Extramural Research: Money, People, and Science

Michael S Lauer, MD
Deputy Director for Extramural Research
National Institutes of Health

NIH Fall 2020 Regional Seminar Keynote Address
Tuesday, October 27, 2020
Virtual Meeting

Disclosures: None
Opinion: Celebrating R and D expenditures badly misses the point

Daniel Shapiro\textsuperscript{a,1} and Kent Vrana\textsuperscript{b}

\textsuperscript{a}Department of Humanities, Pennsylvania State College of Medicine, Hershey, PA 17033; and
\textsuperscript{b}Department of Pharmacology, Pennsylvania State College of Medicine, Hershey, PA 17033

akin to an airline proclaiming, “we use more gasoline than any other airline!” or “we spend more per year transporting our passengers!” Consider the appearance and potential con-
What Should Our Story Be?

A New Finish Line

Money

People

Science

Proposal → Grant Award → Trial/study Completion → Publish → Citations

Current finish line

Optimal finish line

Shapiro D, Vrana K. PNAS 2015;112:9496-7
Initiates grant proposal:
- New project
- Continuing project

NIH Grant Proposal

Assess programs
Approve applications
Public members

National Advisory Councils

Scientists evaluate scientific merit of grant proposal

Program Officer

Institute Director

Makes final decision
Allocates funds
Justification to Congress

NIH National Institutes of Health
Office of Extramural Research
A New Finish Line

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Shapiro D, Vrana K. PNAS 2015;112:9496-7
Showing NIH budget trends in current and constant dollars.
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Shapiro D, Vrana K. PNAS 2015;112:9496-7
Office of Research Administration

Handling the business of research, so faculty can perform the research

Jefferson’s Office of Research Administration (ORA) assists researchers in applying for, and managing sponsored funding through our mission, which is:

https://www.jefferson.edu/university/research_administration.html
Scientists: Under Stress…

SUFFERING IN SCIENCE

We asked young scientists to tell us their concerns. This is what they said.

- Desperate pursuit of grants
- Long hours, but no time for science
- Extreme competition … to cut corners
- Dependence on senior scientists
- Administrative overload … No help

Nature 2016;538:446-9
What’s Behind All This?

POINT OF VIEW

Strategies from UW-Madison for rescuing biomedical research in the US

Abstract A cross-campus, cross-career stage and cross-disciplinary series of discussions at a large public university has produced a series of recommendations for addressing the problems confronting the biomedical research community in the US.

DOI: 10.7554/eLife.09300.001

“We identified two core problems:

• Too many researchers vying for too few dollars.
• Too many postdocs competing for too few positions.

Most other issues can be viewed as symptoms.”
Too Many Researchers?

Awardees, Applicants, and Cumulative Investigator Rate for all RPGs over Time

Fiscal Year

Number (1000s) or Percent


Awardees
Applicants
Cumulative Investigator Rate

NIH National Institutes of Health
Office of Extramural Research
Some Good News: Unique Awardees Over Time

Awardees for all RPGs over Time

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Number (1000s)</th>
</tr>
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<tbody>
<tr>
<td>2003</td>
<td>25.0</td>
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</tr>
<tr>
<td>2018</td>
<td>33.0</td>
</tr>
<tr>
<td>2019</td>
<td>33.5</td>
</tr>
</tbody>
</table>

NIH National Institutes of Health
Office of Extramural Research
Funding Rate = 100 * (Number Awardees / Number Applicants)

With recent budget increases curve has turned
“The Director of the National Institutes of Health shall … 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.”
THE NEXT GENERATION OF BIOMEDICAL AND BEHAVIORAL SCIENCES RESEARCHERS:
BREAKING THROUGH

Committee on the Next Generation Initiative
Board on Higher Education and Workforce
Policy and Global Affairs

A Consensus Study Report of
The National Academies of
SCIENCES • ENGINEERING • MEDICINE

NIH ADVISORY COMMITTEE TO THE DIRECTOR (ACD)
NEXT GENERATION RESEARCHERS INITIATIVE WORKING GROUP REPORT
December 2018

And Now: Science

A New Finish Line

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Optimal finish line

Shapiro D, Vrana K. PNAS 2015;112:9496-7
Another Approach to the Story: Pasteur’s Quadrant

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Relevance</th>
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</thead>
<tbody>
<tr>
<td>Pure Basic Research</td>
<td>Use-Inspired Basic Research</td>
</tr>
<tr>
<td>Bohr</td>
<td>Pasteur</td>
</tr>
<tr>
<td>Pure Applied Research</td>
<td>Edison</td>
</tr>
</tbody>
</table>

Adapted from Stokes 1997, Brookings Institution
### Thinking About COVID-19

<table>
<thead>
<tr>
<th>Pure Basic Research</th>
<th>Use-Inspired Basic Research</th>
</tr>
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<tbody>
<tr>
<td>Viral Biology</td>
<td>Pre-Clinical Drug and Vaccine Development</td>
</tr>
<tr>
<td></td>
<td>Pure Applied Research</td>
</tr>
<tr>
<td></td>
<td>Pivotal Clinical Trials, Implementation Science</td>
</tr>
</tbody>
</table>

COVID-19 Treatment and Prevention: “ACTIV” Program

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
An Unprecedented Partnership for Unprecedented Times

Figure. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership

**Partnership leadership group**

**Executive committee**

**Cochairs**
- Francis Collins, NIH
- Paul Stoffels, Johnson & Johnson

**Members**
- Mikael Dolsten, Pfizer
- Anthony Fauci, NIH
- Gary Gibbons, NIH
- William Pao, Roche
- Janet Woodcock, FDA

**Working groups**

**Preclinical**
- Increase access to animal models
- Identify informative assays

**Therapeutics clinical**
- Prioritize and test potential therapeutic agents
- Develop master protocol for clinical trials

**Clinical trial capacity**
- Develop survey instruments
- Develop inventory of clinical trial networks
- Guide deployment of innovative solutions

**Vaccines**
- Accelerate evaluation of vaccine candidates
- Identify biomarkers to speed approval
- Provide evidence to address safety concerns

Francis S. Collins, MD, PhD
Office of the Director, National Institutes of Health, Bethesda, Maryland.

Paul Stoffels, MD
Johnson & Johnson, New Brunswick, New Jersey.

Collins FS, Stoffels P. JAMA 2020;323:2455-7
COVID-19 Testing: The “RADx” Program

National Call for Innovative Technologies
Rolling submissions and selections begin April 29, 2020

Phase 0
“Shark tank”-like rapid-selection process

Phase 1
Validation and risk review

Phase 2
Clinical tests, regulatory approval, and scaling up

End of Summer or Fall 2020

Fast Track for Advanced Technologies: the RADx-ATP Program

Deploy Millions of Tests per Week

"Big Science"

All of Us

BRAIN Initiative

Cell Type

Circuit Diagrams
Diverse Scientific Portfolio

Diet and disease risk

Age-related bone loss

Diagnoses with CRISPR

Bionic pancreas type 1 diabetes

Concerns

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Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding

The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects on the biomedical enterprise in the areas affected by the HHS declared public health emergency for COVID-19. Due to the potential exceptional impact, we want to assure our recipient community that NIH will be doing our part to help you continue your research.

Letters

30% of women experienced harassment

Sexual Harassment and Discrimination Experiences of Academic Medical Faculty
Recent high-profile cases of sexual harassment illustrate that such experiences still occur in academic medicine.\(^1\) Less is known about how many women have directly experienced such behavior. Most studies have focused on trainees, single

Jagsi R et al. JAMA 2016;315:2120-1

http://cansort.med.umich.edu/our-team/reshma-jagsi-md-d-phil/
“The characteristics … most associated with higher rates … are (a) **male dominated gender ratios and leadership** and (b) an **organizational climate** …”

“Organizational climate is, by far, the greatest predictor …”: risks of complaining, lack of sanctions, sense that complaints not taken seriously.

Might extramural NIH practices be affecting these?

http://sites.nationalacademies.org/shstudy/index.htm
CHANGING THE CULTURE TO END SEXUAL HARASSMENT

December 2019

“NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.”
Avoid “Passing the Rogue”

Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award

Notice Number:
NOT-OD-20-124

Key Dates

Release Date: June 11, 2020

Related Announcements

NOT-OD-18-172 - Clarification of NIH’s Policy Regarding a Change in Program Director’s/Principal Investigator’s Status

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

The purpose of this notice is to clarify NIH expectations regarding change in status, including absence of Program Director / Principal Investigator (PD/PI) and other Key Personnel named in the Notice of Award (NoA) of NIH grants, as well as change in recipient institution. NIH expects that funded biomedical and behavioral research occurs within an environment that is safe, healthful, and conducive to high-quality work.
Anti-Sexual Harassment: for NIH Awardee Organizations and Those Who Work There

Learn about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards.

NIH's Commitment

NIH is committed to doing our part to support a safe and respectful work environment across the entire biomedical research enterprise. NIH does not tolerate harassment of any kind, including sexual harassment, at research institutions that receive NIH funding, or anywhere NIH-funded activities are conducted.

Notify NIH about a concern that sexual harassment is affecting an NIH funded project at a grantee institution

While NIH can and will follow up on all concerns related to NIH-funded research, NIH strongly encourages individuals to report allegations of sexual harassment or assault to the appropriate authorities, which may include your local police department or your organization/institution equal employment opportunity (EEO) or human resources offices.

Fields marked with an ✽ are required.

Your first name (Optional)

Your last name (Optional)

Your email address (Optional)

https://public.era.nih.gov/shape/public/notificationForm.era
• N=179,238 faculty appointments in 2019 (42% women)
• Ranks and percent women
  – Instructor 59% women
  – Assistant Professor 48% women
  – Associate Professor 39% women
  – Professor 26% women

AAMC Faculty Roster, December 31, 2019 snapshot
Refer to AAMC T9 Medical Faculty Sex Rank 2019 data file for corresponding faculty appointment number, percentages and embedded formulas.

Pearson, Katrina (NIH/OD) [E], 9/10/2020
Research Grant Investigators: Percent Women

- Career (“K”)
- RPGs
- Centers
- SBIR/STTR


Percent Women:
- 0%
- 10%
- 20%
- 30%
- 40%
- 50%
- 60%
Other Concerns: COI, Disclosure

Threats to the U.S. Research Enterprise: China’s Talent Recruitment Plans

STAFF REPORT

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

UNITED STATES SENATE

Enhancing the Security and Integrity of America’s Research Enterprise

The White House Office of Science and Technology Policy

www.whitehouse.gov/ostp

www.ostp.gov

@WHOSTP

https://www.hsgac.senate.gov/subcommittees/investigations/hearings/securing-the-us-research-enterprise-from-chinas-talent-recruitment-plans

Another Concern: Peer Review Integrity

Open Mike

Case Study in Review Integrity: Abuse of Power

Posted on September 2, 2020 by Mike Lauer

What would you do if, as the Dean of Research at a major university, a group of students, postdocs, and junior faculty reported that they had been pressured into writing reviewer critiques for a senior faculty member? Continue reading →

Posted in blog, Open Mike | Tagged Confidentiality, Peer review | 1 Reply

https://nexus.od.nih.gov/all/category/blog/open-mike/
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• Application preparation, submission
• Human subjects’ research
• Inventions, patents, contracts
• “Open Mike”
• Policy, compliance, FCOI
• Sexual harassment

... And much more...