# Extramural Research in the Era of COVID-19

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

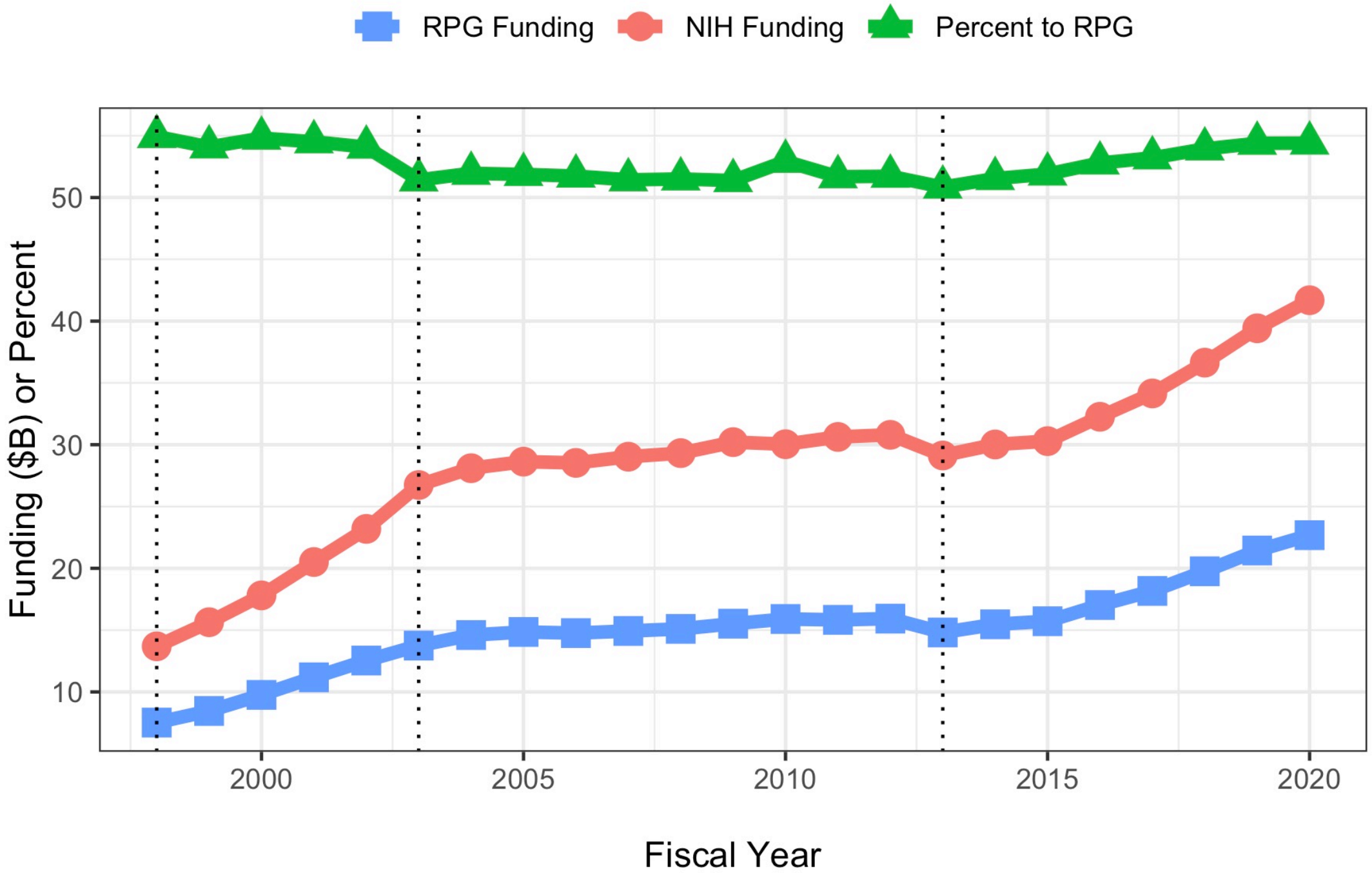
NIH DPCPSI Council of Councils
Thursday, May 20, 2021
Virtual Meeting
Disclosures: None

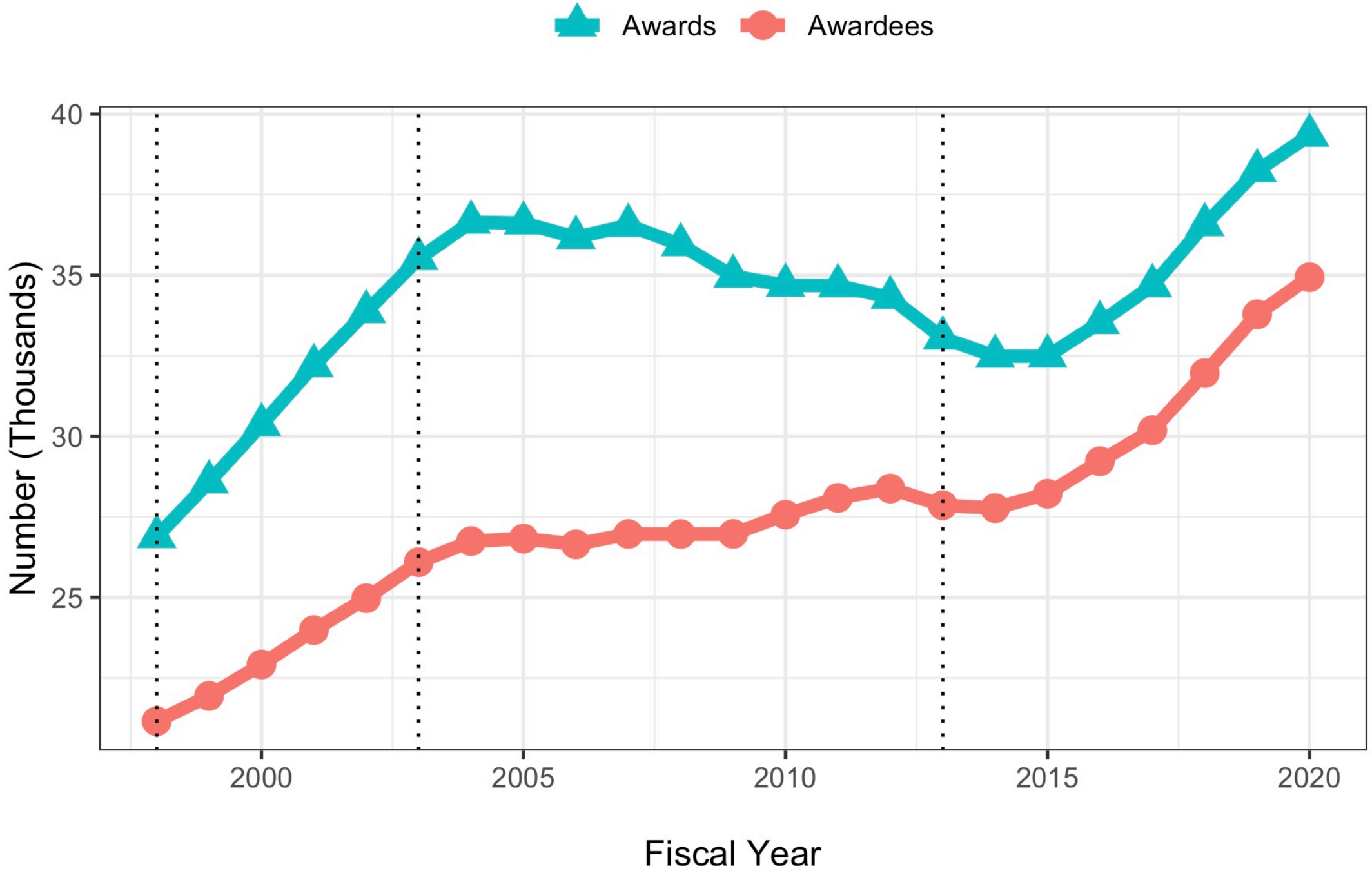
# Overview

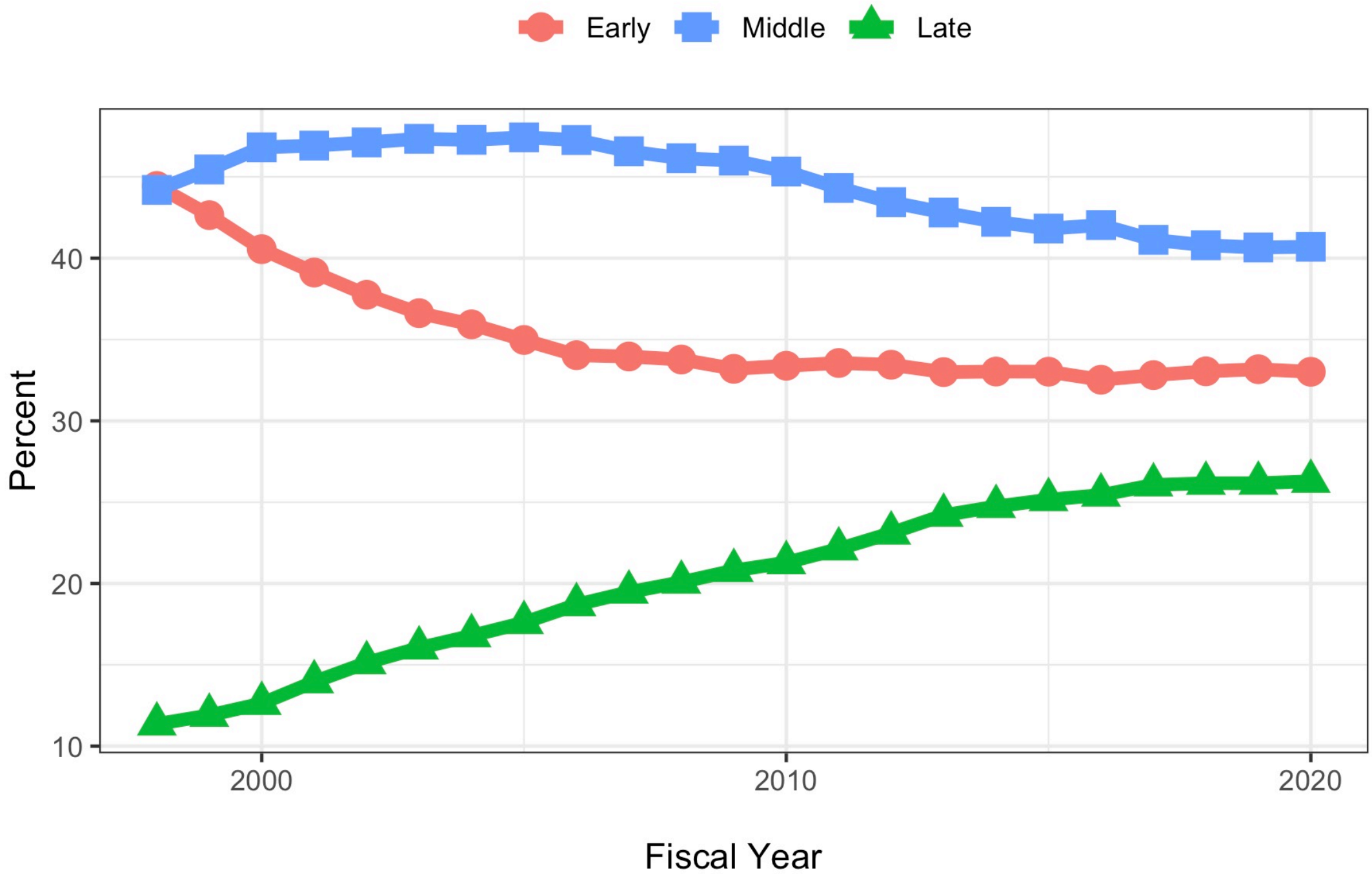
- Grant trends, focus on Research Project Grants (RPGs)
  - Applications, awards; applicants, awardees; workforce
  - Grant costs and composition
- Non-COVID-19 research in the era of COVID-19
  - Extramural surveys
  - Some steps NIH is taking
- Assuring research integrity

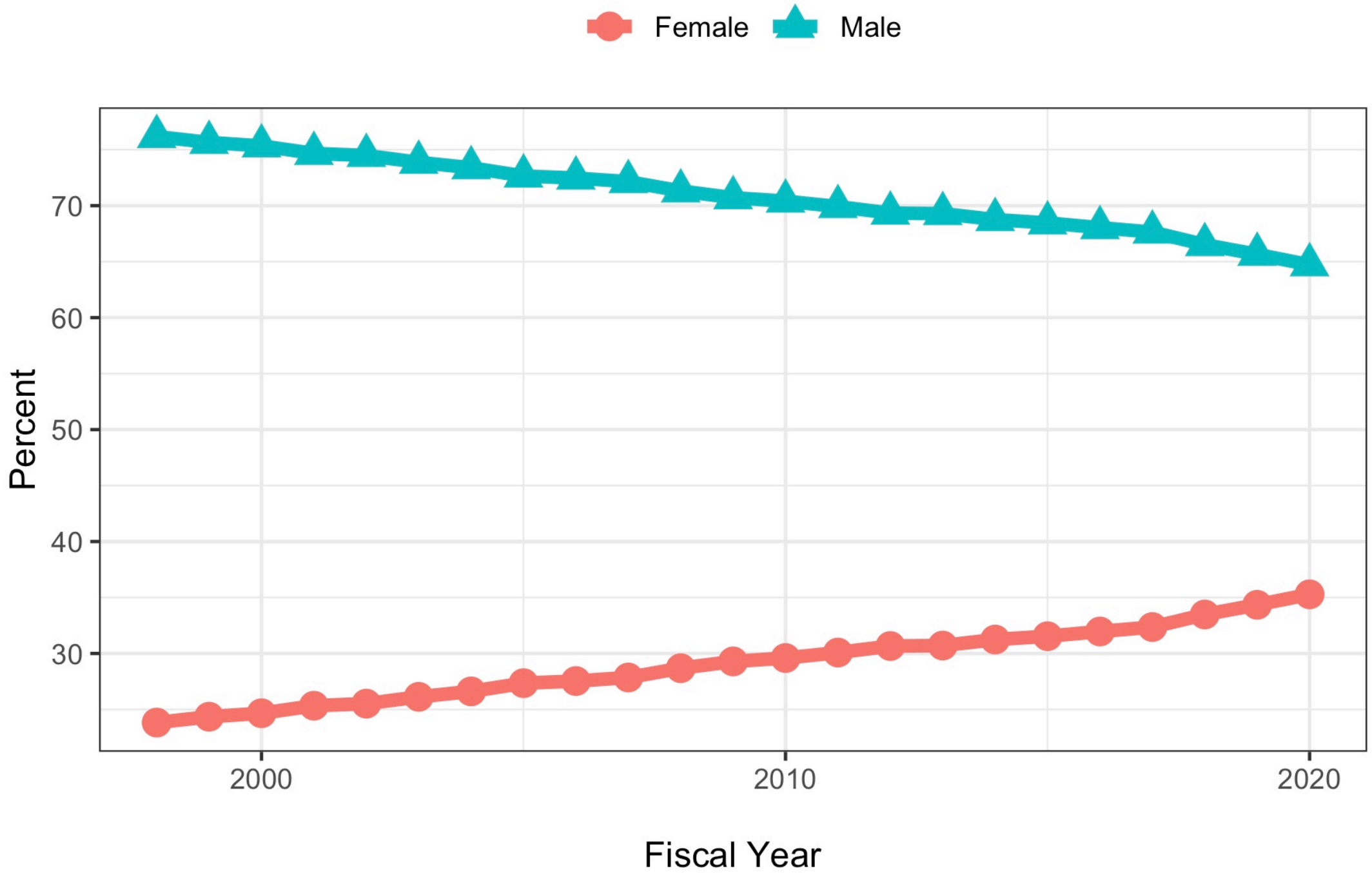
# RPGs and the Extramural Funding Landscape

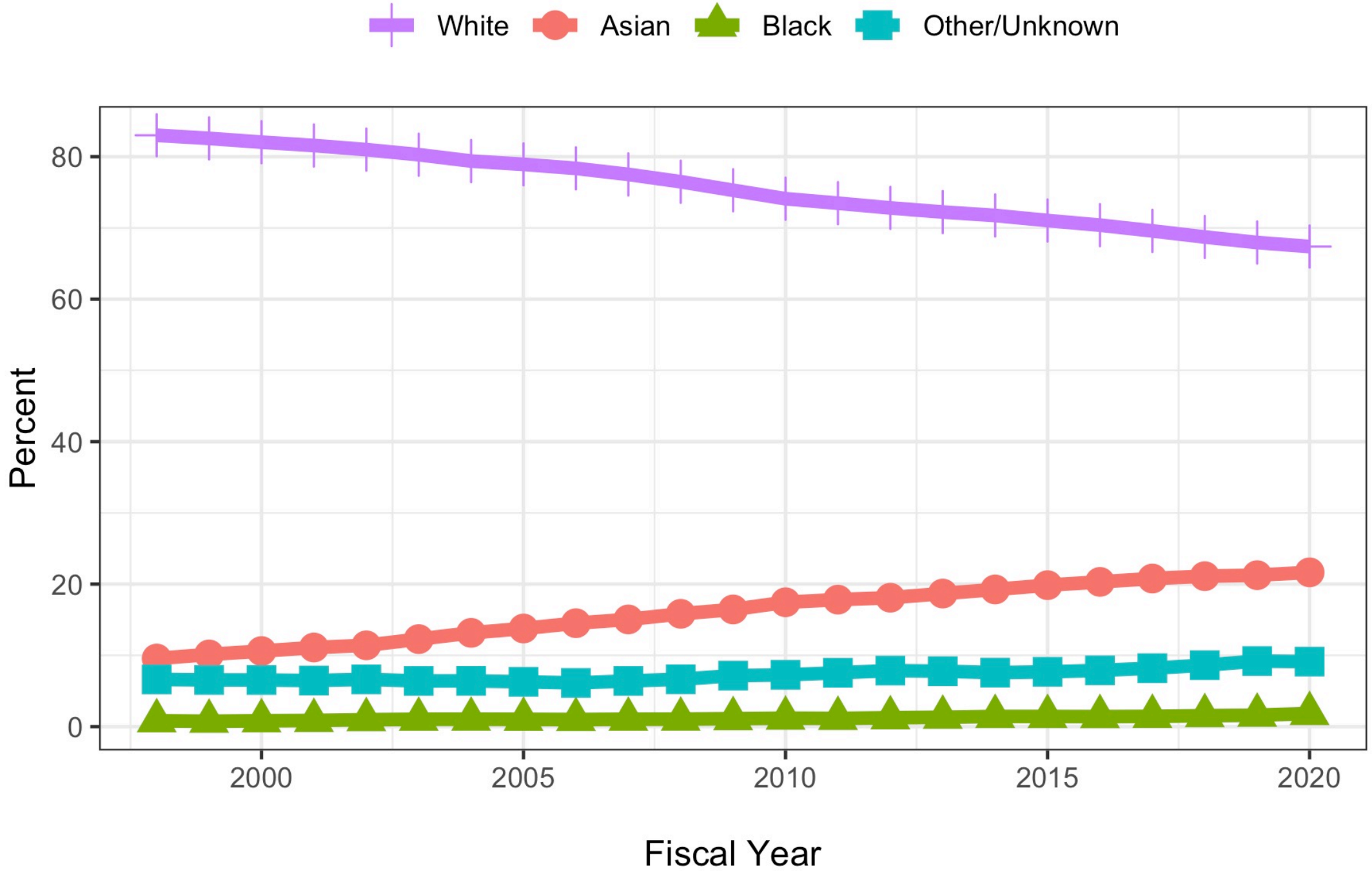
| Mechanism | Amount ($B) | Percent NIH Budget |
|---|---|---|
| Research Projects (RPG) | 22.7 | 54.4 |
| SBIR/STTR | 1.12 | 2.7 |
| Research Centers | 2.69 | 6.5 |
| Other Research | 2.74 | 6.6 |
| Training | 0.92 | 2.2 |
| Research Contracts | 3.29 | 7.9 |
| Intramural Research | 4.47 | 10.7 |
| RMS | 2.01 | 4.8 |

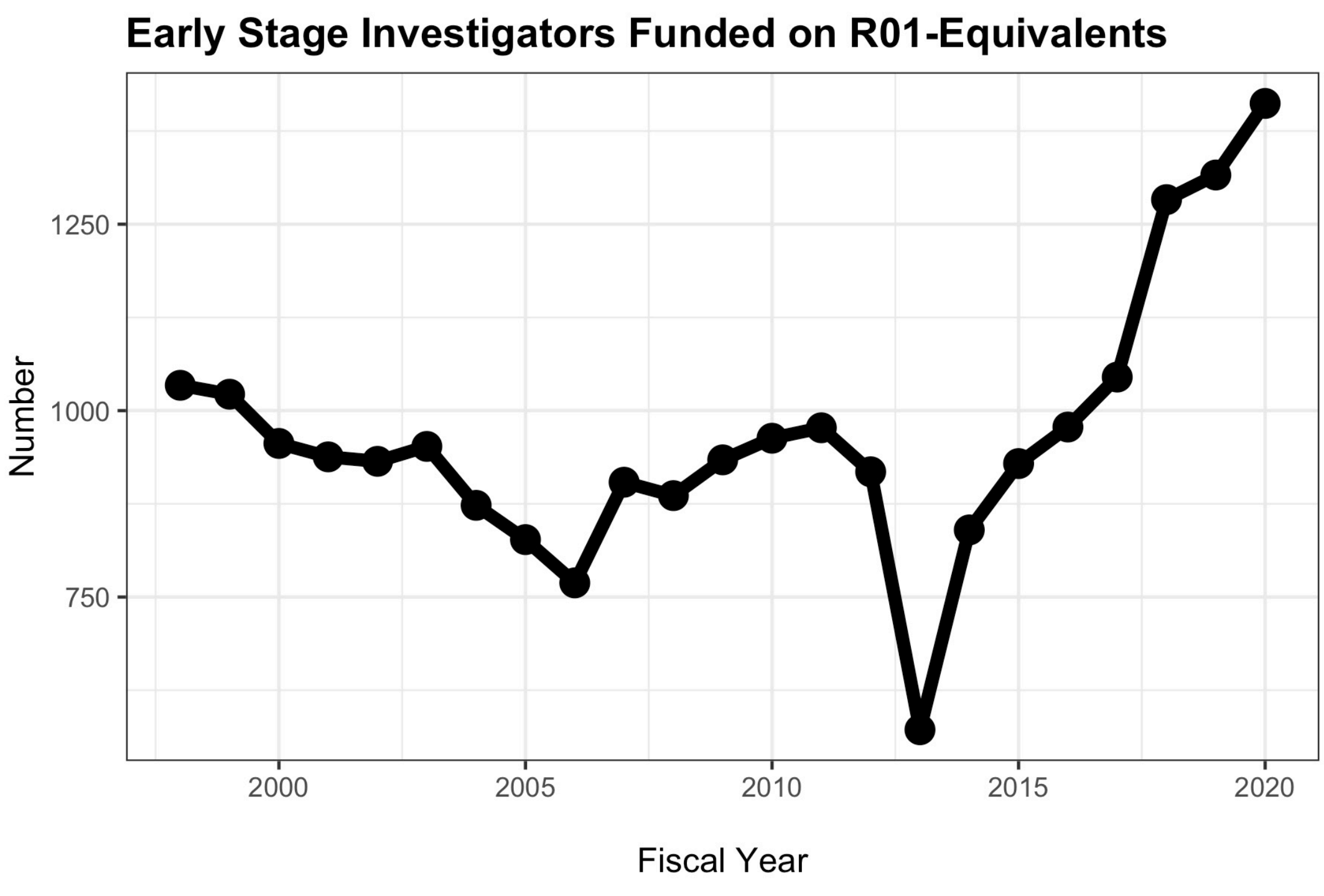

RPG Funding
NIH Funding
Percent to RPG
Funding ($B) or Percent
50
40
30
20
10
2000
2005
2010
2015
2020
Fiscal Year

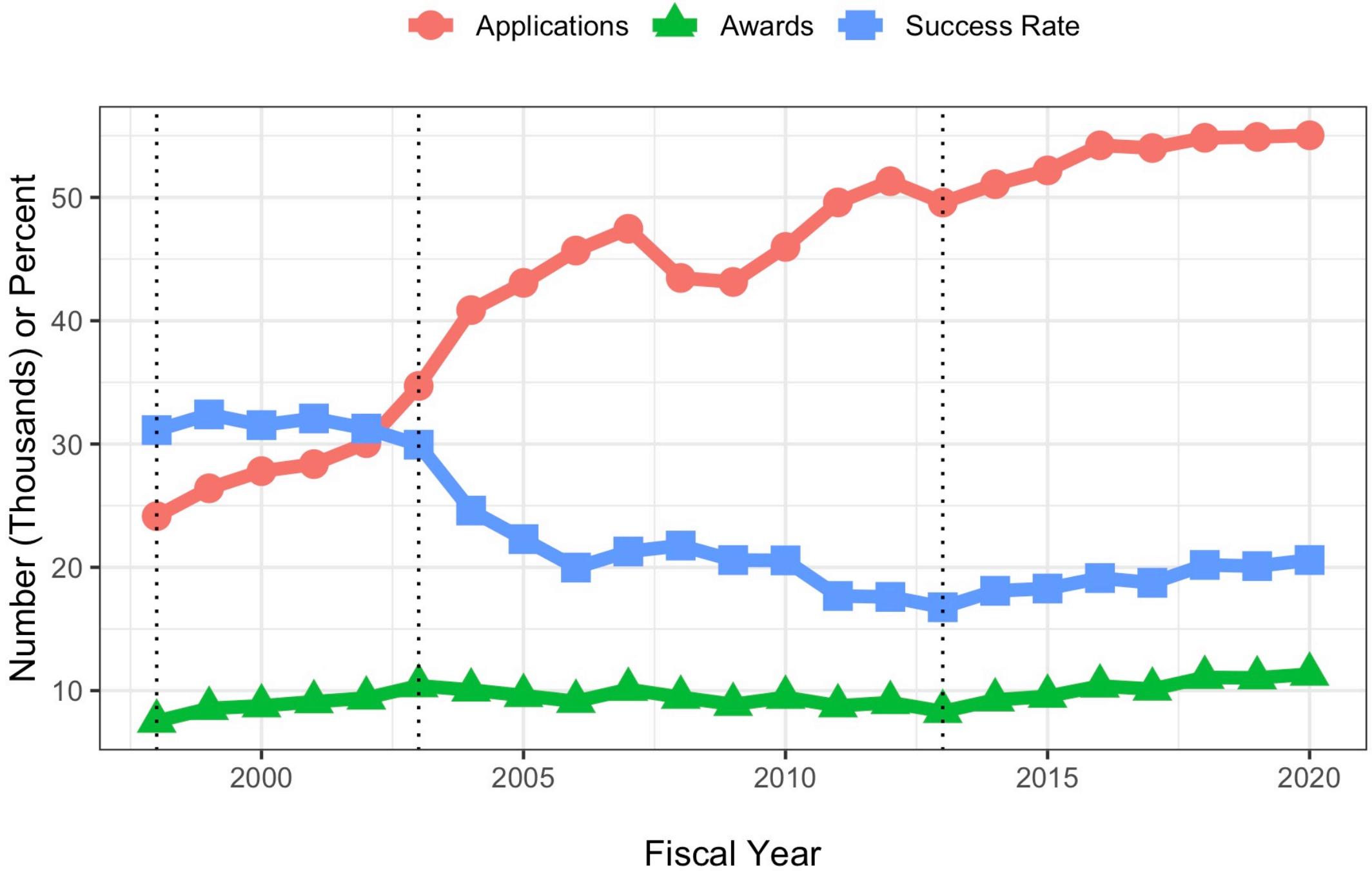

Awards
Awardees
40
35
30
25
Number (Thousands)
2000
2005
2010
2015
2020
Fiscal Year

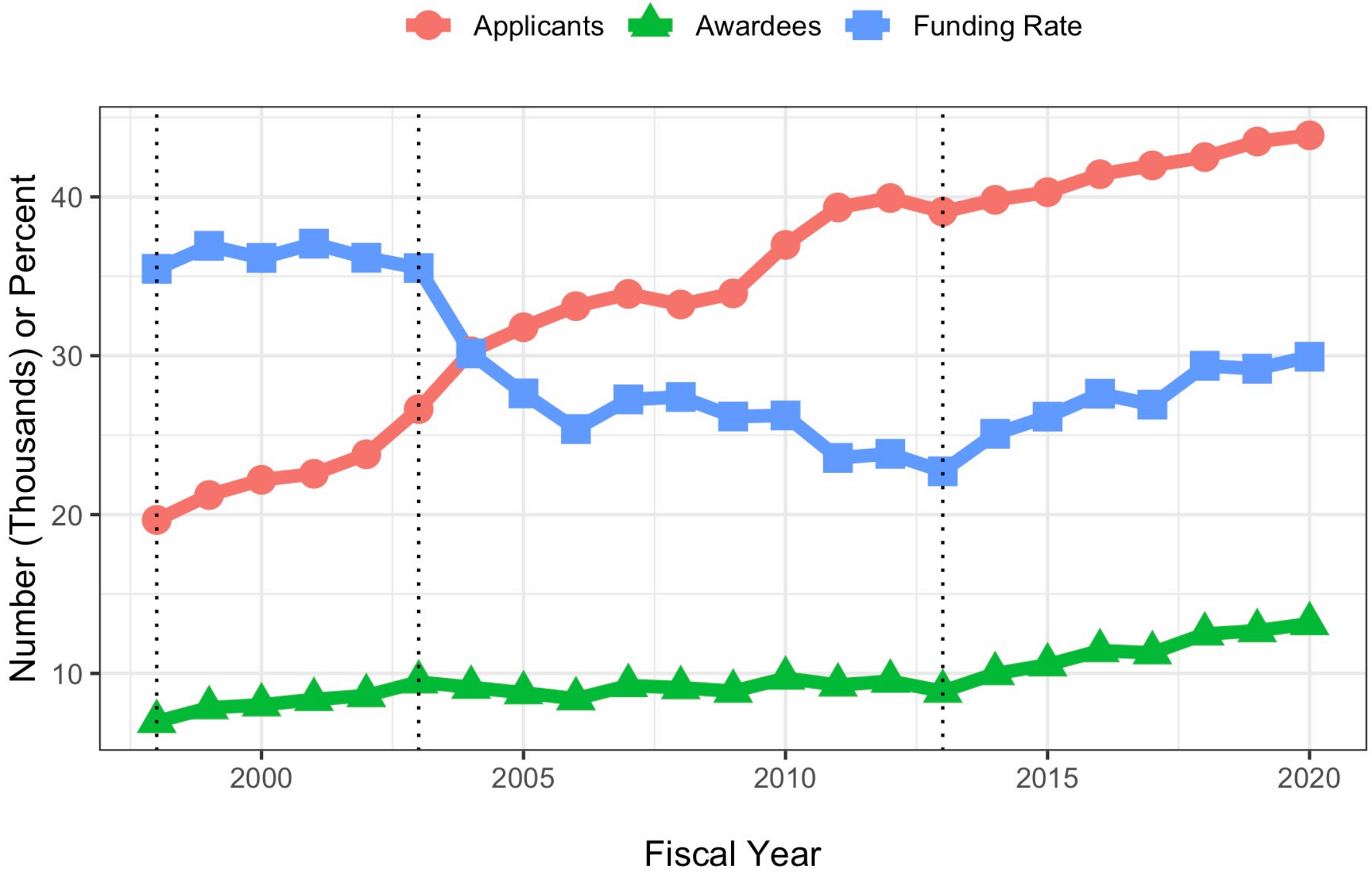

Early
Middle
Late
Percent
40
30
20
10
2000
2010
2020
Fiscal Year

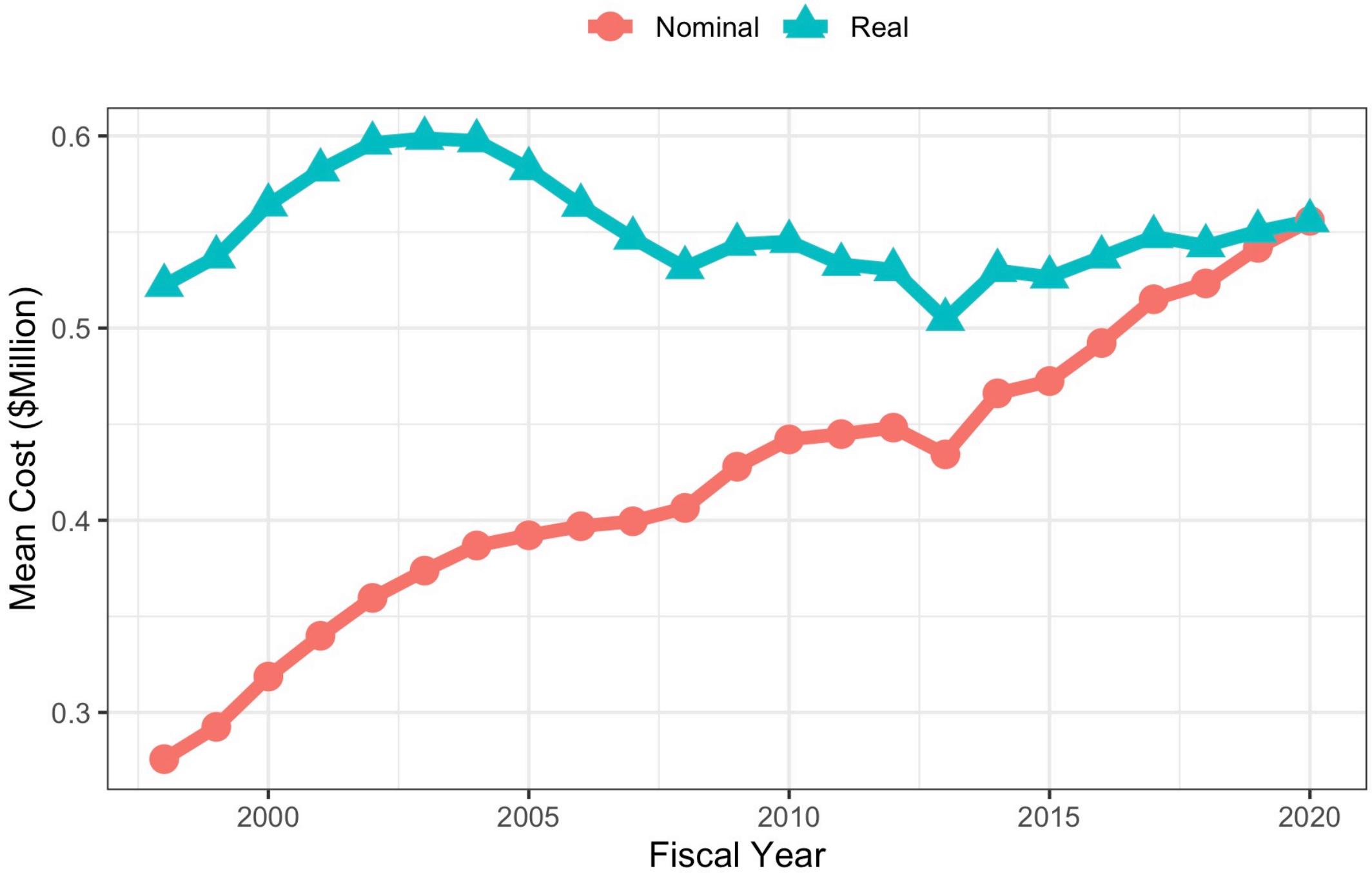

Female
Male
70
60
50
40
30
Percent
2000
2010
2020
Fiscal Year

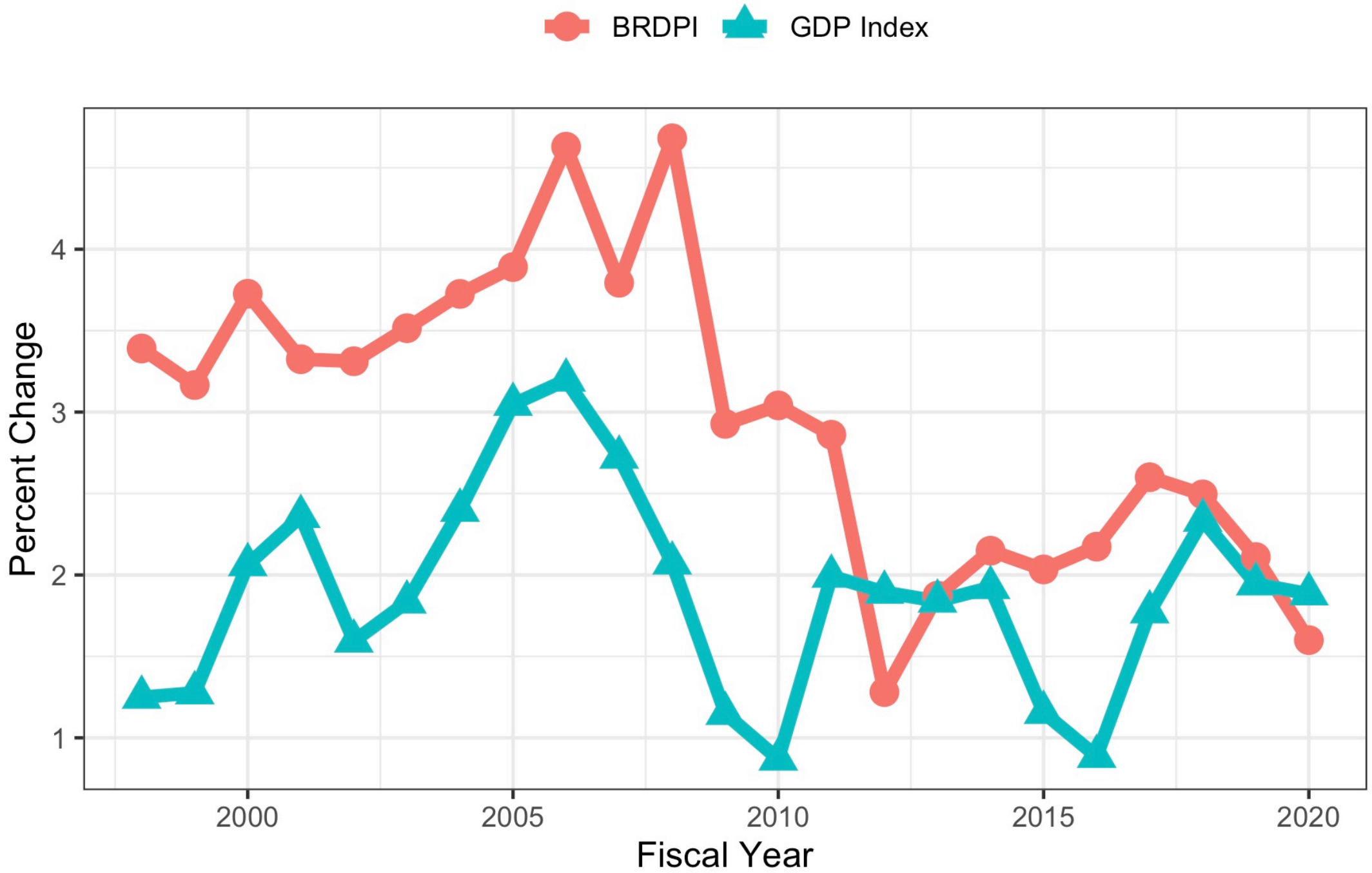

White
Asian
Black
Other/Unknown
80
60
40
20
0
Percent
2000
2005
2010
2015
2020
Fiscal Year

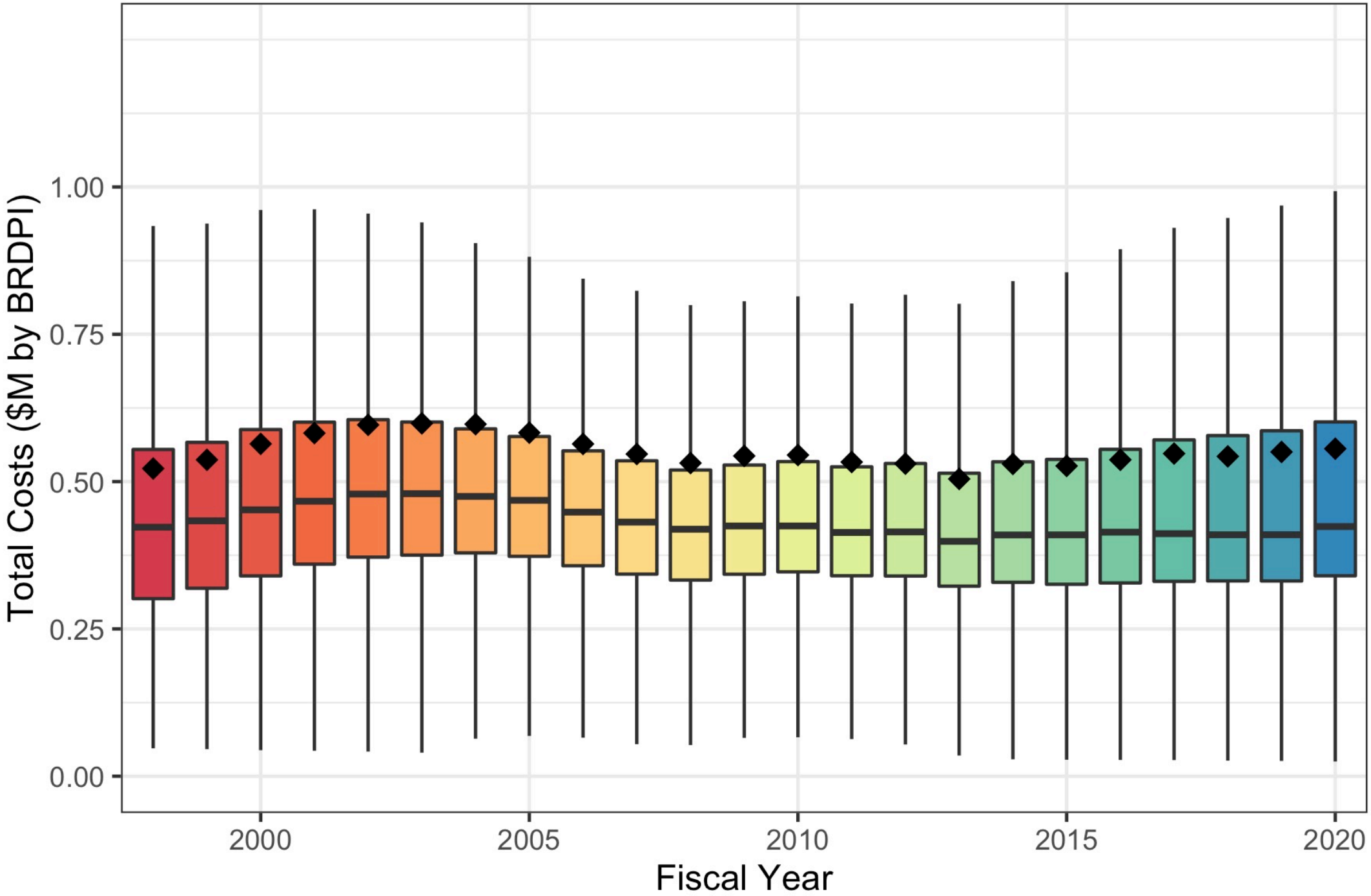

Early Stage Investigators Funded on R01-Equivalents
Number
1250
1000
750
2000
2005
2010
2015
2020
Fiscal Year


Applications
Awards
Success Rate
Number (Thousands) or Percent
50
40
30
20
10
2000
2005
2010
2015
2020
Fiscal Year


Applicants
Awardees
Funding Rate
Number (Thousands) or Percent
40
30
20
10
2000
2005
2010
2015
2020
Fiscal Year


Nominal
Real
0.6
0.5
0.4
0.3
Mean Cost ($Million)
2000
2005
2010
2015
2020
Fiscal Year


BRDPI
GDP Index
Percent Change
4
3
2
1
2000
2005
2010
2015
2020
Fiscal Year


Total Costs ($M by BRDPI)
1.00
0.75
0.50
0.25
0.00
2000
2005
2010
2015
2020
Fiscal Year

# 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

# Non-COVID Research …

THE WALL STREET JOURNAL.


https://www.wsj.com/articles/medical-research-is-locked-down-too-11588629492

OPINION | COMMENTARY

## *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 grin halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disar

STAT

## Covid-19 has shuttered scientific labs. It could put a generation of researchers at risk

*By* Justin Chen

May 4, 2020

*Kena Betancur/Getty Images*

# Learning From You!

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## 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

Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.



https://nexus.od.nih.gov/all/2020/10/05/encouraging-participation-in-upcoming-nih-surveys-to-identify-impacts-of-covid-19-on-extramural-research/

# Thank You for Your Input

HOME OPEN MIKE MORE TOP STORIES NEW RESOURCES TIPS BEFORE YOU SUBMIT YOU ASK, WE ANSWER

## 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

Share Tweet Share 3 Comments

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.

*Marie A. Bernard, M.D., Deputy Director of the National Institute on Aging, Acting Chief Officer for Scientific Workforce Diversity*

**Background**

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

https://nexus.od.nih.gov/all/2021/03/25/the-impact-of-the-covid-19-pandemic-on-the-extramural-scientific-workforce-outcomes-from-an-nih-led-survey/

# 2020 NIH Extramural Surveys:

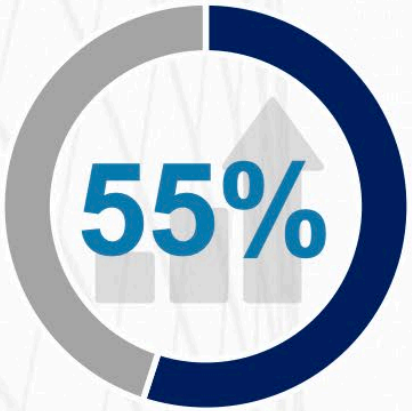
## The Impact of COVID-19 on the Research Community

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.

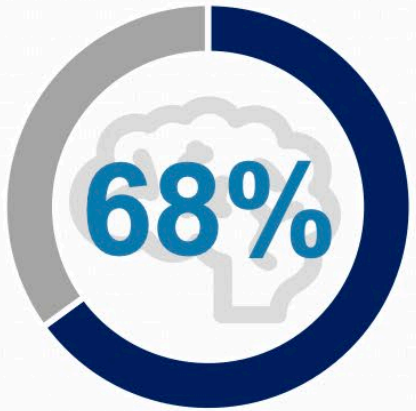
https://grants.nih.gov/sites/default/files/NIH%20COSWD_COVID19%20Impact_Infographic_vF_Updated_3-19.pdf

# High-Level Findings

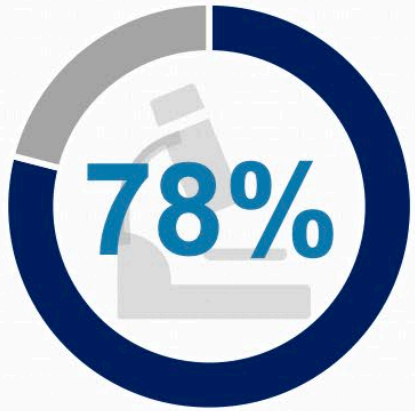
At a high-level, survey findings emphasized the impact of COVID-19 on the **career trajectory**, **mental health**, and **research productivity** of extramural researchers:




of respondents said **the pandemic will have a negative impact their career trajectory**



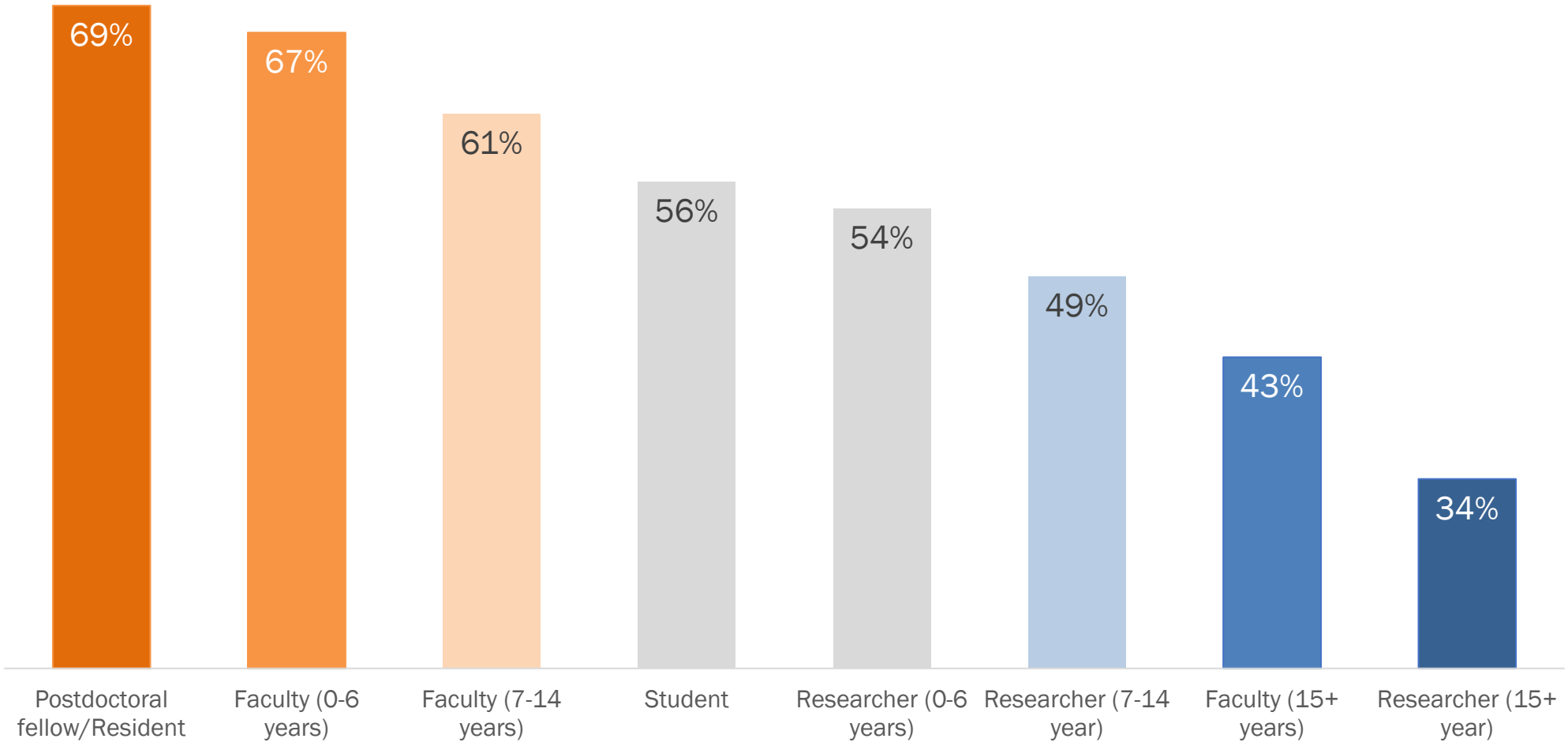

of respondents said **societal/political events negatively affected their mental health**, more than other factors



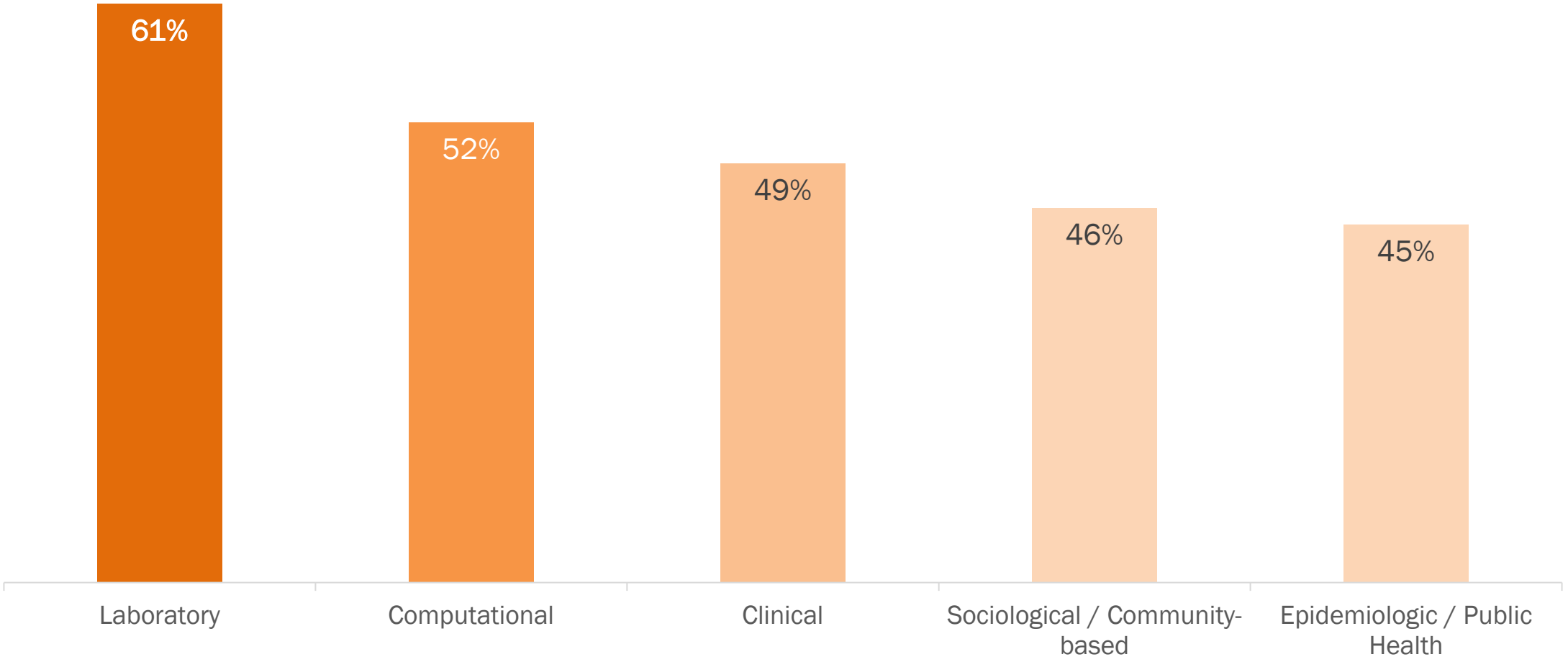

of respondents reported **lower levels of productivity** since the pandemic began

https://grants.nih.gov/sites/default/files/NIH%20COSWD_COVID19%20Impact_Infographic_vF_Updated_3-19.pdf

# Impact on Career Trajectory by Career Stage



# Impact on Career Trajectory by Type of Research



# Impact on Career Trajectory by Race & Gender

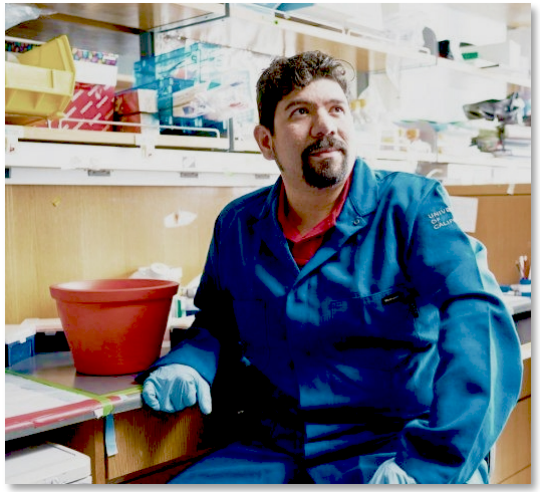
| Race by Gender | % Impacted |
|---|---|
| Asian, Men | **67%** |
| Asian, Other Gender | **64%** |
| Asian, Women | **62%** |
| White, Other Gender | **61%** |
| Two or More Races, All Genders | **59%** |
| **All Respondents** | 55% |
| AIAN, Women | 41% |
| African American, Men | 40% |
| African American, Women | 39% |
| NHPI, Men | 31% |
| African American, Other Gender | 22% |

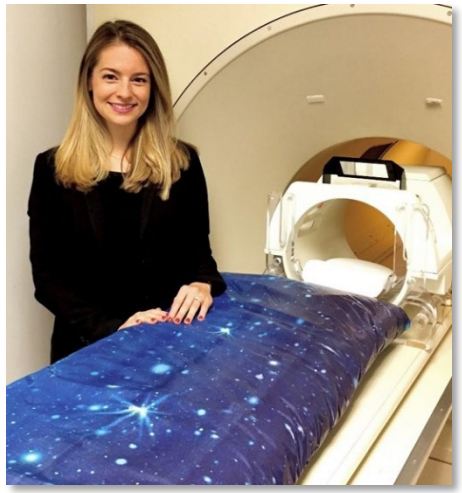
# Most Important Predictors of Career Trajectory Concerns

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

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

Announcement of Childcare Costs for Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellows

**Notice Number:**
NOT-OD-21-074

**Key Dates**

| | |
|---|---|
| **Release Date:** | March 15, 2021 |

- $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

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

# Responsible Conduct of Research

- Conducting research
  - "Classic" integrity: fabrication, falsification, plagiarism
  - Other: peer review, harassment, non-disclosure
- Responsibility to conduct the right research
  - Focus on COVID-19

# Consequences of Repeated Misconduct …

The New York Times

**Duke University to Pay $112.5 Million to Settle Claims of Research Misconduct**

Duke University's medical school. A dozen papers by a former researcher in the pulmonary, allergy and

" 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.'"

https://www.nytimes.com/2019/03/25/science/duke-settlement-research.html

# US Government Worries


"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."

https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related

# The Vocabulary Has Changed …

RESEARCH ARTICLE

## Perceptions of research integrity climate differ between academic ranks and disciplinary fields: Results from a survey among academic researchers in Amsterdam

Tamarinde L. Haven[1]*, Joeri K. Tijdink[1,2], Brian C. Martinson[3], Lex M. Bouter[1,2]

"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."

PLoS ONE 14(1): e0210599.
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

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html

# Pandemic – The Harms are Real

Early report

## Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

*A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith*

**Summary**

**Background** We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

**Methods** 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

**Findings** Onset of behavioural symptoms was associated by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in 11 children and reactive ileal lymphonodular hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0.003$), low haemoglobin in four children, and a low serum IgA in four children.

**Interpretation** We identified a new associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

*Lancet* 1998; **351:** 637–41
*See Commentary page*

**Introduction**

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and bloating and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

**Patients and methods**

12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (diarrhoea, abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward for 1 week, accompanied by their parents.

*Clinical investigations*

We took histories including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S). Neurodevelopmental psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria.[1] Developmental records included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic-resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

*Laboratory investigations*

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary

RETRACTED

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Consequences of Undervaccination — Measles Outbreak, New York City, 2018–2019

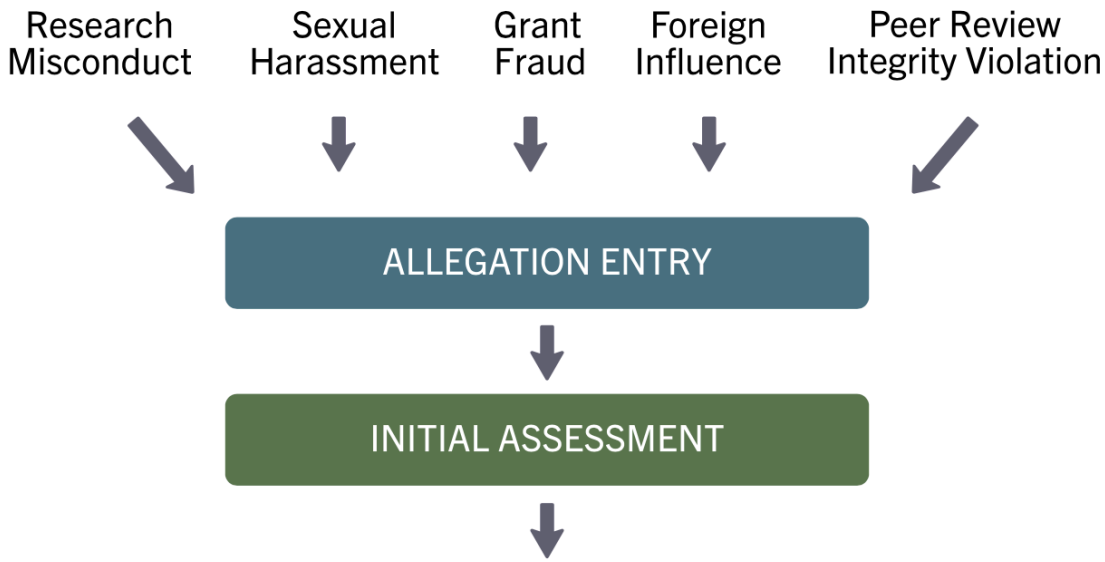
J.R. Zucker, J.B. Rosen, M. Iwamoto, R.J. Arciuolo, M. Langdon-Embry, N.M. Vora, J.L. Rakeman, B.M. Isaac, A. Jean, M. Asfaw, S.C. Hawkins, T.G. Merrill, M.O. Kennelly, B. Maldin Morgenthau, D.C. Daskalakis, and O. Barbot

https://www.nejm.org/doi/pdf/10.1056/NEJMoa1912514?articleTools=true

# Responsible Conduct of Research

- 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




https://grants.nih.gov/grants/policy/harassment/actions-oversight/allegation-process.htm.

EDITORIAL

# Combating sexual harassment

Sexual harassment, including gender harassment, presents an unacceptable barrier that prevents women from achieving their rightful place in science, and robs society and the scientific enterprise of diverse and critical talent. As the largest single funder of biomedical research in the world, the U.S. National Institutes of Health (NIH) bears a responsibility to take action to put an end to this behavior. In 2019, the NIH began to bolster its policies and practices to address and prevent sexual harassment. This included new communication channels to inform the agency of instances of sexual harassment related to NIH-funded research. This week, the NIH announces a change that will hold grantee institutions and investigators accountable for this misconduct, to further foster a culture whereby sexual harassment and other inappropriate behaviors are not tolerated in the research and training environment.

Last year, an Advisory Committee to the Director (ACD) of the NIH presented a report and recommendations to end sexual harassment. A major theme of this report was the need for increased transparency and accountability in the reporting of professional misconduct, especially sexual harassment. The cases of sexual harassment that surfaced in the wake of the U.S. National Academies of

**"...National Institutes of Health (NIH) bears a responsibility to... put an end to this behavior."**

principal investigator (PI) or the transfer of a grant by an NIH grantee institution. Two important areas required more attention: differentiating between instances where an institution removed a PI from a grant because of findings or concerns of sexual harassment from other reasons (such as medical leave or job change); and preventing "passing the harasser," in which a scientist who changed institutions could evade the consequences of findings of sexual harassment.

To close these gaps, the NIH has issued new guidance to grantees that sets clear expectations for reporting to the NIH when a grantee institution has a finding of sexual harassment of a PI named on an NIH grant. The notice also makes it clear that the NIH expects its grant recipients who request changes in either investigators or movement of a grant to a new recipient institution to promptly inform the agency, whether changes are related to concerns about safety and/or work environments (e.g., because of concerns about harassment, bullying, retaliation, or hostile working conditions) (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-124.html). This includes situations where a PI, or other senior personnel, are removed from a grant during the investigation of a serious allegation. The NIH will use such information in making decisions related to

**Carrie D. Wolinetz** is the associate director for Science Policy and acting chief-of-staff to the NIH Director, National Institutes of Health, Bethesda, MD, USA. carrie.wolinetz@nih.gov

**Michael S. Lauer** is the deputy director for Extramural Research, National Institutes of Health, Bethesda, MD, USA. michael.lauer@nih.gov

**Francis S. Collins** is the director of the National Institutes of Health, Bethesda, MD, USA. collinsf@od.nih.gov

https://science.sciencemag.org/content/368/6497/1291

## 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

*"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)."*

# Lying on Grant Applications to Serve Foreign Interests

JUSTICE NEWS

**Department of Justice**

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, November 12, 2020

## 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.

# Lying to Serve Foreign and Personal Interests …

**Department of Justice**

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, February 3, 2021

## 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.

# “Deep Informatics”

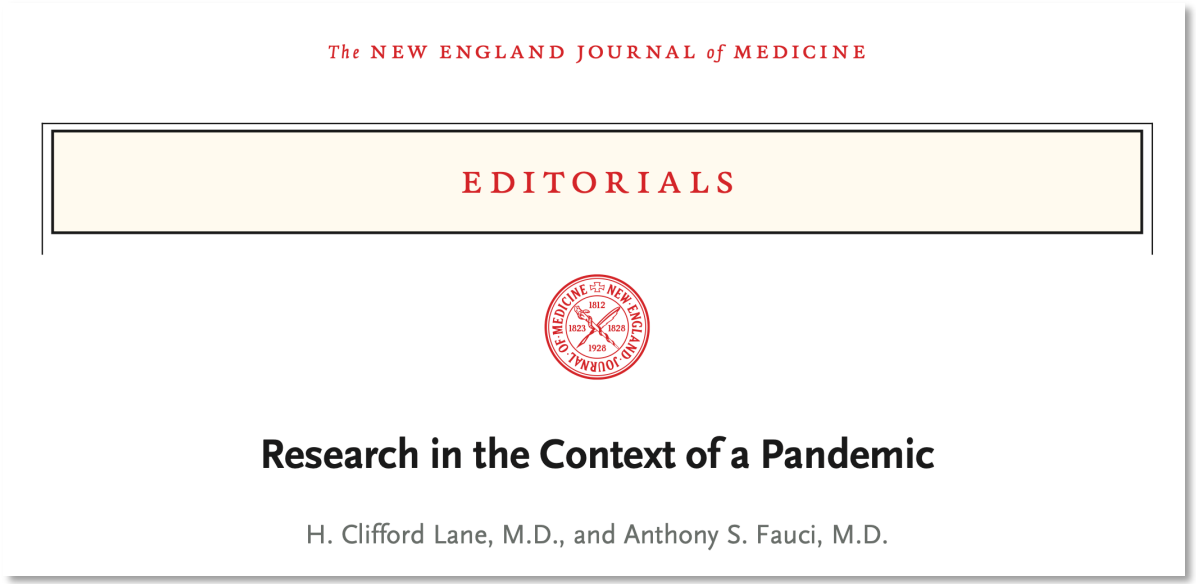
“During that same period, in 2016, Yang established a business in China known as ‘Deep Informatics.’ The indictment further alleges that Yang promoted his business in China by relating that its products were the result of years of research supported by millions of dollars of U.S. government funding. 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.”

https://www.justice.gov/opa/pr/former-university-florida-researcher-indicted-scheme-defraud-national-institutes-health-and

# Responsible Conduct of Research

- Conducting research
  - "Classic" integrity: fabrication, falsification, plagiarism
  - Other: peer review, harassment, non-disclosure
- Responsibility to conduct the right research
  - Focus on COVID-19

# In the Context of Pandemic



The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

**Research in the Context of a Pandemic**

H. Clifford Lane, M.D., and Anthony S. Fauci, M.D.

"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."



https://www.nejm.org/doi/pdf/10.1056/NEJMe2024638?articleTools=true

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

L.R. Baden, H.M. El Sahly, B. Essink, K. Kotloff, S. Frey, R. Novak, D. Diemert, S.A. Spector, N. Rouphael, C.B. Creech, J. McGettigan, S. Khetan, N. Segall, J. Solis, A. Brosz, C. Fierro, H. Schwartz, K. Neuzil, L. Corey, P. Gilbert, H. Janes, D. Follmann, M. Marovich, J. Mascola, L. Polakowski, J. Ledgerwood, B.S. Graham, H. Bennett, R. Pajon, C. Knightly, B. Leav, W. Deng, H. Zhou, S. Han, M. Ivarsson, J. Miller, and T. Zaks, for the COVE Study Group*



https://www.nejm.org/doi/pdf/10.1056/NEJMoa2035389?articleTools=true

# Concerns

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Research Letter

FREE

July 27, 2020

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

Krishna Pundi, MD[1]; Alexander C. Perino, MD[1]; Robert A. Harrington, MD[1]; Harlan M. Krumholz, MD, SM[2]; Mintu P. Turakhia, MD, MAS[1]

Author Affiliations | Article Information

*JAMA Intern Med.* 2020;180(10):1398-1400. doi:10.1001/jamainternmed.2020.2904

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768882

# Cacophony vs Harmony

JAMA Network

JAMA®

**Robert M. Califf, MD**
Verily Life Sciences (Alphabet), South San Francisco, California.

**Adrian F. Hernandez, MD, MHS**
Duke Clinical Research Institute, Durham, North Carolina; and Division of Cardiology, Department of Medicine, Duke University School of Medicine, Durham, North Carolina.

**Martin Landray, MBChB**
Nuffield Department of Population Health, University of Oxford, Headington, Oxford, United Kingdom.

VIEWPOINT

## Weighing the Benefits and Risks of Proliferating Observational Treatment Assessments

## Observational Cacophony, Randomized Harmony

"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