Simplifying Research Regulations and Policies: Optimizing American Science – A NASEM Report

October 23, 2025

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Simplifying Research Regulations and Policies: Optimizing American Science – A NASEM Report

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Speakers

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NATIONAL ACADEMIES *Sciences Engineering Medicine*

Simplifying Research Regulations and Policies: Optimizing American Science

COGR Membership Meeting

Lisa Nichols, Committee Member

Stacy Pritt, Committee Member

Alex Helman, Study Director

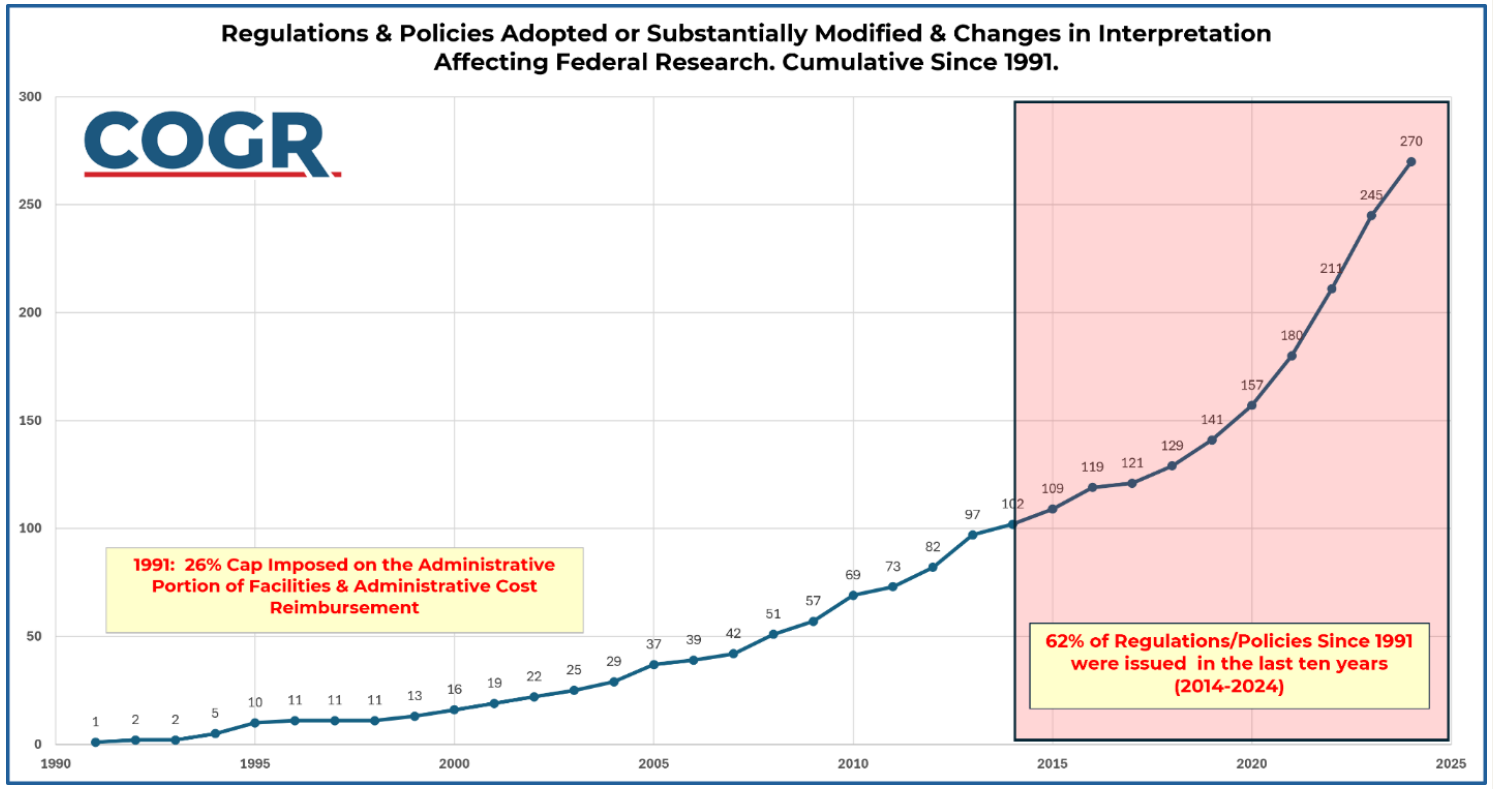
OCTOBER 23, 2025

Background

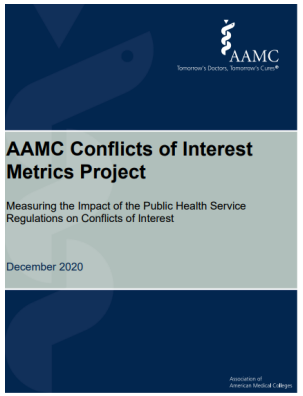
01

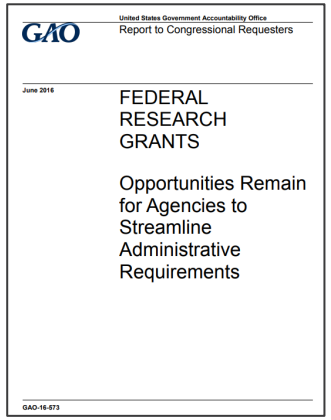
Excessive Regulations and Policies Hinder Innovation

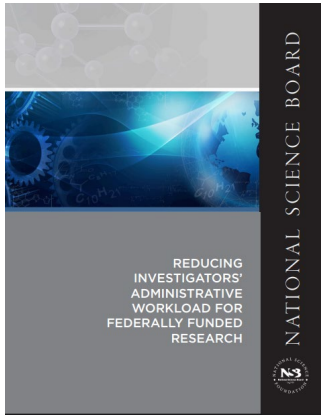
- Regulations are critical to ensure accountability, transparent, ethical, and safe science that is rigorous, reliable, and reproducible
- Excessive, duplicative, and inconsistent policies and regulations are hampering scientific progress and have dramatically increased in the past decade
- Researchers spend 44% of their research time on administrative tasks



Past and Concurrent Efforts







- Many groups have examined this issue before
- Several reports have released guidance and recommendations for simplifying research regulations and policies
- There has been uptake of some recommendations but at an insufficient scale
- Greater concerted effort is needed to drive change

Why Now?

- The U.S. needs science operating at maximum productivity to stay ahead of global competition
- Policy climate is right for optimizing regulation
- AI presents opportunities to further increase efficiency

Statement of Task

The committee will produce a brief report that presents a **menu of prioritized options for federal actions to improve regulatory efficiency affecting researchers and their institutions, including initiatives by the White House and executive agencies or Congress**. The options presented will describe the **anticipated impacts on reducing different types of administrative workload**, noting potential unintended consequences, while minimizing risk to accountability and research performance. Finally, the committee will describe, to the extent possible, **new developments, such as the application of new technologies like artificial intelligence, that could improve administrative efficiency**.

Committee and Staff

Alan Leshner, American Association for the Advancement of Science *(retired)*

David Apatoff, Arnold & Porter LLP *(retired)*

Linda Coleman, Stanford University

Kelvin Droegemeier, University of Illinois Urbana-Champaign

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Jordan Graves, Program Coordinator

Committee Approach

- Held open sessions in May and June
- Call for information open May-July
- Compressed timeline
- Options vs. Recommendations
- Organization

Option 2.2: Ensure a single lead agency has jurisdiction over misconduct allegations for research with multiple funding agencies

Goal:
Increase clarity of which agency's procedures apply for a given misconduct case and reduce duplicative oversight.

Approach:
Current Federal Research Misconduct Policy states that "if more than one federal agency has jurisdiction over allegations of research misconduct, those agencies could work together to designate a lead agency."[a] While this intends to ensure a single agency has oversight over a misconduct case involving research funded by multiple agencies, it is not a requirement. The policy could be changed to require a lead agency and set clear criteria for how a lead agency would be determined.

Pros:
- Reduces uncertainty about which agency guidelines to follow in misconduct cases.
- Prevents potentially having to deal with multiple agency guidelines.

Cons:
- Still allows agency variation in approaches to misconduct.
- Does not prevent differing standards being applied to misconduct allegations based on agency guidelines and policies.

Principles for Regulatory Reform

02

Cross-cutting Principles

1

Harmonize regulations and requirements

Harmonizing regulations and requirements to the greatest extent possible across all agencies. This may require compromising on the type, specificity, and format of information that a given agency requests.

2

Tier new regulations or requirements to the risks involved

Take an approach to compliance that is tiered to risk, where the rigor of regulatory requirements aligns with the level of risk of an activity to society or regulatory objectives.

3

Use technology to simplify compliance to the greatest extent possible

Available technology that leverages artificial intelligence and machine learning can automate and may simplify regulatory compliance processes.

Areas of Research Regulation

- Grant proposals and management
- Research misconduct
- Financial conflicts of interest
- Protecting Research Assets:
  - Research security
  - Export controls
  - Cybersecurity and data management
- Research involving biological agents
- Human subjects research
- Research using nonhuman animals

Options for System-Wide Change

03

Problem: Insufficiently centralized U.S. government oversight of the regulatory environment has led to too many overly complex, duplicative, and occasionally contradictory regulations, requirements, and reporting processes across federal agencies

Overarching Option 1

Establish a permanent function within the Office of Management and Budget (OMB) with the authority to coordinate cross-agency requirements

- OMB could create a permanent *Assistant Director for Institutional Research Coordination and Community Engagement*
- Collaborate with OIRA, OSTP, and use the NSTC to institute harmonization
- Oversee the development of policies and requirements and how agencies implement them and identifying means to accelerate agency implementation when necessary

Overarching Option 2

Appoint a Federal Research Policy Board

- Could consist of representatives from federal funding agencies and academic research institutions
- Could make recommendations concerning the conception, development, and harmonization of policies having similar purposes across research funding agencies
- Authorized in the 21st Century Cures Act, but was never established and congressional authority expired in 2021

Options in Specific Regulatory Areas

04

Grant Proposals and Management

Problem: Inconsistent, complex and burdensome grant processes across federal agencies

Grant Proposals and Management Option 1.1

Introduce a federal-wide, two-stage pre-award process

- Agencies could operationalize a common “letter of intent” (LOI) mechanism across funding opportunities
- Subject-specific review panels would evaluate the LOIs to assess the merit of the proposed research before requesting a full-length proposal
- OIRA could review LOI proposal templates to reduce redundancies and harmonize formats

Grant Proposals and Management Option 1.4

Update cost accounting and financial compliance requirements

- OMB could update and amend the Uniform Guidance to eliminate expectation for filing financial disclosure statements at every transaction in favor of periodic updates on a pre-determined schedule
- OMB could propose a centralized disclosure system that satisfies financial reporting requirements across multiple grants and agencies

Financial Conflict of Interest in Research

Problem: Inconsistent financial conflict of interest (FCOI) in research procedures and requirements

Financial Conflict of Interest Option 3.1

Create a uniform FCOI in research policy

- Federal agencies can be directed to adopt one standard for FCOI in research that mirrors or adopts the National Science Foundation's policy
- Adoption of NSF's FCOI policy will ensure alignment under a proven framework that maintains research integrity

Financial Conflict of Interest Option 3.2

Revert to the earlier $10,000 Public Health Service significant financial interest threshold with periodic adjustments for inflation

- PHS can increase the threshold for significant interest to $10,000
- To account for inflation, PHS could publish an annually updated SFI amount using the notice of opportunity to transition process

Protecting Research Assets

Problem: Fragmented and inconsistent U.S. research compliance that results in conflicting rules, duplicate forms, and divergent risk reviews

Research Security Option 4.1

Implement NSPM-33 common disclosure forms and table without deviation as the primary means to identify CoCs

- Establish federal-wide use of the NSPM-33 pre- and post-award disclosure table, housed on the NSF website
- Additionally, develop federal-wide disclosure FAQs
- Common forms could be uniformly used for identifying conflicts of commitment that should not be addressed in conflict-of-interest policy

Research Security Option 4.2

Use the SECURE Center as an interactive research security information hub

- Make the NSF-funded SECURE Center the central hub for research security resources, communications, and tools
- Build a shared clearinghouse of policies, processes, checklists, FAQs, and training to standardize implementation across institutions
- Add AI-driven dashboards and query tools; use SECURE Analytics to assess risk and prevent foreign interference

Research Misconduct

Problem: There are currently different standards for research misconduct proceedings across agencies, creating inconsistencies and a lack of flexibility

Research Misconduct Option 2.1

Agencies could follow a single, flexible federal misconduct policy

- The Federal Research Misconduct Policy could be revised to provide a single set of flexible requirements for handling research misconduct allegations
- Each federal funding agency could defer to the Federal Research Misconduct Policy and eliminate their separate procedures

Research Misconduct Option 2.2

Ensure a single, lead agency has jurisdiction over misconduct allegations for research with multiple funding agencies

- The Federal Research Misconduct Policy could be changed to require a lead agency to handle misconduct cases with multiple funding agencies, rather than suggesting a lead agency could be designated
- The policy could also be revised to set clear standards for how a lead agency would be determined

Research Involving Biological Agents

Problem: Complex and overlapping regulations for research involving biological agents

Research Involving Biological Agents Option 5.1

Adopt a more centralized, coordinated U.S. government-wide approach to regulating research involving biological agents and toxins

- Establish a single federal lead to register and empower Institutional Biosafety Committees
- Adopt the *Biosafety in Microbiological and Biomedical Laboratories* document as the authoritative guidance for containment and biosafety practices
- Maintain the Federal Select Agent Programs' risk-tiered oversight of high-consequence pathogens

Research Involving Biological Agents Option 5.2

Simplify and harmonize current NIH/Department of Agriculture/CDC guidelines, and exempt low-risk activities

- Review and revise NIH Guidelines and BMBL to eliminate unnecessary oversight for activities that pose minimal risk.
- Remove redundant review, approval and reporting requirements to save researchers and institutions time without compromising safety.
- Continue periodic evaluations of covered agents by the Federal Select Agent Programs to ensure oversight remains relevant and risk-based.

Human Subjects Research

Problem: Single-IRB implementation hurdles for multisite studies

Human Subjects Research Option 6.9

Develop federal guidance clarifying institutional responsibilities under the single IRB policy

- Led by HHS, federal agencies could develop and disseminate clear guidance clarifying the distinct roles and responsibilities of single IRBs versus institutional oversight obligations
- Guidance could address common issues such as managing "local context" requirements, reporting mechanisms, and delineating what remains under institutional purview

Human Subjects Research Option 6.11

Encourage adoption of SMART IRB recommendations and local context tools

- Continue and expand federal support for the development, refinement, and dissemination of SMART IRB harmonization guidelines
- Federal agencies requiring or supporting single IRB could actively encourage and support institutions and IRBs in adopting these guidelines and tools

Human Subjects Research

Problem: Limited guidance on integrating non-human-subjects requirements within human research protection programs

Human Subjects Research Option 6.15

Establish a federal integration task force with clear authority and timelines

- OSTP or OMB could coordinate a cross-agency task force to review the intersection of human subjects regulations and oversight in data security, research security, export controls, and privacy regulations
- The task force could clarify how intersecting non-human subjects regulations should integrate with human subjects oversight

Human Subjects Research Option 6.16

Develop a federal interactive compliance integration tool

- Federal agencies could jointly develop an interactive, web-based digital tool that helps institutions, IRBs, and investigators determine which non-human subjects federal requirements apply to specific protocols
- The tool could provide advice on how to integrate these requirements into Human Research Protection Program workflows

Research Using Non-human Animals

Problem: Burdensome and overly detailed NIH OLAW requirements due in part to an overly stringent interpretation of the *Guide for the Care and Use of Laboratory Animals*

Research Using Non-human Animals Option 7.4

Streamline guidance to only the PHS Policy and *the Guide*, and interpret *the Guide* as it was intended

- Use the two required documents, PHS Policy and *the Guide*, as the main guidance from OLAW and eliminate multiple paperwork-based requirements
- Provide institutions the flexibility to interpret and use *the Guide* as intended
- Clarify any guidance that remains does not have legal or regulatory authority

Research Using Non-human Animals Option 7.5

Update digital infrastructure and Animal Welfare Assurance Processes for OLAW in alignment with analogous HHS oversight offices

- Align OLAW processes with other HHS office entities that also require assurances or registrations, including OHRP, ORI, and OSP
- These offices utilize digital platforms for registration and assurance reviews and have streamlined the information required; OLAW could mirror this approach to reduce time spent on assurances

Final Thoughts

05

- Regulations and requirements have proliferated without sufficient checks, resulting in uncoordinated and duplicative requirements
- A comprehensive reexamination is needed to ensure regulations and policies continue to support the integrity, security, transparency, and ethical conduct of research
- Leveraging emerging technologies, such as AI, can help increase efficiency
- Balancing oversight and reducing administrative workloads can liberate and catalyze needed scientific discovery and innovation

Thank You for Listening

- Continuing dissemination through June of 2026
- Briefings include: OSTP, OMB, Congressional staff, FDP
  - Others will be rescheduled post-shutdown
- Reach out to ahelman@nas.edu

NationalAcademies.org/Research-Regulations

Poll Everywhere

Pollev.com/cogrstaff949 Ask a question from your seat!

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