COGR℠

Advancing Effective Research Policy

May 7, 2025

RE: Request for Information: Deregulation
FR Doc. 2025-06316

Submitted to: Russell T. Vought
Director
Office of Management and Budget
https://www.federalregister.gov/documents/2025/04/11/2025-06316/request-for-information-deregulation#open-comment

Dear Mr. Vought:

We appreciate the opportunity to make recommendations to reduce red tape encumbering federally supported research conducted at research institutions. Reducing the regulatory burden will help maximize taxpayers' research investments and accelerate and bolster American science, technology, and innovation, which underpin our nation's security, health, and economic competitiveness.

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for 229 research universities and affiliated academic medical centers and research institutes. Our work strengthens the longstanding research partnership ("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.

Addressing excessive, duplicative, and outdated federal research regulations and requirements is essential to improving the ability of researchers and their institutions to productively perform research on behalf of the federal government. This is an important action the federal government should take to help ensure the United States remains the global science, technology, and innovation leader.

COGR members take seriously their responsibility to be excellent stewards of taxpayer funds so that they can perform research efficiently and effectively. We recognize regulations are necessary to ensure the responsible conduct of research and sound stewardship of federal funds, but all too often the ability of research institutions to conduct research in the most effective manner is impeded by an ever-increasing number of overlapping, duplicative, and inconsistent regulations issued by multiple federal agencies.

In the table accompanying this letter, we offer 16 recommendations to eliminate, streamline, and/or harmonize specific federal regulations and agency policies. *COGR's highest priority recommendations are shaded in red and will eliminate significant work that impedes research with no corresponding benefit to the public.*

We believe these ideas can be implemented in a timely way that minimizes disruptions while maintaining the accountability Americans expect. **It is imperative that actions taken to deregulate research follow the Administrative Procedures Act to help ensure stakeholder input is considered so that final actions, and their timelines for implementation, are well-informed and achievable**. Recent actions by the Administration and federal research agencies have added new duplicative and burdensome certification and financial reporting requirements for research grant recipients. This runs counter to the Administration's efforts to reduce regulations.

We are prepared to work with you on these and other ideas you may be considering. Our members are committed to their role in the nation's research enterprise and to reforging the Partnership and its vital contributions to America's security, health, and economic competitiveness.

Thank you for your consideration.

Sincerely,

Matt Owens
President

COGR
Advancing Effective Research Policy

May 7, 2025

For questions about this table, contact memberservices@cogr.edu.

NO.	TOPIC		REGULATION & SOURCE AUTHORITY	INITIAL GOAL(S)	RFI CATEGORY	ISSUE/WHY IT'S NOT WORKING	IMPROVING EFFICIENCY
1	**Biosketch and Current and Pending Support Reporting Requirements**	**REGULATION**	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.	The cost of agency variations exceeds the benefits to the public.	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."
2	**Research Project Proposal Development**	**POLICY**	NSF PAPPG Proposal Preparation - https://www.nsf.gov/policies/pappg/24-1/ch-2-proposal-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].	The cost of implementing disparate agency variations far outweighs the benefits to the public.	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.
3	**EPA Regulations That Impact Academic Research Facilities**	**REGULATION**	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.	Regulations are duplicative and burdensome to US businesses.	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.

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4	**Agency support for federal assistance awards, including proposal submission portals, grants management systems, and billing and financial reporting systems.**	**REGULATION & POLICY**	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.	Agency-specific solutions are outdated and out of compliance with OMB Memorandum, Public Law 106-107, and the Cross-Agency Priorities (CAP) goals. The costs associated with implementing disparate agency requirements exceed the benefits to the public.	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.
5	**Financial Conflicts of Interest**	**REGULATIONS & POLICY**	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.	The threshold for what constitutes a significant financial interest differs greatly among agencies without support why a particular threshold has been chosen and agencies to not adjust thresholds periodically to reflect inflation. The costs associated with implementing disparate agency requirements exceeds the benefits to the public.	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.
6	**Research Misconduct**	**REGULATION, POLICY, ORDER & DIRECTIVE**	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 cost of agency variations exceeds the benefits to the public.	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.
7	**iEdison Reporting**	**POLICY**	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.	The costs associated with implementing disparate agency requirements exceeds the benefits to the public.	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.

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8	**Human Subject Research Protections Under the Common Rule and FDA Regulations**	**REGULATION**	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.	The presence of two sets of regulations that may apply to the same research is duplicative and **unduly burdensome to US businesses.**	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.
9	**Animal Welfare Act (9 CFR Part 2) and PHS Policy for Humane Care and Use of Laboratory Animals**	**REGULATION & POLICY**	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.	The PHS Policy for the Humane Care and Use of Laboratory Animals, as implemented by the Department of Health and Human Services Office of Laboratory Animal Welfare (OLAW) exceed the authorizing statutory authority under the Health Research Extension Act of 1985 (P.L. 99-158). The Dept. of Health and Human Services and U.S. Dept. of Agriculture both regulate laboratory animal health, safety, and welfare.	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.
10	**Research Security (Cybersecurity, Risks Assessments and Training)**	**REGULATION & POLICY**	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	The costs associated with implementing disparate agency requirements exceed the benefits to the public. The cost of requiring research institutions to provide research security training to personnel before an award is made is wasteful and inefficient. It does not consider the fact that training may need to be tailored to address the circumstances of the final award.	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.
11	**Fixed Amount Awards for Fundamental Research Grants**	**REGULATION FOR BLOCKING TERM; POLICY FOR LIMITED USE OF FAWS**	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.	Regulation is outdated. The costs associated with implementing disparate agency requirements exceeds the benefits to the public.	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.
12	**FFATA Reporting**	**REGULATION FOR AGENCIES TO COLLECT THE DATA**	Part 170-Reporting Subaward and Executive Compensation Information	Transparency of lower tier (subaward) funding to organizations	The regulation is outdated. The federal government is not taking advantage of information already provided to the agencies.	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.

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13	**Subrecipient Monitoring**	**REGULATION**	2 CFR 200.331-332	Prescribes steps the prime awardee must take when issuing subawards to a collaborating institution.	Regulation is outdated. The costs associated with implementing the Uniform Guidance requirements far outweighs the benefits to the public.	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
14	**Data Management and Sharing**	**POLICY**	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.	The costs associated with implementing disparate agency requirements exceeds the benefits to the public. While the intent of the regulation is sound, there are issues with the timing and resourcing of managing data.	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.
15	**ClinicalTrials.gov**	**REGULATION & POLICY**	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.	Regulations are inconsistent. NIH regulations at 42 CFR Part 11 implementing requirements for defining "applicable trials" to be reported in ClinicalTrials.gov exceed statutory authority 42 U.S.C. Sec. 282 .	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.
16	**Federal Invention Reporting Requirements**	**POLICY**	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.	The costs associated with implementing disparate agency requirements exceed the benefits to the public.	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*

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