COGR℠
Advancing Effective Research Policy

December 23, 2025

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White House Office of Science and Technology Policy
Submitted Electronically: *http://www.regulations.gov*

RE: Office of Science and Technology Policy (OSTP) Request for Information - Accelerating the American Scientific Enterprise (Docket ID No. OSTP-TECH-2025-0100)

Dear Deputy Chief Murphy:

We write to provide information in response to the OSTP's request for information, Accelerating the American Scientific Enterprise (the "RFI"), published in the Federal Register on November 26, 2025 (90 FR 54412).

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 230 research universities and affiliated academic medical centers and research institutes. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

COGR appreciates the opportunity to provide information responsive to the RFI. We strongly support OSTP's objective of strengthening American competitiveness through the continued support and expansion of a robust scientific enterprise, while reducing administrative burdens and modernizing research policy. In Appendix A accompanying this letter, we respond to specific questions in the RFI. The listed question numbers refer to the RFI's numbering.

We are committed to advancing the federally sponsored research that underpins the nation's research enterprise and its vital contributions to America's security, health, and economic competitiveness. We stand ready to share our expertise and work collaboratively with OSTP to ensure federal research policies are effective, clearly implemented, and aligned with the shared goal of advancing science in the public interest.

Sincerely,

M. M. Owens

Matt Owens
President

APPENDIX A

(i) What policy changes to Federal funding mechanisms, procurement processes, or partnership authorities would enable stronger public-private collaboration and allow America to tap into its vast private sector to better drive use-inspired basic and early-stage applied research?

More effective collaboration across the research ecosystem requires federal policies that provide clear, consistent, and harmonized partnership authorities that align with long-standing statutes such as the Bayh–Dole Act. The proliferation of non-standard mechanisms, including other transaction authority (OTA)-based agreements, cooperative agreements with specialized terms, and bespoke program requirements, creates complexity for both researchers and administrators. Standardizing baseline terms and offering consistent templates would meaningfully reduce administrative burden, streamline partnerships and negotiations, and allow involved parties to devote more resources to conducting research rather than navigating compliance inconsistencies.

The Federal Demonstration Partnership (FDP) Faculty Workload Survey has consistently shown that principal investigators at academic research institutions spend over 40% of their research time on administrative tasks,[1] rather than mentoring students, conducting experiments, or engaging in collaboration. Policies that reduce duplicative reporting, harmonize requirements across agencies, and eliminate unnecessary documentation directly improve universities' ability to engage in partnerships at scale.

More importantly, effective partnerships require an indirect cost recovery model that reimburses universities for the full, actual cost of research. Institutions have long provided significant subsidies for the conduct of federal research at their facilities.[2] Further reductions in indirect cost rates will make the performance of federal research financially unsustainable for many institutions and severely reduce the number of high-performing recipients who can afford to obtain the talent, materials, equipment, and facilities necessary to carry out advanced research projects that fulfill national research priorities.

(ii) How can the Federal government better support the translation of scientific discoveries from academia, national laboratories, and other research institutions into practical applications? Specifically, what changes to technology transfer policies, translational programs, or commercial incentives would accelerate the path from laboratory to market?

To strengthen the translation of academic and national laboratory discoveries into practical applications, academic research institutions need federal policies that reinforce, not weaken, the technology transfer system. Reaffirming the principles of the Bayh–Dole Act and rejecting proposals that would impose a federal claim on licensing revenues is critical to sustaining the staffing, patenting, compliance, and commercialization infrastructure that academic research institutions must maintain to help move discoveries to the marketplace.

Bayh–Dole already requires that licensing revenue be used for public benefit. Statutorily, universities are required to share royalties with inventors, and all remaining revenue must be reinvested into

[1] *See*, 2007, 2012, and 2018 Faculty Workload Surveys at Faculty Workload Survey - The Federal Demonstration Partnership.

[2] See, American Association of Universities, Frequently Asked Questions about Facilities and Administrative (F&A) Costs of Federally Sponsored University Research at Question 3 (accessed Dec. 7, 2025). Federal data show that colleges and universities pay for 25 percent of total academic R&D expenditures from their own funds. This university contribution amounted to $37.3 billion in FY23, including $6.8 billion in reimbursed F&A costs."

research, education, and commercialization activities.[3] These funds support patent protection, translational research, technology transfer operations, startup formation, and entrepreneurship programs. Universities use licensing income to fill gaps in the innovation pipeline that federal grants and contracts do not cover, especially the costly and high-risk early stages of commercialization. A federal claim on this revenue would significantly weaken institutions' ability to comply with Bayh–Dole's core objectives. It would impede, rather than enhance, the translation of federally funded discoveries for public benefit.

Instead, early-stage technologies would greatly benefit from expanded funding for: translational research programs (including proof-of-concept funding), prototyping support, and programs such as the National Science Foundation's Innovation Corps (I-Corps) and the National Institutes of Health's Research Evaluation and Commercialization Hubs (REACH). Such efforts have proven to be successful. According to NSF, the I-Corps program has trained more than 5,800 individuals and launched more than 1,400 startups that have raised over $3.16 billion in follow-on funding since the program's inception.[4]

Meaningful federal support for innovation intermediaries, including university technology transfer offices, incubators, accelerators, and entrepreneurial training programs, would meaningfully accelerate the path from laboratory to market.

(iii) What policies would encourage the formation and scaling of regional innovation ecosystems that connect local businesses, universities, educational institutions, and the local workforce—particularly in areas where the Federal government has existing research assets like national laboratories or federally-funded research centers?

Universities already serve as foundational anchors for regional innovation ecosystems, a role well documented by the Heartland Forward's *Research to Renewal: Advancing University Tech Transfer* report[5], which concludes that universities' educational, research, and technology transfer activities are often the strongest predictors of local business creation, wage growth, and knowledge-intensive economic activity. The federal government can further strengthen these ecosystems by providing universities with effective, efficient policies that offer stability and predictability, thereby reducing the obstacles to expanding this catalytic role. Reducing administrative barriers would enable universities to effectively engage small and medium-sized firms, rural communities, and civic partners.

Additionally, federal investment in shared research infrastructure such as testbeds, prototyping facilities, and workforce-training centers would enhance regional capacity to attract and scale innovation-driven enterprises, particularly in areas where federal research assets are already present.

Numerous successful federal investments have already demonstrated the impact of this approach. For example, federally supported facilities like the Cornell NanoScale Science and Technology Facility, part of the National Nanotechnology Coordinated Infrastructure, provide shared cleanroom and nanofabrication capabilities that have helped launch startups and strengthen advanced-manufacturing ecosystems across upstate New York. Similarly, the DOE Manufacturing Demonstration Facility at Oak Ridge National Laboratory has enabled companies of all sizes to collaborate with researchers on advanced composites, additive manufacturing, and robotics prototyping—capabilities that universities then integrate into regional manufacturing partnerships and workforce training programs. In the mobility sector, the federally supported M-City autonomous vehicle testbed at the University of Michigan has accelerated the development of automotive and

[3] See, 35 U.S.C. § 202(c)(7)
[4] www.nsf.gov/funding/initiatives/i-corps/impact-data
[5] https://heartlandforward.org/case-study/research-to-renewal-advancing-university-tech-transfer/

mobility startups while drawing significant private-sector investment to the region.

By expanding and sustaining investments like these, particularly in communities that already host federal research assets, the federal government can significantly enhance universities' capacity to drive regional innovation, economic development, and workforce opportunities.

(iv) How can Federal policies strengthen the role played by small- and medium-sized businesses as both drivers of innovation and as early adopters of emerging technologies?

Academic research institutions rely heavily on mutually beneficial relationships with small and medium-sized businesses (SMBs), both as partners in federally funded research and as licensees that help commercialize early-stage technologies. According to AUTM data, in 2021, approximately 78% of new university technology licenses or options were executed by small businesses (under 500 employees) or startups[6], underscoring the critical role SMBs play in bringing federally funded innovations to the marketplace. Federal policies that streamline the SBIR and STTR award process and simplify conflict-of-interest requirements would make it easier for SMBs to collaborate with academic researchers, accelerating the development of products resulting from federally funded research. Increased support for university-affiliated incubators and accelerators could give SMBs access to scientific expertise, equipment, and entrepreneurial coaching that would otherwise be cost-prohibitive. Additionally, federal programs that incentivize SMBs, such as federal tax incentives that enhance R&D credits or tax offsets for companies that commercialize early-stage academic inventions, to adopt and pilot emerging technologies developed by academic research institutions would help bridge the "valley of death" between prototype and market-scale validation. Strengthening these partnerships would expand innovation capacity and provide critical commercialization pathways for university research outcomes.

(viii) How can the Federal government leverage and prepare for advances in AI systems that may transform scientific research—including automated hypothesis generation, experimental design, literature synthesis, and autonomous experimentation? What infrastructure investments, organizational models, and workforce development strategies are needed to realize these capabilities while maintaining scientific rigor and research integrity?

AI is dramatically transforming the way research and research administration are conducted. Yet, the technology also raises concerns about research integrity and rigor, such as those expressed by NIH in its recent notice, Supporting Fairness and Originality in NIH Research Applications.[7] NIH stated that it "will not consider applications that are either substantially developed by AI, or contain sections substantially developed by AI, to be the original ideas of applicants." Yet, this blanket prohibition does not adequately account for the range of AI and its potential legitimate uses; for example, should a researcher-developed AI application that the researcher applies solely to his or her own research data sets to develop a protocol be evaluated in the same manner as a protocol developed by using a commercial AI tool applied to public data on the internet? Accordingly, one of the most important steps that the federal government can take to facilitate the effective and appropriate use of AI would be to work with stakeholders to establish a clear and consistent set of expectations across all research funding agencies for the way in which AI may or may not be used in (a) preparing research proposals and (b) conducting research. This resource should include consistent definitions for common terms and clear statements about scope and applicability of federal requirements, as well as account for differences in both the type of AI tools that are used and the data to which they are applied.

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[6] Table Inv-3, National Center for Science and Engineering Statistics, "Invention, Knowledge Transfer, and Innovation." (Published February 29, 2024)

[7] NOT-OD-25-132 (Jul. 17, 2025).

(ix) What specific Federal statutes, regulations, or policies create unnecessary barriers to scientific research or the deployment of research outcomes? Please describe the barrier, its impact on scientific progress, and potential remedies that would preserve legitimate policy objectives while enabling innovation.

COGR provided a detailed table listing specific federal regulations, policies, and requirements that impede scientific research without producing concomitant benefits in our response to the Office of Management and Budget (OMB) request for information on May 7, 2025.[8] The table identifies each requirement, its authority, and its intended goal. It also describes why the requirement is duplicative, outdated, or overly burdensome, and provides suggestions for improving efficiency. We include, as Appendix B, a table containing the same relevant information submitted in our response to OMB's request for information, provided for OSTP's consideration of specific federal requirements that should be modified or removed.

(xii) What policy mechanisms would ensure that the benefits of federally-funded research—including access to resulting technologies, economic opportunities, and improved quality of life—reach all Americans?

Any federal policy aimed at ensuring that the benefits of federally funded research reach the public must effectively balance the spectrum of research outputs, including both commercializable innovations and non-commercializable results such as publications and data. While the former research outcomes are critical drivers of economic growth, job creation, and national competitiveness, the latter outputs are equally essential as foundational building blocks for future innovation and as direct contributors to improvements in health, safety, and quality of life.

Public access and data sharing policies implemented by federal funding agencies are intended to ensure that results and findings from federally funded research are made available to the public, but because they fail to adequately address publishing costs and/or to provide real incentives for publishers to lower those costs, they may have the perverse impact of reducing the number of publications. For example, NIH recently issued an RFI on Maximizing Research Funds by Limiting Allowable Publishing Costs[9] that included for comment proposals that would disallow all publication costs or set various limits on what can be paid per publication and/or for all publications.

Unfortunately, these proposals do nothing to address the trends at publishers to increase revenue via increased article processing charges (APCs) for publication in Open Access (OA) journals and move to hybrid journals that have higher APCs, or to improve transparency about additional publication fees that authors must pay above and beyond published APCs.[10] Instead, they merely shift even more of the publication cost burden to researchers and institutions, which, when considered in today's overall trend of less research cost recovery, will ultimately lead to fewer publications. Accordingly, OSTP should consider policy initiatives that will address the root causes of reduced publication access, including actions that financially support the development of effective publication mechanisms by academic research institutions and scholarly societies, while still providing robust peer review and editorial support. Further, OSTP should also consider developing measures that promote full transparency from publishers about all costs associated with publishing articles in Open Access journals.

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[8] FR Doc.2025-06316 (April 11, 2025)
[9] NOT-OD-25-138 (Jul. 30, 2025).
[10] *See, generally,* D. Pollock and H. Staines, News & Views: Open Access Charges – Price Increases Back on Trend (Mar. 13, 2025); S. Haustein, et. al., "Estimating global processing charges paid to six publishers for open access between 2019 and 2023," (submitted Jul. 23, 2024) at https://doi.org/10.48550/arXiv.2407.16551.

Place-based investments, such as regional innovation hubs anchored by universities, national laboratories, and local industry, help distribute the economic and societal returns of research beyond traditional innovation centers. Expanded support for proof-of-concept, prototyping, and translational research programs enables early-stage discoveries to progress toward practical application. At the same time, targeted capacity-building initiatives allow a broader range of institutions, including regional universities and minority-serving institutions, to participate meaningfully in the research enterprise. Policies that encourage small- and medium-sized business engagement—through streamlined SBIR/STTR pathways, early-adopter procurement incentives, and tax incentives for licensing and deploying university-developed technologies—can accelerate commercialization and local job creation. At the same time, sustained federal investment in university technology transfer offices, incubators, accelerators, and shared testbeds lowers barriers to market entry and supports community-based entrepreneurship.

(xiii) How can the Federal government strengthen research security to protect sensitive technologies and dual-use research while minimizing compliance burdens on researchers?

Institutions of higher education remain fully committed to strengthening research security while preserving openness and collaboration that are fundamental to scientific progress. To achieve these dual aims, federal policy should prioritize the reaffirmation of the principles of National Security Decision Directive (NSDD) – 189[11] and the harmonization of security and disclosure requirements across agencies. Currently, academic research institutions must navigate overlapping and inconsistent foreign engagement reporting obligations, foreign influence reviews applied even to low-risk research or previously-encouraged collaborations, and cybersecurity regulations that are not calibrated for open-access policies. A harmonized, risk-based, proportional approach would better align protections with actual vulnerabilities while enabling universities to sustain global collaborations that advance U.S. scientific leadership.

An effective federal research security policy that minimizes compliance burdens on researchers must be risk-based and proportionate. Eliminating duplicative requirements, aligning security controls with actual risk, and issuing clear, practical implementation guidance with reasonable timelines would enable universities to meet national security objectives while preserving the openness, international partnerships, and scientific excellence that drive the nation's innovation enterprise.

[11] Reaffirmation of NSDD-189 is one of the recommendations made by the Jason Report (Published December 6, 2019)

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APPENDIX B

TOPIC	REGULATION & SOURCE AUTHORITY	INITIAL GOAL(S)	ISSUE/WHY IT'S NOT WORKING	IMPROVING EFFICIENCY
Biosketch and Current and Pending Support Reporting Requirements	NDAA 2021 Section 223, https://www.congress.gov/116/plaws/publ283/PLAW-116publ283.pdf p. 3470	Develop a single format, across all agencies, for researchers to provide their professional credentials and other research funding.	Not all agencies have implemented the NSTC Common forms. Those that have implemented the forms require non-standard data elements. Lack of harmonization across agencies creates inefficiency, impeding full automation and complicating training efforts. The federal system ideal for automating these forms (i.e., SciENcv), has only been implemented by NSF. Other agencies have not adopted SciENcv, resulting in inefficiencies in automating compliance. Definition of "gifts" that can be excluded from reporting does not conform with definition of "gifts" used by the Internal Revenue Service.	Implement the final NSTC forms across all agencies without variation. Develop and share a single database regarding PI profiles (i.e., SciENcv) and sponsored activities, and require all agencies to use it. Require agencies to populate SciENcv with current and pending support from all federal granting agencies to eliminate the need for recipients to engage in extensive duplicate data entry. Implement APIs for SciENcv to facilitate institution data feeds. Adopt the IRS definition and examples of "gifts" in the context of evaluating funding as a "gift" or "current and pending/other support."
Research Project Proposal Development	NSF PAPPG Proposal Preparation - preparation#d-proposal-contents-171 NIH Grant Proposal Guide – How to Apply - https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide NASA Grant and Cooperative Agreement Manual - https://www.nasa.gov/wp%20-content/uploads/2025/03/gcam-mar-2025.pdf?emrc=982b64 Other federal agencies like USDA, DOE and DOD have unique program-specific guides. Public Law 106-107, also known as the Federal Financial Assistance Management Improvement Act of 1999 - https://www.govinfo.gov/content/pkg/PLAW-106publ107/pdf/PLAW-106publ107.pdf	Provide federal agencies with the information they need to review, evaluate, and select research projects for funding[i].	Every funding agency has its own set of requirements for proposal submission[ii].	Develop a single application and process across all funding agencies. Reduce workload for applicants and agencies by implementing a 2-step process: 1) Reduce the length of the initial research plan proposal to 5 pages or less and link to SciENcv for the PI's professional credentials. 2) If the project is selected for funding, PI would submit additional forms and details if needed. Use fixed amount awards with modular budgets for fundamental research awards of up to $500K/year. See fixed amount awards information below. No additional training will be required unless a project is awarded.
EPA Regulations That Impact Academic Research Facilities	Revision to Toxic Substances Control Act (TSCA) - Revision to Risk Determination for Methylene Chloride - https://www.epa.gov/system/files/documents/2022-11/MC_Final%20Revised%20RD_10.26.22-final%20%281%29.pdf 40 CFR 702 - https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-702	To facilitate health and safety of members of the public exposed to this chemical.	Methylene Chloride (also known as dichloromethane or DCM) is one of the most commonly used solvents in laboratories. The EPA put TSCA revisions in place to comply with Executive Order 13990 (Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis), which the Trump Administration revoked in 2025. https://www.federalregister.gov/documents/2021/01/25/2021-01765/protecting-public-health-and-the-environment-and-restoring-science-to-tackle-the-climate-crisis Methylene chloride is currently regulated under OSHA Regulations at 29 CFR 1919.112. The duplicative regulation by the EPA is unnecessary, particularly in laboratory settings designed to protect workers or where personal protective equipment standards are enforced. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.119	Remove the EPA standard and let the current regulation by OSHA stand as is.

TOPIC	REGULATION & SOURCE AUTHORITY	INITIAL GOAL(S)	ISSUE/WHY IT'S NOT WORKING	IMPROVING EFFICIENCY
Agency support for federal assistance awards, including proposal submission portals, grants management systems, and billing and financial reporting systems.	Lack of implementation for OMB Memorandum M-18-24 Strategies to Reduce Grant Recipient Reporting Burden (2018) https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/09/M-18-24.pdf CAP Goals from the first Trump Administration - https://trumpadministration.archives.performance.gov/CAP/overview/ Numerous proposal submission portals (eRA/ASSIST (NIH) Research.gov (NSF), NSPIRES (NASA), FedConnect (DOE), STRIPES (DOE), eBRAP (DOD CDMRP), grants management system (eRA Commons (NIH), Research.gov (NSF), etc.), and billing and financial reporting systems (PMS, ACM$).	Use government-wide data standards to modify existing or design new grant systems; Work with other agencies and OMB to reduce the number of existing legacy systems and grant recipient burden via sharing quality services and systems; and, Assess existing grant-making policies and business processes to identify further opportunities to reduce burden by identifying unnecessary or duplicate data collection and/or reporting requirements and legal or regulatory barriers hindering efficiencies in the grant-making process.	There are dozens of portals and processes across federal agencies for grant submissions, billing, and financial reporting. Each portal requires administrators and researchers to meet varying federal requirements, learn new systems, and keep current with agency-specific system requirements.	Select and develop one portal for all federal grant applications. All federal portals should utilize Login.gov and permit multiple institutional administrative contacts. All federal payment systems should support bulk upload or an API for efficient data entry. Streamline and standardize reporting and billing for assistance awards to eliminate duplicative financial reporting.
Financial Conflicts of Interest	HHS 42 CFR Part 50 Subpart F - https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F NSF Conflict of Interest Policy - https://www.nsf.gov/policies/conflict-of-interest DOE Conflict of Interest for Financial Assistance - https://www.energy.gov/management/department-energy-interim-conflict-interest-policy-requirements-financial-assistance NASA Conflict of Interest Disclosures for Grant and Cooperative Agreement Recipients - https://www.federalregister.gov/documents/2023/08/31/2023-18802/conflict-of-interest-policy-for-recipients-of-nasa-financial-assistance-awards	Promote objectivity in research and prevent researchers' financial conflicts that could bias the research results.	Each federal agency has developed its own conflict of interest policy and procedure, disclosure thresholds, reporting requirements, etc. which applies to research. Recipient institutions must create manual systems or use the most stringent requirements for disclosure, adding additional work for researchers and reviewers. Further, the $10K disclosure threshold set by NSF (and NIH) in 1995 has never been adjusted for inflation.	Implement one COI policy to govern all federally funded research based on the NSF Policy. Alternatively, if PHS policy is utilized as the model, eliminate the requirement for disclosure of sponsored/reimbursed travel. Consolidate existing reporting to one federal agency that collects the information needed. Limit COI training to one time before the first award acceptance. Establish consistent FCOI agency reporting requirements across all funding agencies modeled on the NSF policy that requires agency reporting only of unmanageable FCOIs, with institutions retaining responsibility for oversight of all manageable FCOIs.
Research Misconduct	Department of Energy 2 CFR 910.132 - https://www.ecfr.gov/current/title-2/subtitle-B/chapter-IX/part-910/subpart-B/section-910.132 Environmental Protection Agency Order Classification No. 3120.5 - https://www.epa.gov/sites/default/files/2020-11/documents/epa_order_3120.5_policy_and_procedures_for_addressing_research_misconduct.pdf National Aeronautics and Space Agency 14 CFR Part 1275 - https://www.ecfr.gov/current/title-14/chapter-V/part-1275 National Endowment for the Humanities Research Misconduct Policy - https://www.neh.gov/grants/manage/research-misconduct-policy National Science Foundation 45 CFR Part 689 - https://www.ecfr.gov/current/title-45/subtitle-B/chapter-VI/part-689 Public Health Service 42 CFR Part 93 - https://www.ecfr.gov/current/title-42/chapter-I/subchapter-H/part-93 US Department of Agriculture 2 CFR Part 422 - https://www.ecfr.gov/current/title-2/subtitle-B/chapter-IV/part-422 Veterans Administration, Veterans Health Administration Directive 1058.02 - https://www.va.gov/ORO/Docs/Misconduct/VHA_Directive_1058_02_D_2020-07-10.pdf	To set forth a policy and process for institutions to review allegations of research misconduct in federally funded research.	The lack of harmonization in these regulations and/or requirements makes it extremely difficult and overly burdensome for institutions with multiple funding sources to develop uniform internal policies and processes for reviewing and adjudicating allegations of research misconduct concerning federally funded research. Differing federal requirements impede the efficient conduct of researcher training and place unnecessary burdens on institutions in their administration of allegation review proceedings.	Adopt a "common rule" approach to administering research misconduct proceedings by having all executive branch agencies and departments sign on to a single rule governing these proceedings, similar to the common rule approach used for human subject research protections at 45 C.F.R. Part 46. Use the Public Health Service Administration's regulations at 42 C.F.R. Part 93 ("PHS Policy") as this "common rule" because it is comprehensive, prevalent, and was very recently subject to notice and comment rulemaking (i.e., the current version of the rule was adopted in September 2024). Federal agencies' adoption of a single rule for handling research misconduct allegations would promote more efficient and consistent proceedings, facilitate researcher training, and improve institutional compliance.
iEdison Reporting	Agency-prescribed reporting of patents and inventions as prescribed in DOE F205.11 - https://www.energy.gov/sites/prod/files/2016/07/f33/patent_certification_instructions_example.pdf DOD DD Form 882 - https://www.esd.whs.mil/Directives/forms/dd0500_0999/DD882/ NASA New Technology Reports (NTRs) - https://invention.nasa.gov/faqs.php Form HHS 568 - https://grants.nih.gov/grants/hhs568.pdf	Recipients must report patentable inventions developed using federal funding, and the subsequent commercialization thereof, as required under the Bayh-Dole Act of 1980.	Requiring duplicactive reporting and having multiple systems for reporting inventions arising from federally supported research creates considerable inefficiencies and unnecessarily complicated administrative processes for both researchers and their institutions. This lack of harmonization becomes even more burdensome when an invention is supported by multiple federal agencies, each with its own project closeout systems and potentially Bayh-Dole reporting requirement processes. Managing these disparate procedures and systems demands excessive time and effort, heightens the potential for reporting mistakes or oversights, and can ultimately hinder timely compliance and the successful transition of innovations to the marketplace.	Mandate the use of iEdison by all federal funding agencies. Eliminate the dual reporting of inventions as part of the closeout process, e.g., closeout documents pertaining solely to inventions.

TOPIC	REGULATION & SOURCE AUTHORITY	INITIAL GOAL(S)	ISSUE/WHY IT'S NOT WORKING	IMPROVING EFFICIENCY
Human Subject Research Protections Under the Common Rule and FDA Regulations	Common Rule at 45 CFR Part 46 - https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46 FDA Regulations at 21 CFR Part 50 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50 FDA Regulation 21 CFR Part 56 - https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56	Protecting the health, safety, and welfare of human subjects who participate in research projects, including clinical investigations.	Differing federal requirements impede the efficient conduct of researcher training and place unnecessary burdens on institutions in their administration of allegation review proceedings.	Establish FDA as the sole federal agency regulating human subject research concerns for clinical investigations subject to FDA jurisdiction. Establish the Common Rule as the regulation that governs human subjects research that do not involve FDA regulated test articles.
Animal Welfare Act (9 CFR Part 2) and PHS Policy for Humane Care and Use of Laboratory Animals	Animal Welfare Act - https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A/part-2 PHS Policy for Humane Care and Use of Laboratory Animals - https://olaw.nih.gov/policies-laws/phs-policy.htm Health Research Extension Act of 1985 (P.L. 99-158) - https://olaw.nih.gov/policies-laws/hrea-1985.htm	Ensuring the health, safety and welfare of animals used in federally funded research.	PHS and USDA have overlapping, duplicative, and sometimes inconsistent regulations.	Establish USDA as the sole agency for prescribing regulations for research using species of animals covered by the Animal Welfare Act. Establish PHS (Office of Laboratory Animal Welfare) as the sole agency for prescribing regulations for research using species of animals not covered by the Animal Welfare Act. Review the PHS Policy for the Humane Care and Use of Laboratory Animals to determine if it comports with its statutory authority at 42 U.S.C. Sec. 289(d), particularly with respect to its requirement that institutions use the Guide for the Care and Use of Laboratory Animals as the basis for developing and implementing an institutional program for activities involving animals. Permit institutions that have AAALAC accreditation to rely on this accreditation as establishing their compliance with government regulatory standards and for ongoing program oversight.
Research Security (Cybersecurity, Risks Assessments and Training)	CHIPS and Science Act - https://www.congress.gov/bill/117th-congress/house-bill/4346/text Cybersecurity Maturity Model Certification for DoD - https://dodcio.defense.gov/CMMC/Resources-Documentation/ Guidance for Implementing National Security Presidential Memorandum 33 (NSPM-33) on National Security Strategy for United States Government-Supported Research and Development" Federal Register: Federal Acquisition Regulation: Controlled Unclassified Information - https://www.federalregister.gov/documents/2025/01/15/2024-30437/federal-acquisition-regulation-controlled-unclassified-information	Protect the results of US fundamental research from foreign bad actors Enable agencies to appropriately identify and safeguard FCI and CUI in a project. Train researchers and IT professionals on the handling and storage of CUI. Preserve the principles of fundamental research in the application of cybersecurity requirements to ensure that federally funded research remains available to the broader scientific community and society. Incorporate cybersecurity requirements into the research security framework	Agencies are applying new requirements to all research, including low-risk activities. Consider risk levels before adding new safeguards. Agencies are implementing unique training timelines (e.g., before proposal submission, at the time of award, every three years, only once), and different risk assessment rubrics (DOD, Army, DARPA, NIH, DOE, NSF) that hamper the development of compliant processes and training. Agencies also require unique reporting of travel across agencies, including reporting of personal travel (e.g., vacation) and other travel unrelated to the award. These measures increase cost and burden without corresponding public benefit. Agencies are implementing new cybersecurity requirements for all fundamental research, regardless of whether sensitive information is involved, in addition to adding requirements for the handling and storage of CUI.	Harmonize risk assessment requirements across all agencies into a single risk matrix/rubric, for example, research that includes classified information (high risk), CUI-based research (medium risk), or research not using classified or CUI information (low risk). Permit institutions to set appropriate standards for all non-CUI or non-classified research information. Harmonize the definition of CUI and CUI training across agencies by requiring training modules offered by NARA. See joint association response to the Federal Register : Federal Acquisition Regulation: Controlled Unclassified Information. https://www.cogr.edu/sites/default/files/FAR%20CUI%20NPRM_ACE_AAU_APLU_COGR_EDUCAUSE%20Comments%2003-17-25.pdf Provide clear guidelines for FCI and CUI, including a singular definition of CUI to be used by all authoritative sources (NARA registry). Retain current CUI management requirements. Implement a universal training requirement for all agencies to decrease cost and burden on contractors without increasing risk. Limit research travel reporting to trips paid for by federal funds.
Fixed Amount Awards for Fundamental Research Grants	Definition of fixed amount awards in 2 CFR 200.1 - https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-A/subject-group-ECFR2a6a0087862fd2c/section-200.1 Use of these awards, per 2 CFR 200.201(b)(4) - https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-C/section-200.201 Support Implementation of the President's management Agenda and Other Administrative Priorities – 2020 - https://www.federalregister.gov/documents/2020/01/22/2019-28524/guidance-for-grants-and-agreements	2 CFR 200, Uniform Guidance, was meant to streamline fixed amount award requirements. The 2020 version of the Uniform Guidance emphasized performance-based awards that could be issued by federal granting agencies in low-risk situations to reduce burden and focus on performance accountability.	The 2024 revision of the Uniform Guidance requires additional certification of costs at the end of the grant period (2 CFR 200(b)(4)) for fixed amount awards, which is inconsistent with the definition of fixed amount awards and adds unnecessary burden on performance-based awards, as raised in 2020. Federal sponsors have not adequately utilized fixed amount awards for low-risk recipients.	Remove the new requirement (under 2 CFR 200.201 (b) (4)) to certify that all expenditures were incurred in accordance with the allowability of cost factors as CFR 200.201 (b) (1) prescribes that when the award amount is negotiated using the cost principles (or other pricing information) no "expected routine monitoring of the actual costs incurred by the recipient" is required. Require federal funding agencies to use fixed amount awards whenever possible, e.g., for all basic research awards of up to $500K/year.
FFATA Reporting	Part 170-Reporting Subaward and Executive Compensation Information	Transparency of lower tier (subaward) funding to organizations	Hundreds of recipient organizations must report new subawards monthly in SAM.gov. The information being reported is already known by the funding awarding agencies.	Require federal grant agencies and GSA to coordinate and populate subaward data in SAM.gov as needed.

TOPIC	REGULATION & SOURCE AUTHORITY	INITIAL GOAL(S)	ISSUE/WHY IT'S NOT WORKING	IMPROVING EFFICIENCY
Subrecipient Monitoring	2 CFR 200.331-332	Prescribes steps the prime awardee must take when issuing subawards to a collaborating institution.	The vast majority of subawards are issued to institutions that receive prime awards from federal funding agencies, which means that federal agencies have already determined that these institutions are qualified to manage federal awards. Therefore, the exponential monitoring by hundreds of organizations is duplicative, expensive and offers no additional benefit to the government.	Eliminate the requirement to perform duplicative risk assessments for subrecipients for whom the government is making prime awards. Limit the risk assessment to confirming that the performing subrecipient has an audit report in the federal clearinghouse (census.gov) showing no findings specifically relevant to the funding passed through to the subrecipient. Eliminate the new requirement in the Uniform Guidance that mandates recipients to inform agencies when additional conditions are included in subawards §200.332 Requirements for pass-through entities. https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR031321e29ac5bbd/section-200.332
Data Management and Sharing	NIH Data Management and Sharing Policy (2020) - https://www.federalregister.gov/documents/2020/10/30/2020-23674/final-nih-policy-for-data-management-and-sharing-and-supplemental-information NSF Data Management and Sharing (PAPPG 26-1 Draft, expanded) Department of Energy Requirements and Guidance on Digital Research Management Data - https://www.energy.gov/datamanagement/doe-requirements-and-guidance-digital-research-data-management Other federal agencies have unique agency-specific guides.	Improve data maintenance and monitoring practices. Improve data integrity. Facilitate broad sharing of research results.	Federal funding agencies have developed different, and sometimes multiple within the same agency, procedures for sharing research data. Institutions may be required to maintain data after the end of the award, at which point there are no funds to support the work.	Coordinate and simplify standards Harmonize procedures across agencies, while leaving flexibility for research disciplines to set appropriate standards. Provide support to organizations that maintain data repositories to make the data easier for researchers and the public to locate.
ClinicalTrials.gov	42 U.S.C. Sec. 282 42 CFR Part 11 - https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-11 PHS ClinicalTrials.gov - **https://clinicaltrials.gov/** NIH's Definition of a Clinical Trial - https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition FDA's Definition of a Clinical Trial - https://cdn.clinicaltrials.gov/documents/ACT_Checklist.pdf	Ensure the listing of clinical trials and their results in the ClinicalTrials.gov site.	NIH and FDA use different definitions of clinical trials resulting in inconsistent application of this rule and additional burden in developing compliance systems and training. On its ClinicalTrials.gov website (https://clinicaltrials.gov/policy/reporting-requirements) NIH states that its final rule at 42 CFR Part 11 "expands the FDAAA 801 [codified at 42 U.S.C. Sec. 282] requirements by requiring the submission of results information for trials of unapproved products.	NIH should align its regulations at 42 CFR Part 11 with the authorizing statute. NIH should harmonize its definition of clinical trial with the FDA definition of clinical investigation to decrease the resulting burden in determining when NIH-supported clinical trials are also subject to the reporting requirement to clinicaltrials.gov.
Federal Invention Reporting Requirements	Agency-prescribed reporting of patents as prescribed in 35 USC 202(c)(6).	Reporting of patentable inventions developed using federal funding, and commercialization thereof, as required under the 35 CFR Part 401.	There is a lack of uniformity among agencies in the form of the Government Support Clause, in their time to respond to waiver request and extensions of time for election of title, and information required to complete invention utilization reporting. These differences among agencies increase the cost and burden of compliance and jeopardize the potential commercialization of federally funded technologies.	Require a standardized format for the Government Support Clause in patents prescribed in 35 USC 202(c)(6). https://www.govinfo.gov/content/pkg/USCODE-2021-title35/html/USCODE-2021-title35-partII-chap18.htm Require mandatory response time for waiver requests and extension of time for election of title with approval as being the default if no answer is received. Require agencies to use the IAWGBD patent utilization questions only without agency-specific supplements. https://www.nist.gov/iedison/2023-utilization-questions-update

[i] Researchers prepare more than 50K grant applications annually to NIH (https://report.nih.gov/nihdatabook/category/4 and about 40K applications to NSF https://nsf-gov-resources.nsf.gov/files/FY-2023-MeritReviewDigest.pdf?VersionId=3sAgeSb0hEErbqkmbPj3gBu5I7QSzCSO).

[ii] Proposals in response to these instructions can run 40-50 pages or more, yet the success rate for federal agencies runs only 20-30%, creating significant additional work for a low likelihood of funding. See https://report.nih.gov/nihdatabook/category/4 and https://nsf-gov-resources.nsf.gov/files/FY-2023-MeritReviewDigest.pdf?VersionId=3sAgeSb0hEErbqkmbPj3gBu5I7QSzCSO