

Challenges and Opportunities Facing Research Institutions in this Dynamic Regulatory Environment

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Innovation**

Disclosures

No conflicts of interest to disclose

Outline



US Research Enterprise



Reproducibility “Crisis”



Retractions of scholarly publications



Public trust in Science



Federal Funding



Recommendations



Call to Action

U.S. Research Enterprise

U.S. R&D AND INNOVATION IN A GLOBAL CONTEXT: THE DATA DASHBOARD

Gross domestic Expenditure on R&D (GERD) is a measure of the total amount of R&D expenditure in a country. The measure can be looked at through various units of measure, as well as separated by type of entity that funded the R&D.

Data is provided through the OECD MSTI dashboard, accessed April 2025

Funder

- All
- Business
- Government
- Higher Education

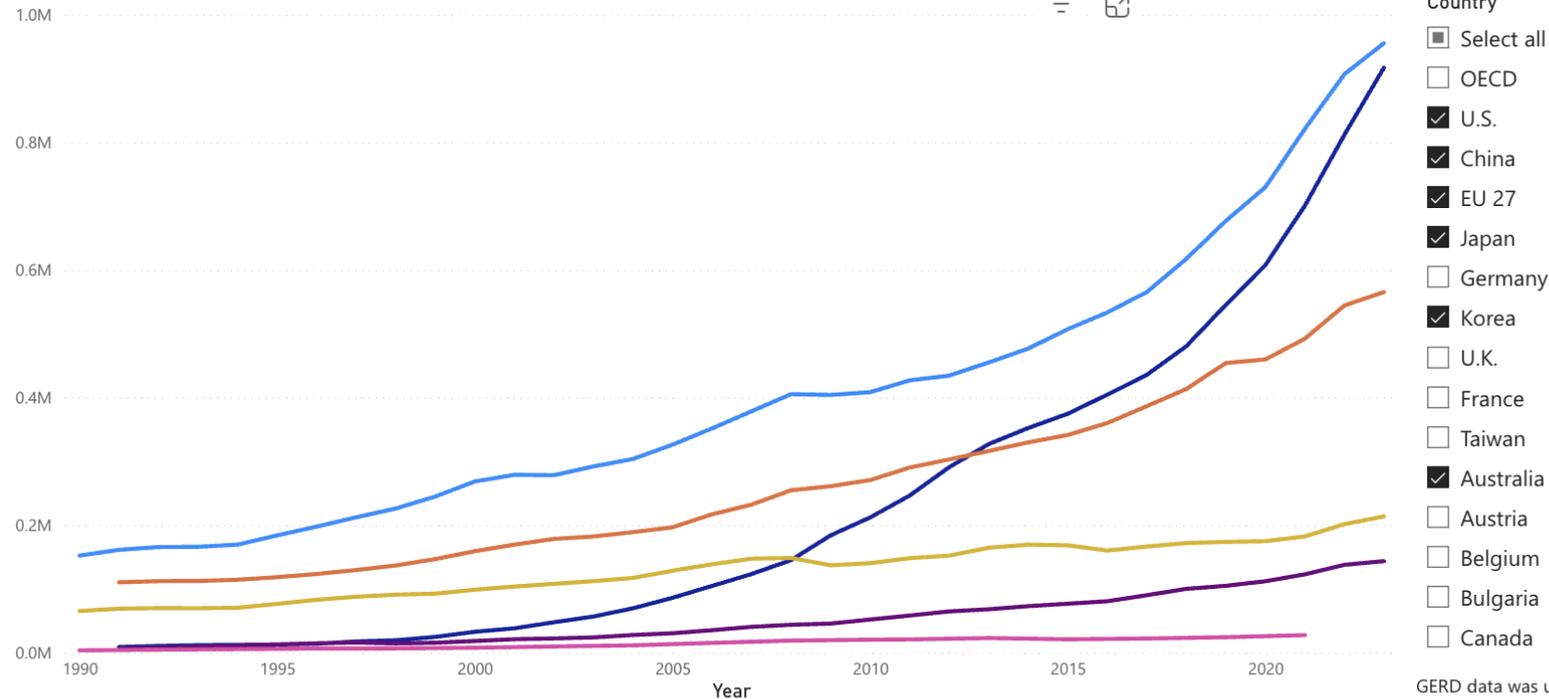
Unit of Measure

- As a Percent of GDP
- Constant, 2020
- Current
- Growth Rate



Constant and Current dollars are presented in millions of US Dollars, with PPP
Percent of GDP is presented as a fraction (1= 100%)

GERD



GERD data was used to generate figures for section 1 and 2 of the [report](#).

- Intro
- Total R&D**
- Govt R&D
- Business R&D
- Basic R&D
- Personnel
- Publications
- Patents

U.S. Research Enterprise

U.S. R&D AND INNOVATION IN A GLOBAL CONTEXT: THE DATA DASHBOARD

Top Publications are calculated as the top 1% most cited publications in their field for any given year, so long as each paper receives at least 3 citations. This lower threshold aims to remove volatile fields from the highly cited lists. Top paper counts by country are provided for a selection of S&E fields.

Data is provided by Clarivate's Essential Science Indicators, accessed April 2025.



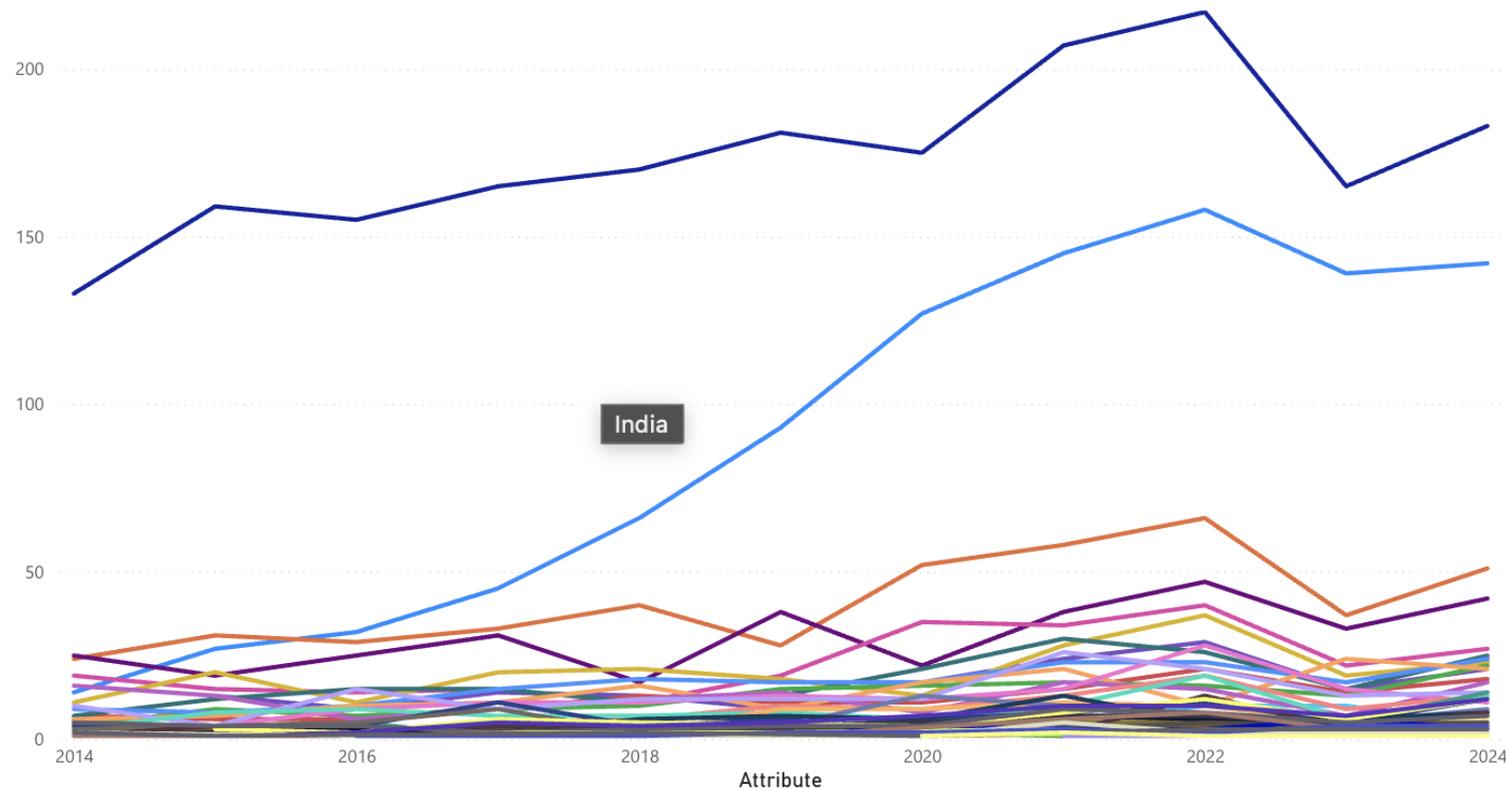
Topic

- All
- Biology
- Chemistry
- Computer Science
- Math
- Medicine- General & Internal
- Medicine- Research & Experimental
- Physics

Country

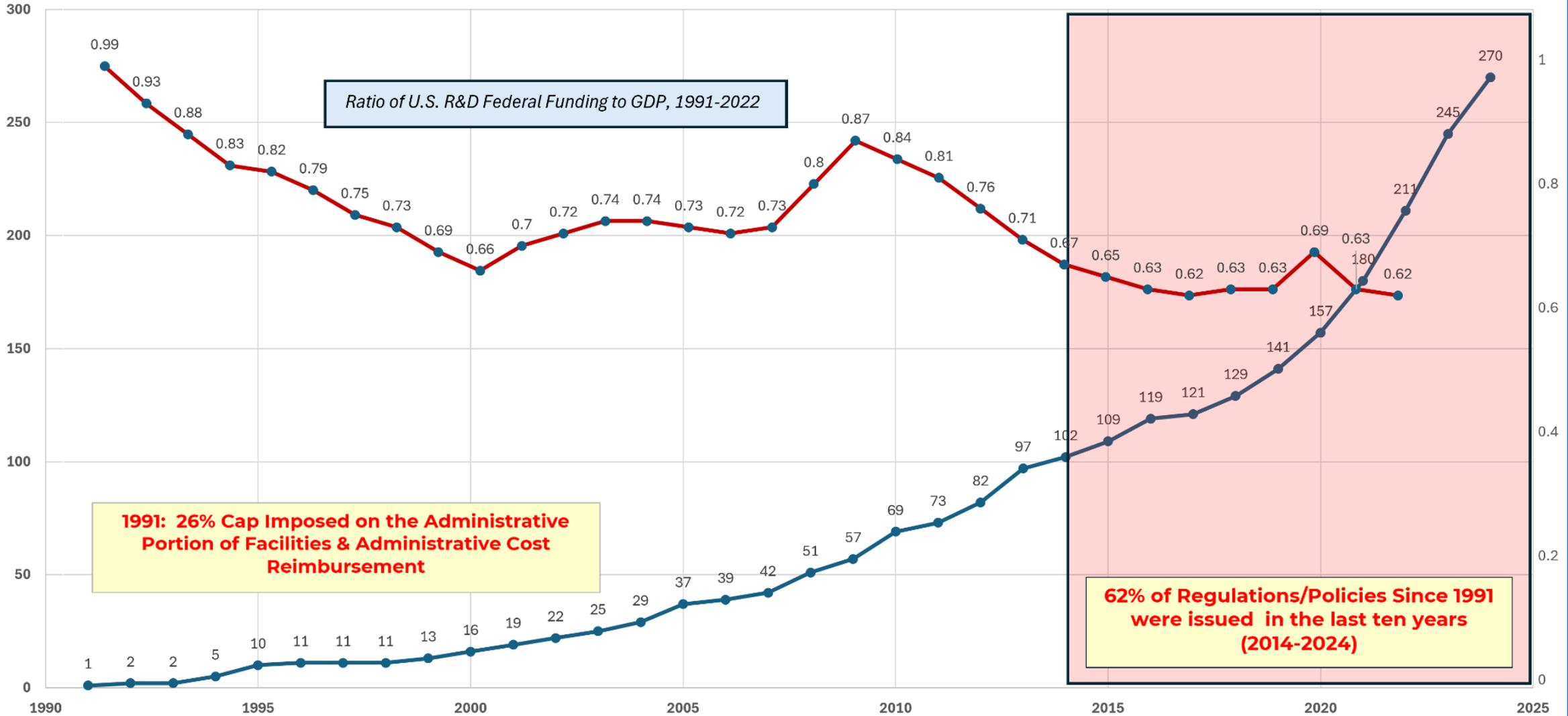
- Select all
- China
- U.S.
- U.K.
- Germany
- Italy
- Australia
- Canada
- India
- France
- Spain

Top 1% Publications



Publication data was used to generate the figures in section 4 of the [report](#).

Regulations & Policies Adopted or Substantially Modified & Changes in Interpretation Affecting Federal Research. Cumulative Since 1991.



Integrity leads to Impact



Reproducibility

Scientific reproducibility refers to the ability of an independent researcher or team to replicate the results of a scientific study using the same methods, data, and conditions. It's a cornerstone of scientific integrity and progress.



The Reproducibility Crisis in Science

A significant portion of published scientific findings cannot be reliably replicated.

- **Causes include pressure to publish, poor experimental design, selective reporting, and lack of transparency.**
- **Consequences include wasted resources, diminished public trust, and high failure rates in fields like preclinical biomedical research.**
- **Emergence of metascience aims to improve research practices and reproducibility.**

References:

Cobey, K. D., et al. (2024). Biomedical researchers' perspectives on the reproducibility of research. *PLOS Biology*, 22(11), e3002870. <https://doi.org/10.1371/journal.pbio.3002870>

Randall, D., & Welser, C. (2018). The irreproducibility crisis of modern science: Causes, consequences, and the road to reform. National Association of Scholars. <https://www.nas.org/reports/the-irreproducibility-crisis-of-modern-science/full-report>

Simkus, A., et al. (2025). Statistical perspectives on reproducibility: Definitions and challenges. *Journal of Statistical Theory and Practice*, 19, Article 40. <https://doi.org/10.1007/s42519-025-00459-x>

Begley, C. G., & Ellis, L. M. (2012). Drug development: Raise standards for preclinical cancer research. *Nature*, 483(7391), 531–533. <https://doi.org/10.1038/483531a>



Prevalence and Institutional Gaps

- **A 2023 scoping review found replication success rates below 40% in some fields.**
- **Nature survey of ~9,500 researchers: Over 70% of scientists failed to reproduce another researcher's results.**
- **72% of biomedical researchers believe there is a reproducibility crisis; 27% call it 'significant'.**
- **Only 16% report institutional procedures to enhance reproducibility.**
- **83% say replication studies are harder to fund than novel research.**

Baker, M. (2016). 1,500 scientists lift the lid on reproducibility. *Nature*, 533(7604), 452–454. <https://doi.org/10.1038/533452a>

Cobey, K. D., Ebrahimzadeh, S., Page, M. J., Thibault, R. T., Nguyen, P.-Y., Abu-Dalfa, F., & Moher, D. (2024). Biomedical researchers' perspectives on the reproducibility of research. *PLOS Biology*, 22(11), e3002870. <https://doi.org/10.1371/journal.pbio.3002870>



U.S. Government's Response to the Reproducibility Crisis

- **May 2025 Executive Order: 'Restoring Gold Standard Science' mandates transparency, reproducibility, and ethical rigor in federally funded research.**
- **OSTP issued guidance requiring agencies to report how reproducibility is reflected in funding and review practices.**
- **NIH's Rigor and Transparency policy integrates reproducibility into grant reviews and encourages validation and replication studies.**
- **NSF promotes reproducibility through funding, training, and institutional reforms.**

References:

White House. (2025). Executive Order on Restoring Gold Standard Science.

National Institutes of Health. (2024). Rigor and Transparency Policy. <https://grants.nih.gov/policy/reproducibility/index.htm>

National Science Foundation. (2022). Dear Colleague Letter: Reproducibility and Replicability in Science. <https://www.nsf.gov/funding/opportunities/dcl-reproducibility-replicability-science>

Office of Science and Technology Policy. (2025). Agency Guidance on Scientific Integrity and Reproducibility.



Retractions of scholarly literature

Scholarly retractions are formal withdrawals of published academic work due to errors, misconduct, or ethical concerns.

They play a vital role in maintaining the integrity of the scientific record, but they also raise important questions about credibility, accountability, and systemic vulnerabilities in research.



Retraction Trends Over the Past Decade

- **Over 10,000 research papers retracted in 2023 — a record high.**
- **Retraction rates have tripled compared to a decade ago.**
- **Highest rates observed in China, Saudi Arabia, Pakistan, and Russia.**
- **Life sciences, especially cancer biology, are most affected.**

References:

Retraction Watch. (2023). Annual Retraction Index. <https://retractionwatch.com>

Else, H. (2023). Publishers withdraw more than 10,000 papers for manipulated peer review. *Nature*. <https://doi.org/10.1038/d41586-023-02075-2>

Thorp, H. H. (2024). Trust edges up—slightly. *Science*, 386(6724), 83 1. <https://doi.org/10.1126/science.adu7081>



Causes and Impact of Retractions

- **Common causes: honest error, plagiarism, data fabrication, peer-review manipulation.**
- **Rise of 'paper mills' producing fraudulent research.**
- **Improved detection via AI tools and watchdogs like Retraction Watch.**
- **Impact: credibility crisis and erosion of public trust in science.**

References:

Retraction Watch. (2023). Annual Retraction Index. <https://retractionwatch.com>

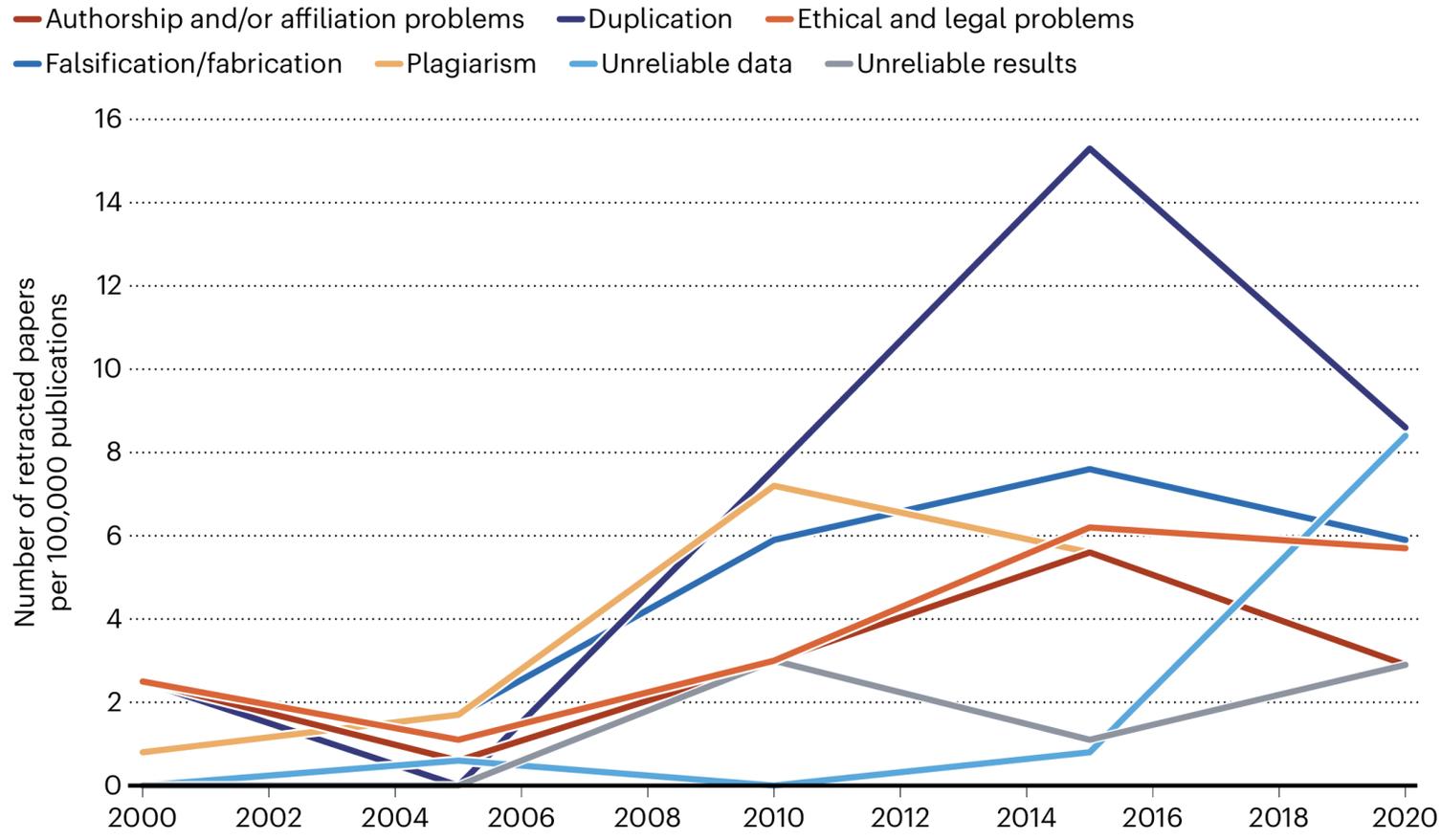
Else, H. (2023). Publishers withdraw more than 10,000 papers for manipulated peer review. *Nature*. <https://doi.org/10.1038/d41586-023-02075-2>

Thorp, H. H. (2024). Trust edges up—slightly. *Science*, 386(6724), 831. <https://doi.org/10.1126/science.adu7081>

Retractions and misconduct

MISCONDUCT RETRACTIONS

The number of biomedical research papers retracted because of reasons related to misconduct has risen since 2000.



References:

Else, H. (2023). Publishers withdraw more than 10,000 papers for manipulated peer review. *Nature*. <https://doi.org/10.1038/d41586-023-02075-2>
F. Freijedo-Farinas et al. *Scientometrics* 129, 2867–2882; 2024

Public's trust in science



Decline During the Pandemic

- **Trust peaked early in COVID-19, then declined**
- **U.S. adults with 'great deal' of confidence in scientists:**
 - 39% in 2020 → 23% in 2023
- **Positive impact perception dropped:**
 - 73% pre-pandemic → 57% in 2023

Polarization and Political Influence

- **Trust increasingly polarized by political affiliation**
- **Democrats show higher trust than Republicans**
- **Political rhetoric and leadership influenced perceptions**
- **Scientific institutions face scrutiny during Trump era**



Global Perspective

- **Trust in scientists remains moderately high globally**
- **Varies by region and influenced by:**
 - Transparency
 - Integrity
 - Alignment with public priorities
- **Misinformation and populism contribute to skepticism**

Wellcome Global Monitor (2020). Trust in science and scientists globally.
National Science Board (2022). Science and Engineering Indicators: Public Attitudes and Understanding.



Public Trust in Science: A Fragile Recovery

Key Findings from Pew Research (Oct 2024):

- 76% of Americans express confidence in scientists (up from 73% in 2023).
- Partisan divide persists:
 - Democrats: 88% trust scientists; 61% want more policy influence.
 - Republicans: 66% trust scientists; 64% prefer scientists stay out of policy debates.

Perceptions of Scientists:

- 89% view scientists as intelligent.
- **Only 45% see them as good communicators.**
- Traits like social awkwardness (49%) and superiority (47%) remain concerns.

Rebuilding Trust & Engagement

Challenges:

- Lingerinɡ skepticism from the pandemic era.
- Misconceptions shaped by media and cultural stereotypes.

Opportunities:

- **Strategic engagement: Scientists must balance objectivity with societal dialogue.**
- **Katharine Hayhoe: “Engaging with society isn’t a betrayal of science; it’s a fundamental part of its purpose.”**

Call to Action:

- **Foster transparency, empathy, and ethical responsibility.**
- **Invest and reward quality**
- **Communicate science with clarity and humanity.**

Federal Funding of Research & Development

Generational changes could occur



Major Budget Reductions are possible

Proposed FY26 Federal Budget

- **National Science Foundation (NSF): 57% cut**
- **National Institutes of Health (NIH): 40% cut**
- **NASA Science Programs: 47% cut**
- **Department of Energy Office of Science: 14% cut**
- **National Institute of Standards and Technology (NIST): 28% cut**

American Association for the Advancement of Science. (2024). Trump administration proposes deep cuts to federal science funding. *Science Policy Review*, 12(1), 45–52. <https://doi.org/10.1126/sciadv.abc1234>

Shift in Research Priorities

- **Deprioritization of climate and equity research.**
- **Emphasis on strategic technologies:**
 - Artificial Intelligence
 - Quantum Computing
 - Advanced Manufacturing
 - Biosecurity and Space Exploration
- **Preference for applied science over basic research.**

National Security Focus

Increased funding for defense-related R&D.

Encouragement for universities to align with national security goals.

Structural Changes

Agency consolidation for centralized oversight.

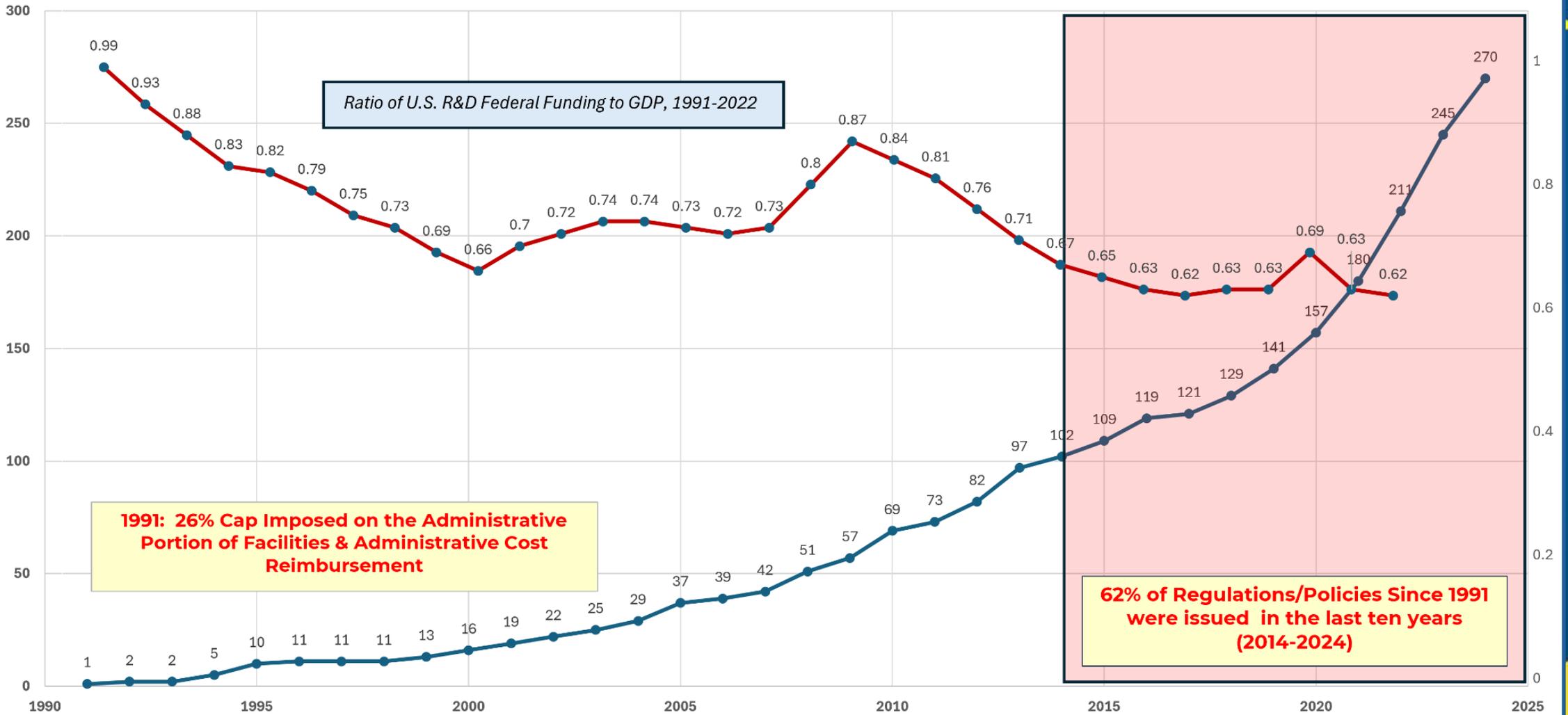
Greater emphasis on public-private partnerships and translational research.

F&A (Indirect) Rates

The Facilities and Administrative (F&A) costs of research are also referred to as the “indirect costs”, "overhead" of research

- **expenses that are difficult to attribute to specific research projects on an individual basis** (e.g., libraries, physical lab operation and maintenance, utility costs, security, and other similar needs).
- Drexel University's indirect costs support includes, but not limited to:
 - Core lab and equipment
 - Library
 - Office of Research and Innovation
 - Research Accounting Services
 - General purpose hardware, electronics, services
 - Utilities
 - Office of General Counsel
 - IT
 - Office Supplies
 - Rental, repair, and maintenance of buildings

Regulations & Policies Adopted or Substantially Modified & Changes in Interpretation Affecting Federal Research. Cumulative Since 1991.



Changes to Federal Indirect Cost Model

Proposed Changes

- **Uniform 15% cap on indirect cost rates across federal agencies**
- **Replaces previously negotiated rates (e.g. 8–52%)**

Potential Impacts

- **Budget shortfalls for institutions**
- **Staff reductions and infrastructure cuts**
- **Critics argue the cap undervalues true research costs**

Introduction to the FAIR Model

- **FAIR: Fiscal Accountability in Research**
- **Developed by Joint Associations Group (JAG)**
 - Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Association of American Medical Colleges (AAMC), American Council on Education (ACE), Association of Independent Research Institutes (AIRI), Council on Governmental Relations (COGR), National Association of College and University Business Officers (NACUBO), National Association of Independent Colleges and Universities (NAICU), American Association of State Colleges and Universities (AASCU), Science Philanthropy Alliance (SPA)
- **Aims to improve transparency and reduce administrative burden**



Key Features of the FAIR Model

- **Eliminates** “F&A” terminology and the associated rate proposal preparation by creating **new trackable costing categories** that are easier to understand
- Accommodates **all types and sizes** of institutions
- Increases **accountability and transparency** via explicit costing of key research support
- Clarifies institutional use of **reimbursed funds by tracking costs in specific and allowable categories**
- Aligns project costs with the **type of work** being performed
- Accounts for **geographic cost differentials**
- Funds government-mandated **regulatory compliance**
- Aligns funding structure more closely with that allowed by **private foundations** by treating more items as direct costs
- **Will require changes** to Uniform Guidance ([2 CFR Part 200](#)) and policies



Proposed FAIR Model

Expanded Option		Base Option	
Research Performance Costs (RPC)		Research Performance Costs (RPC)	
Senior Key Personnel (e.g., PIs)	\$\$	Senior Key Personnel (e.g., PIs)	\$\$
Other Personnel (e.g., grad students)	\$\$	Other Personnel (e.g., grad students)	\$\$
Supplies	\$\$	Supplies	\$\$
Publication costs	\$\$	Publication costs	\$\$
Etc...	\$\$	Etc...	\$\$
Essential Research Performance Support (ERPS)		Essential Research Performance Support (ERPS)	
<i>Regulatory Compliance (RC)</i>	\$\$	<i>Regulatory Costs (RC)</i>	\$\$
<i>Award Monitoring, Oversight, and Reporting (AMOR)</i>	\$\$	<i>Award Monitoring, Oversight, and Reporting (AMOR)</i>	\$\$
<i>Essential Research Performance Facilities (ERPF) (% of budget)</i>	%		
<i>Research Information Services (RIS)</i>	\$\$		
General Research Operations (GRO) (% of budget)	15%	General Research Operations (GRO) (% of budget)	15%

Available for all institutions and especially attractive for those with insufficient administrative resources, or lacking the type of research appropriate for, the Expanded Option

10% of total Budget

FAIR Model Adoption Timeline

- Presented to Congress and OMB
- Potential implementation within two years
- Ongoing feedback from academic institutions

Integrity leads to Impact



What is a research institution to do?

Promoting a Culture of Integrity

- **Best practices: data management, preregistration, open science**
- **Training and mentorship programs (students, staff, and researchers)**
- **Institutional policies and whistleblower protections**
- **Team science and shared responsibility**



Promoting a Culture of Integrity

- **Mentors and leaders**
- **Departmental norms and psychological safety**
- **Encouraging speaking up and ethical behavior**

Drexel University's Efforts to Promote Research Integrity and Rigor

- **Policy and Compliance Infrastructure:**

- Redouble our efforts to ensure appropriate Research Policies and Procedures
- Research Compliance & Regulatory Affairs team oversees compliance and ethical standards
 - Human Research Protection Program ensures ethical treatment of human subjects

- **Training and Education Initiatives:**

- Philadelphia Symposium on Research Credibility and Excellence 2018
 - Collaboration with UPenn and Temple University
- Responsible Conduct of Research (RCR) Training – Sept 18, 2025
 - Required for NIH-supported researchers; covers ethics, data management, authorship
- Clinical Research Training Series – March to Sept 2025
 - Covers regulatory administration, informed consent, protocol compliance
- Embrace Metascience efforts

References:

Drexel University. (2025). Office of Research & Innovation. <https://drexel.edu/research/>

Drexel University. (2025). Responsible Conduct of Research Training. <https://drexel.edu/research/compliance/research-integrity/rcr/>

Drexel University. (2025). Clinical Research Training Series. <https://drexel.edu/research/resources/clinical-research-training/>



Metascience: The Science of Science

Definition:

Metascience investigates how scientific research is conducted, communicated, and evaluated—aiming to improve the reliability, efficiency, and integrity of science itself.

Core Focus Areas:

- **Reproducibility & Replication: Can results be independently verified?**
- **Peer Review & Publishing: How do editorial processes shape science?**
- **Incentives & Culture: What drives researchers' choices?**
- **Statistical Rigor: Are methods sound and results trustworthy?**
- **Open Science: Promoting transparency and data sharing**
- **Impact Metrics: Evaluating scientific influence and productivity**

Why It Matters:

- **Identifies biases and inefficiencies**
- **Strengthens scientific credibility**
- **Guides policy and funding decisions**
- **Enhances public trust in science**

Reference:

Ioannidis, J. P. A. (2018). Meta-research: Why research on research matters. *PLoS Biology*, 16(3), e2005468. <https://doi.org/10.1371/journal.pbio.2005468>



How Metascience Improves Research Practices

Research Design

Metascience promotes preregistration, better study design, and transparency.

Peer Review

Metascience evaluates peer review systems and suggests improvements.

Publication

Encourages open access, data sharing, and reporting standards.

Evaluation

Analyzes reproducibility, replicability, and scientific impact.

References:

- Cobey, K. D., et al. (2024). Biomedical researchers' perspectives on the reproducibility of research. *PLOS Biology*, 22(11), e3002870.
- Randall, D., & Welser, C. (2018). The irreproducibility crisis of modern science. *National Association of Scholars*.
- Simkus, A., et al. (2025). Statistical perspectives on reproducibility. *Journal of Statistical Theory and Practice*, 19, Article 40.



Call to Action

Invest in and reward quality



Call to Action

- **What each person can do to uphold integrity**
- **Encourage reflection: 'What would you do if...?'**
- **Promote best practices and incentivize quality research activities**
- **Engage the public**
- **Collective vision for the future of research integrity**

Discussion

Questions or comments?