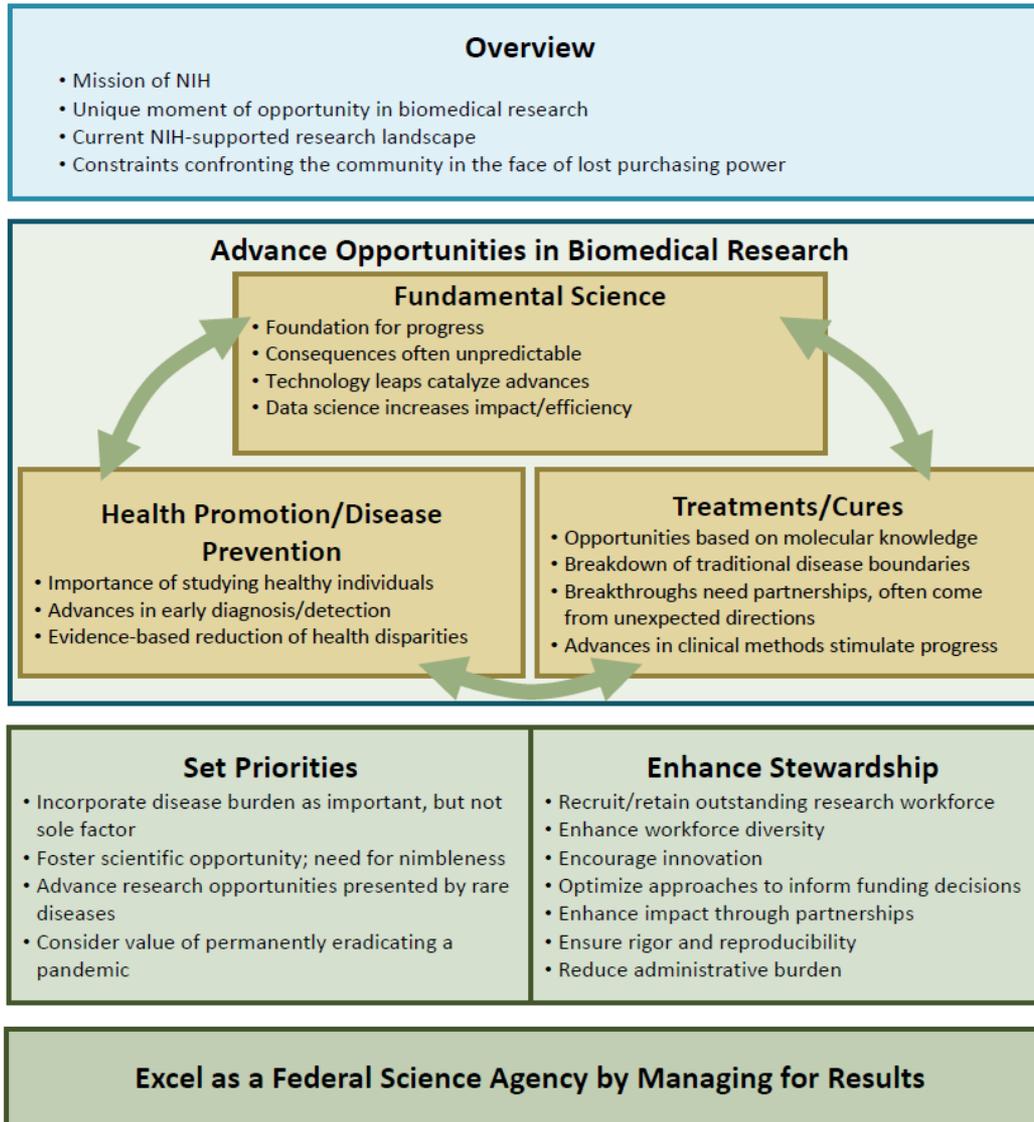
115<sup>th</sup> Meeting of the Advisory Committee to the Director  
December 15<sup>th</sup>, 2017



Lawrence A. Tabak, DDS, PhD  
Principal Deputy Director, NIH  
on behalf of NGRI ACD WG



# NIH-Wide Strategic Plan Framework



# NIH-Wide Strategic Plan: Objective 3 – Enhance Stewardship

## Underlying Principles

### Objective 2

#### Set Priorities

- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity; need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic

### Objective 3

#### Enhance Stewardship

- **Recruit/retain outstanding research workforce**
- **Enhance workforce diversity**
- **Encourage innovation**
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden
- Employ risk management strategies

### Objective 4

Excel as a Federal Science Agency by Managing for Results

# Policy Supporting the Next Generation Researchers Initiative

Notice Number: NOT-OD-17-101

## Key Dates

**Release Date:** August 31, 2017

**Implementation Date:** August 31, 2017

## Next Generation Researchers Policy

Consistent with the directives of the 21st Century Cures Act, the Next Generation Researchers policy requires institutes and centers (ICs) to prioritize awards that will fund Early Stage Investigators (ESIs) and Early Established Investigators (EIs).

**Early Stage Investigator (ESI):** An ESI is a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found at <https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm>. ESIs are encouraged to enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons profile to ensure their correct identification.

Under the Next Generation Researchers policy, meritorious R01-equivalent applications with ESI PD/PIs will be prioritized for funding. ICs will put this prioritization into effect starting in fiscal year (FY) 2017. The goal for FY 2017 will be to fund approximately 200 more ESI awards than in FY 2016.

By providing funding priority for ESIs, NIH intends to encourage funding applications that involve researchers earlier in their career. An NIH R01-equivalent research grant application with more than one PD/PI (MPI) will be prioritized for funding only if all MPIs have ESI status.

**Early Established Investigator (EEI):** An EEI is a PD/PI who is within 10 years of receiving their first substantial, independent competing NIH R01-equivalent research award as an ESI. A meritorious application with a designated PD/PI EEI may be 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.

# ACD Next Generation Researchers Initiative Working Group (NGRI WG)

- The NIH Director established a working group of the ACD, the NGRI WG, to refine and implement the initiative
- The NGRI WG membership is diverse and includes investigators at all levels – from graduate student to professor - working in different types of institutions, and engaged in a broad range of disciplines

## Policy Supporting the Next Generation Researchers Initiative

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**Notice Number:** NOT-OD-17-101

**Key Dates**

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**Related Announcements**

[NOT-OD-08-121](#) - Rescinded

[NOT-OD-09-013](#) - Rescinded

[NOT-OD-09-134](#) - Rescinded

**Issued by**

National Institutes of Health ([NIH](#))

**Purpose**

This notice announces a new policy designed to invest in the next generation of researchers; this policy implements, in part, Section 2021 of the 21st Century Cures Act<sup>1</sup>. This policy supersedes previous notices on new and early stage investigators (NOT-OD-08-121, NOT-OD-09-013 and NOT-OD-09-134).

<https://acd.od.nih.gov/working-groups/nextgen.html>

# NGRI WG



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Northern Kentucky University



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Postdoctoral PRAT Fellow  
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**Jose Florez, MD, PhD,**  
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**Michael Levitt, PhD**  
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# NGRI WG



**Jon Lorsch, PhD**  
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**Timothy Reddy, PhD**  
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Principal Deputy Director,  
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**Bruce Weinberg, PhD**  
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The Ohio State University

## Charge to NGRI WG

- Advise NIH leadership on the development of a trans-NIH NGRI 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 ESIs and EEIs
- Propose recommendations for tracking and assessing funding decisions for ESIs and EEIs with fundable scores to ensure the NGRI is effectively implemented in all areas of research
- Assure 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
- Review analyses to assess the impact of the NGRI policy on the overall NIH scientific portfolio and workforce trends

# Summary of Teleconferences (July 11, 2017-October 11, 2017)

- Review Charge to the NGRI WG
- Review data highlighting that the aging of the scientific workforce is particularly concentrated among older aged individuals (and was more rapid than the workforce as a whole; *Weinberg, PNAS, 2017*)
- Review data highlighting that the number of younger R01 grantees has dropped since 1990 (*Levitt and Levitt, PNAS, 2017*)
  - Number of ESIs remains modest since ESI policy implemented in 2008
  - Difficult for junior investigators to obtain their first competing renewal (so even if successful in obtaining initial funding, they get lost in pipeline)

# Summary of Teleconferences (July 11, 2017-October 11, 2017)

- Review independent assessments to identify evidence-based metrics for research productivity, and determine the impact of NIH grant support on scientific progress
- Current policy is only guide, and will depend on ICs for implementation
  - There are no additional funds to implement NGRI – concern about uncoupling policy goals from means to achieve the goal
- Value of monitoring the number of investigators (rather than the number of grants per se) that NIH funds
- The committee recognizes then need to shift from re-litigating the specific approach outlined in the Grant Support Index (GSI) concept, to providing recommendations about how best to prioritize funds to ensure support for investigators at risk for losing all funding support

# General Policy Goals

- 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
- We must understand and mitigate unintended consequences
- Proposed policies must be rigorously vetted and evidence-based
- There must be robust mechanisms for ongoing monitoring and re-evaluation of policies

# Additional Themes from Telephone Conferences

- Dissatisfaction with the ESI and EEI definitions (more of a focus needs to be placed on the population at risk rather than arbitrary 10 yr “cutoffs”)
  - Prioritize those investigators highest ‘at-risk’ group – ESIs and mid-career PIs dependent on a single R01?
  - More predictive models based on diversity, age, etc. that more robustly capture who is at risk?
- Mid-stage investigators may be most at risk of the diversion of funds to ESIs/EEIs

# Next Generation Researchers Initiative

## Working Group Meeting

Thursday, November 9, 2017

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- |          |   |
|----------|---|
| 10:00 am | <b>Framing the Day</b> <ul style="list-style-type: none"><li>➤ <b>Jose Florez, MD, PhD</b> Associate Professor, Harvard Medical School; WG Co-Chair</li></ul>   |
| 10:30 am | <b>Synopsis of Past Efforts Related to Next Generation Researchers Initiative</b> <ul style="list-style-type: none"><li>➤ <b>Jon Lorsch, PhD</b> Director, National Institute for General Medical Sciences, NIH</li></ul>   |
| 11:15 am | <b>Recommendations from the Advisory Committee to the Director Working Group on Diversity to Inform the Implementation of the Next Generation Researchers Initiative</b> <ul style="list-style-type: none"><li>➤ <b>Hannah Valentine, MD</b> Chief Officer for Scientific Workforce Diversity, NIH</li><li>➤ <b>Elba Serrano, PhD</b> Professor, New Mexico State University</li></ul>  |
| 12:00 pm | <b>Discussion</b>   |
| 12:45 pm | <b>Lunch/Break</b>  |
| 1:15 pm  | <b>Cap NIH Funding for Individual Investigators to Save the Future of Biomedical Science</b> <ul style="list-style-type: none"><li>➤ <b>Mark Peifer, PhD</b> Distinguished Professor of Biology, University of North Carolina at Chapel Hill</li></ul>  |
| 2:00 pm  | <b>Evidence-based Metrics for Research Productivity</b> <ul style="list-style-type: none"><li>➤ <b>Michael S. Lauer, MD</b> Deputy Director for Extramural Research, NIH</li></ul>  |
| 2:45 pm  | <b>Break</b>  |
| 3:00 pm  | <b>Report from the Next Generation of Scientists</b> <ul style="list-style-type: none"><li>➤ <b>Amy Elliott, PhD</b>, Postdoctoral PRAT Fellow, NIH</li><li>➤ <b>Stephanie Page, PhD</b>, Postdoctoral Fellow, University of North Carolina, Chapel Hill</li><li>➤ <b>Timothy Reddy, PhD</b>, Assistant Professor, Duke University</li><li>➤ <b>Juan Pablo Ruiz, PhD</b>, PhD student/NIH Oxford Scholar, NIH</li></ul>   |
| 3:45 pm  | <b>Analysis of IC-Specific and Trans-NIH Approaches to Enhance Funding for ESI/EEIs</b> <ul style="list-style-type: none"><li>➤ <b>Gary Gibbons, MD</b> Director, National Heart, Lung, and Blood Institute, NIH</li><li>➤ <b>Jon Lorsch, PhD</b> Director, National Institute for General Medical Sciences, NIH</li><li>➤ <b>James Anderson, MD, PhD</b>, Director, Division of Program Coordination, Planning, and Strategic Initiatives, NIH</li><li>➤ <b>Shelli Avenevoli, PhD</b>, Deputy Director, National Institute of Mental Health, NIH</li></ul> |
| 4:30 pm  | <b>Break</b>  |
| 4:45 pm  | <b>Next Steps and Review of Timelines for Draft Recommendations</b> <ul style="list-style-type: none"><li>➤ <b>Lawrence A. Tabak, DDS, PhD</b>, Principal Deputy Director, NIH; WG Co-Chair</li><li>➤ <b>Jose Florez, MD, PhD</b> Associate Professor, Harvard Medical School; WG Co-Chair</li></ul>  |
| 5:00 pm  | <b>Discussion and Wrap Up</b>   |
| 5:30 pm  | <b>Adjourn</b>  |

# NGRI WG Meeting

- Report to Working Group from NIH Leadership
  - There was recognition that rollout of policy has been less than optimal
  - 25% funding percentile “target” was thought of as an *average* target across ICs (but this varies widely across ICs)
    - The reasons for this variation are complex
  - NIH is very aware of the work of the NGRI WG and some of the WG’s suggestions are already being considered across the ICs –
    - Rather than anchor those eligible for special consideration at an arbitrary point in time, consider more flexible approaches to ensure support for highly meritorious investigators that are most at risk
    - Require ESI funding in certain areas of science (e.g., Alzheimer’s Disease) to ensure that these resources are not only awarded to established investigators
- FY18 should be a stronger year for implementation of the NGRI policy as we have begun consideration from the start of the FY

# NGRI WG Meeting

- ESI/EEI definitions/Eligibility criteria
  - The time from terminal degree (as part of ESI definition) is felt to be too restrictive
  - Targeted strata of investigators need to be investigated for feasibility (and unintended consequences) when implementing NGRI policies
  - EEI definition tied to former ESI status was viewed as too restrictive
  - Caution is needed in defining ESIs and EEIs exclusively a model in which research groups are run by a sole PI, and/or on R01-type grants
    - Does the focus on single-investigator R01 grants reinforces certain kinds of institutional and personal behavior that many feel are unhealthy, i.e. institutions that expect 2 simultaneous R01s as the gold standard for tenure/promotion, and for PIs to be the sole PI

# NGRI WG Meeting

- ESI/EEI definitions/Eligibility criteria (cont.)
  - Defining resources available to an investigator or record of achieving independent funding may be a more accurate way to define investigators early in their career path (age should not matter)
- Jon Lorsch reviewed modeling data (from 2014-2016) to assess the effect of NIH attempting to reach ESI and EEI targets simply by moving pay lines to meet the target
  - Net result is a wash – in order to meet targets, approximately as many meritorious investigators would lose all NIH funding as ESIs and EEIs gained/retained
  - Problem improved somewhat by not prioritizing funding of 2<sup>nd</sup> grants for EEIs, but many non-ESI/non-EEI PIs still lose all NIH funding
- The committee noted that by not targeting the source of funds, NIH may harm the very groups of investigators they are trying to help

# NGRI WG Meeting

- Report from NextGen Committee Members:
  - More clarity is needed about how the current NGRI policy is being implemented
  - There is very low morale and lack of trust in NIH among NextGen investigators
  - More attention needs to be placed on meaningful collaborations between senior and junior investigators (not as “laborers”, but as trainees/colleagues) in future NGRI policy and mechanisms
  - NGRI needs to be closely tied to diversity - there must be paths of possibility and leadership for under-represented minorities, women, and investigators from regionally diverse areas and differing types of institutions

# NGRI WG Meeting

- Data Needs
  - NIH should support ongoing research using cutting-edge social science methods on next generation researchers to evaluate the impact of policy changes and ensure continuous improvement
    - What is the capacity of the system? i.e. how many investigators can be sustained long-term?
  - More transparency and balance in data presentation is needed
    - NIH does not only fund investigators at Academic Health Centers and we must ensure that investigators at other types of institutions are considered
    - More clarity is needed about gaps in the data and about important trends that could exert a large influence on data interpretation (e.g. more team science; how team science benefits investigators that are early in their careers)
  - What affect has the shift to smaller, perhaps longer, more stable mechanisms (e.g. MIRA/R35 awards) had?

# NGRI WG Meeting

- Data Needs (cont.)
  - Productivity assessments
    - Productivity should be considered at multiple levels – individual, institutional, and global – but need to consider limitations of various measures
    - Productivity measures should go beyond publications, and include other metrics such as number and quality of trainees, patents/licenses/commercial ventures, teaching commitments, service to the scientific community, leadership in team science, institutional citizenship
      - Is there a correlation between more experienced/well-funded investigators and less experienced/poorly funded investigators in terms of service to NIH?
      - Should we consider a mandatory level of NIH service proportional to the level of NIH support?

# NGRI WG Meeting

- Data Needs (cont.)
  - Productivity assessments (cont.)
    - We require a greater understanding about how different institutions with varying “business models” support their investigators
      - How does the diversity of institutional business models influence productivity?
      - How does the variation in cost of living among different geographic areas influence productivity?
      - Data on what percentage of NIH investigators that receive > 80% of their salaries from NIH, as a function of institution type and characteristics of investigator support (e.g, someone who runs a core facility and is supported by 5-10% on multiple grants versus a PI with multiple R01s); number of co-investigators in a given grant

# NGRI WG Meeting

- Data Needs (cont.)
  - Productivity assessments (cont.)
    - Consider adding a “Productivity section” to the NIH Biosketch
    - Caution was raised by some about using productivity metrics to make highly granular decisions
  - Some institutions are being much more savvy about how they judge “team science” in tenure - what affect does this have?
  - How has the shift in demographics of funding, with the influx of engineers, physicists, computer scientists, affected overall distribution of NIH funding?
  - We need to examine the study section variation in defining merit and scores across panels
  - To examine the impact of an unfunded mandate on vulnerable investigators, assess the individual *funding rate* of EEI applicants in comparison to the *success rate* of established investigators after the introduction of the ESI policy

# Analysis of IC-Specific and Trans-NIH Approaches to Enhance Funding for ESI/EEIs

- Examples of successful models:
  - Focus on programs of research and/or PI accomplishments, rather than projects per se (also allow direction change in midst of execution)
  - Prioritize projects that fill a critical knowledge gap in an ICs strategic plan
  - Require an advisory committee for oversight and mentoring
  - Employ selective pay for ESIs (if above payline)
  - Make greater use of “bridge awards” – R56 for those at risk
  - Allow for longer periods of support (e.g., 7 years)/stability
  - Separate reviews for established and early-stage investigators

# Summary of Progress to Date

- The NGRI WG has successfully achieved a milestone of ‘Inclusiveness’ in its deliberations in establishing one of its most diverse WG; and important progress has been made in sharpening a shared understanding of the problem and potential paths forward. This is critically important in re-establishing trust/confidence of NIH stakeholders
- The NGRI WG has achieved a greater appreciation and shared understanding of the current portfolio of practices/options as well as the potential for unintended negative consequences of policy change.
- Substantial progress has been made in refining the focus of the NGRI ‘problem’ on ESI/EEI ‘At-Risk’ groups as a key indicator/metric and intervention point

## Next Steps: Near and Long Term

- NGRI WG will follow this interim report and framework with more specific recommendations at the June 2018 ACD meeting
- Consider WG as an ongoing process to evaluate NGRI implementation over time
- Continued work on developing both short-term and long-term metrics (productivity and other) for evaluating impact of NIH funding
- The NGRI WG has set a goal of providing recommendations that will be sustainable, not just across ICs, types of institutions, and fields of research, but across time



# NIH...

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# Turning Discovery Into Health

