Extramural Research in the Era of COVID-19

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Deputy Director for Extramural Research; Director, Office of Extramural Research
National Institutes of Health

NIH DPCPSI Council of Councils
Thursday, May 20, 2021
Virtual Meeting
Disclosures: None
Overview

• Grant trends, focus on Research Project Grants (RPGs)
  – Applications, awards; applicants, awardees; workforce
  – Grant costs and composition

• Non-COVID-19 research in the era of COVID-19
  – Extramural surveys
  – Some steps NIH is taking

• Assuring research integrity
RPGs and the Extramural Funding Landscape

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Amount ($B)</th>
<th>Percent NIH Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Projects (RPG)</td>
<td>22.7</td>
<td>54.4</td>
</tr>
<tr>
<td>SBIR/STTR</td>
<td>1.12</td>
<td>2.7</td>
</tr>
<tr>
<td>Research Centers</td>
<td>2.69</td>
<td>6.5</td>
</tr>
<tr>
<td>Other Research</td>
<td>2.74</td>
<td>6.6</td>
</tr>
<tr>
<td>Training</td>
<td>0.92</td>
<td>2.2</td>
</tr>
<tr>
<td>Research Contracts</td>
<td>3.29</td>
<td>7.9</td>
</tr>
<tr>
<td>Intramural Research</td>
<td>4.47</td>
<td>10.7</td>
</tr>
<tr>
<td>RMS</td>
<td>2.01</td>
<td>4.8</td>
</tr>
</tbody>
</table>
Possible Causes of Increased Variation

• Greater proportion of solicited projects
  • From 20% in 1998 to 30% in 2015 to 40% in 2020
  • Large projects (e.g. >$5 million per year)
  • Smaller projects (R03 and R21)
• Clinical trials
• Human-participant projects
Summary of Trends

• Increased number of awards and awardees
• Increased number of Early-Stage Investigators
• Increased proportion of women (but well below parity)
• Persistent low proportion of Black investigators
• Increased success, funding rates despite more applications / applicants
• Real costs stable, but variation greater; changed composition
Medical Research Is Locked Down, Too

Clinical trials grind to a halt as patients are told to stay home and research personnel are redeployed.

By Kevin Sheth
May 4, 2020 5:58 pm ET

I lead clinical trials for medications to treat crippling disorders such as stroke and brain hemorrhages. During the past few months, every one of these studies has come to a grind halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disar
Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on October 5, 2020 by Mike Lauer

Encouraging Participation in Upcoming NIH Surveys to Identify Impacts of COVID-19 on Extramural Research

NIH has been working diligently to support the extramural research community since the pandemic began in March. We are now preparing to reach out with surveys to gather data on how COVID-19 is impacting our extramural researchers and their institutions. If you receive
Thank You for Your Input

The Impact of the COVID-19 Pandemic on the Extramural Scientific Workforce – Outcomes from an NIH-Led Survey

By Marie A. Bernard and Mike Lauer
Posted March 25, 2021

One year later, the COVID-19 pandemic has drastically affected our individual lives and communities. We have observed disproportionate effects observed in underserved populations, leaving them vulnerable to higher infection and mortality risk. These effects have led to an increased reliance on biomedical researchers and clinicians to offer public health solutions to this crisis. Within the research workforce, early-career scientists may bear the brunt of pandemic-related mitigation measures at institutions and limitations due to inability to be in the physical workspace.

At NIH, we recognized the many ways the COVID-19 pandemic could adversely affect the biomedical workforce, particularly members of underrepresented groups and vulnerable populations. In October 2020, NIH fielded two online surveys to objectively document COVID-19’s impact on extramural research. One survey assessed the perspective of individual research administration leaders at extramural institutions, and the other survey assessed the perspective of the researchers themselves. In this post, we offer a high-level overview of general trends noted within both surveys. This infographic here also describes the outcomes from the surveys.

Background

The former NIH Chief Officer of Scientific Workforce Diversity, Dr. Hannah A. Valantine, spearheaded the development of the survey

2020 NIH Extramural Surveys:
The Impact of COVID-19 on the Research Community

In October of 2020, 45,348 researchers at domestic, NIH-funded institutions and 224 research leaders from the top 1,000 NIH-funded domestic institutions responded to an NIH COVID-19 Impact on Extramural Research Survey, which aimed to gauge the impact of COVID-19 on the research community.

High-Level Findings

At a high-level, survey findings emphasized the impact of COVID-19 on the career trajectory, mental health, and research productivity of extramural researchers:

- 55% of respondents said the pandemic will have a negative impact on their career trajectory.
- 68% of respondents said societal/political events negatively affected their mental health, more than other factors.
- 78% of respondents reported lower levels of productivity since the pandemic began.

Impact on Career Trajectory by Career Stage

- **Postdoctoral fellow/Resident**: 69%
- **Faculty (0-6 years)**: 67%
- **Faculty (7-14 years)**: 61%
- **Student**: 56%
- **Researcher (0-6 years)**: 54%
- **Researcher (7-14 years)**: 49%
- **Faculty (15+ years)**: 43%
- **Researcher (15+ years)**: 34%
Impact on Career Trajectory by Type of Research

- Laboratory: 61%
- Computational: 52%
- Clinical: 49%
- Sociological / Community-based: 46%
- Epidemiologic / Public Health: 45%
### Impact on Career Trajectory by Race & Gender

<table>
<thead>
<tr>
<th>Race by Gender</th>
<th>% Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian, Men</td>
<td>67%</td>
</tr>
<tr>
<td>Asian, Other Gender</td>
<td>64%</td>
</tr>
<tr>
<td>Asian, Women</td>
<td>62%</td>
</tr>
<tr>
<td>White, Other Gender</td>
<td>61%</td>
</tr>
<tr>
<td>Two or More Races, All Genders</td>
<td>59%</td>
</tr>
<tr>
<td><strong>All Respondents</strong></td>
<td>55%</td>
</tr>
<tr>
<td>AIAN, Women</td>
<td>41%</td>
</tr>
<tr>
<td>African American, Men</td>
<td>40%</td>
</tr>
<tr>
<td>African American, Women</td>
<td>39%</td>
</tr>
<tr>
<td>NHPI, Men</td>
<td>31%</td>
</tr>
<tr>
<td>African American, Other Gender</td>
<td>22%</td>
</tr>
</tbody>
</table>
## Most Important Predictors of Career Trajectory Concerns

<table>
<thead>
<tr>
<th></th>
<th>Top 10 Variables (Negative Class Predictors)</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ability to apply for grants</td>
<td>0.1634</td>
</tr>
<tr>
<td>2</td>
<td>Progress towards promotion/tenure</td>
<td>0.0627</td>
</tr>
<tr>
<td>3</td>
<td>Reduced access to on-site laboratories</td>
<td>0.0604</td>
</tr>
<tr>
<td>4</td>
<td>Reduced access to core facilities</td>
<td>0.0573</td>
</tr>
<tr>
<td>5</td>
<td>Concern for the health of family and friends</td>
<td>0.0510</td>
</tr>
<tr>
<td>6</td>
<td>Reduced access to colleagues</td>
<td>0.0479</td>
</tr>
<tr>
<td>7</td>
<td>Caretaking responsibilities</td>
<td>0.0402</td>
</tr>
<tr>
<td>8</td>
<td>Lost access to expertise</td>
<td>0.0321</td>
</tr>
<tr>
<td>9</td>
<td>Timeline uncertainty for returning to work</td>
<td>0.0277</td>
</tr>
<tr>
<td>10</td>
<td>Personal mental/physical health has impacted productivity</td>
<td>0.0258</td>
</tr>
</tbody>
</table>

AUC = 79.3
NIH’s Priorities for Early Career Investigators

Thanks to Francis Collins
Flexibilities

• No-cost extensions (2nd no-cost extensions)
• Funded extensions for select F and K awards
• Eligibility extensions:
  • Early-Stage Investigator status: ~500 to ~1000
  • K99/R00
• Leniency on late applications
• Preliminary data post-submission
Childcare Allowance

- $2500 / year / Fellow
- Defray child-care costs
  - Children < 13 years, disabled < 18 years
  - Licensed childcare provider
  - Recipient responsible for documentation
- Plan for T awardees in FY2022
Concerns About Integrity

This article has been retracted: N Engl J Med. DOI: 10.1056/NEJMc2021225.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19

Mandeep R. Mehra, M.D., Sapan S. Desai, M.D., Ph.D., SreyRam Kuy, M.D., M.H.S., Timothy D. Henry, M.D., and Amit N. Patel, M.D.

ABSTRACT
• Conducting research
  – “Classic” integrity: fabrication, falsification, plagiarism
  – Other: peer review, harassment, non-disclosure
• Responsibility to conduct the right research
  – Focus on COVID-19
“Vincent E. Price, president of Duke University, said … ‘This is a difficult moment for Duke. This case demonstrates the devastating impact of research fraud and reinforces the need for all of us to have a focused commitment on promoting research integrity and accountability.’”

“Taxpayers expect and deserve that federal grant dollars will be used efficiently and honestly. Individuals and institutions that receive research funding from the federal government must be scrupulous in conducting research for the common good and rigorous in rooting out fraud,” said Matthew G.T. Martin, United States Attorney for the Middle District of North Carolina. “May this serve as a lesson that the use of false or fabricated data in grant applications or reports is completely unacceptable.”

“Breaches of research integrity have shocked the academic community. Initially explanations were sought at the level of individual researchers but over time increased recognition emerged of the important role that the research integrity climate may play in influencing researchers’ (mis)behavior.”

https://doi.org/10.1371/journal.pone.0210599
Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH

Notice Number: NOT-OD-19-020

Key Dates
Release Date: October 17, 2018

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose
The NIH strives to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. To this end, the NIH works with recipient institutions and the HHS Office of Research Integrity (ORI) to maintain the integrity of NIH-funded research. This notice reminds recipient institutions of their responsibilities in

Measles Outbreak, New York City, 2018–2019

Consequences of Undervaccination —


• Conducting research
  – “Classic” integrity: fabrication, falsification, plagiarism
  – Other: peer review, harassment, non-disclosure
• Responsibility to conduct the right research
  – Focus on COVID-19
Overview of Allegation Review Process

- Research Misconduct
- Sexual Harassment
- Grant Fraud
- Foreign Influence
- Peer Review Integrity Violation

ALLEGATION ENTRY

INITIAL ASSESSMENT

ACTIONS TO CONSIDER, DEPENDING ON OUTCOME OF ASSESSMENT

- Contact institution
- Remove individual from peer review service
- Refer to agency/office with oversight responsibility
- Administrative actions
- Regulatory actions

In addition, because NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research, the request for approval should include mention as to whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions).
University Researcher Pleads Guilty to Lying on Grant Applications to Develop Scientific Expertise for China

A rheumatology professor and researcher with strong ties to China pleaded guilty to making false statements to federal authorities as part of an immunology research fraud scheme.

Song Guo Zheng, 58, of Hilliard, appeared in federal court today, at which time his guilty plea was accepted by Chief U.S. District Judge Algenon L. Marbley.
Former University of Florida Researcher Indicted for Scheme to Defraud National Institutes of Health and University of Florida

A former University of Florida (UF) professor and researcher and resident of China has been indicted for fraudulently obtaining $1.75 million in federal grant money from the National Institutes of Health (NIH) by concealing support he received from the Chinese government and a company that he founded in China to profit from that research.
“During that same period, in 2016, Yang established a business in China known as ‘Deep Informatics.’ The indictment further alleges that Yang promoted his business in China by relating that its products were the result of years of research supported by millions of dollars of U.S. government funding. Simultaneously, Yang applied for and was accepted into the People’s Republic of China’s Thousand Talents Program (TTP) in connection with Northwestern Polytechnic University, located in Xi’an, China.”
• Conducting research
  – “Classic” integrity: fabrication, falsification, plagiarism
  – Other: peer review, harassment, non-disclosure
• Responsibility to conduct the right research
  – Focus on COVID-19
“The current literature on the treatment of Covid-19 is filled with anecdotal reports of therapeutic successes in clinical trials with small numbers of patients and observational cohort studies claiming efficacy with little regard to the effect of unrecognized confounders. For the field to move forward and for patients’ outcomes to improve, there will need to be fewer small or inconclusive studies and more studies such as the dexamethasone trial now reported by the RECOVERY Collaborative Group.”

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812  FEBRUARY 4, 2021  VOL. 384  NO. 5

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine


Research Letter

July 27, 2020

Characteristics and Strength of Evidence of COVID-19 Studies Registered on ClinicalTrials.gov

Krishna Pundi, MD¹; Alexander C. Perino, MD¹; Robert A. Harrington, MD¹; Harlan M. Krumholz, MD, SM²; Mintu P. Turakhia, MD, MAS¹

» Author Affiliations  |  Article Information


https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768882
“Another recent study of 20,000 patients treated with plasma infusions from recovering COVID-19 patients claimed evidence of safety and. Expressed optimism for benefit based on low reported event rates, although there was no control group to anchor the observed event rates. If a fraction of these patients had been enrolled in RCTs, the answer for whether this intervention was effective would now be known.”

https://jamanetwork.com/journals/jama/fullarticle/2769139?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jama.2020.16238
Closing Thoughts

• Trends showing effects of increased budgets
• Workforce priorities: early career, women, diversity
• COVID effect on research “bipolar”
• Extensive, and disproportionate, disruption
• Long-term effects unclear
• NIH priorities:
  – Early career / at-risk investigators, certain trials
  – Integrity above all