The Burden of the Paperwork Reduction Act on Federally Funded Scientific Research: DOGE, Where Are You?

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Executive Summary

The Paperwork Reduction Act (PRA) of 1995[1], enacted with the admirable goal of reducing administrative burdens from federal information collections, has, in its broad scope, unintentionally become a significant obstacle to legitimate federal and federally sponsored scientific research. The PRA's current application to research governed by federal oversight policies (i.e., 45 CFR 46 and 21 CFR) fundamentally misaligns with the PRA's original legislative intent, which mainly focused on data collections related to regulatory compliance or the pursuit of government services. The unique nature of scientific research, aimed at generating knowledge and serving the public interest, should not require this additional administrative/regulatory barrier.

The current PRA clearance process creates excessive administrative burdens, causing significant delays, choking innovation[2], and blocking the very evidence-based policy making the government claims to encourage[3]. Building on established precedents, such as the National Institutes of Health (NIH) research exemption through the 2016, 21st Century Cures Act[4], the 2023 exemption granted to the Department of Veterans Affairs for research[5], and the Office of Information and Regulatory Affairs (OIRA)'s guidance on usability testing[6], the problem could be solved through a two-part approach: (1) specific legislative changes to clearly exempt broad groups of scientific research, and (2) practical regulatory reinterpretations and simplified procedures by OIRA for any remaining applicable research. These changes are crucial to strike a proper balance between necessary government oversight and the flexibility needed for effective research, ultimately enhancing the public value of federal information.

1. Overview of the PRA's Purpose and Evolution

The Paperwork Reduction Act (PRA), initially enacted in 1980 and reauthorized in 1995, is a legislative effort to address concerns about the significant amount of time and resources the public was spending to comply with federal agencies' information requests. Its main goal was to create a centralized system, managed by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB), to regulate and reduce the "paperwork burden." At the same time, the Act aimed to ensure the "public benefit and practical utility" of the information collected.[1]

The PRA requires federal agencies to justify their information collection activities, accurately estimate the burden on the public, and offer opportunities for public input during the proposal phase. OIRA approval is typically needed for most collections of identical questions from 10 or more people. The 1995 reauthorization aimed to reinforce the Act's original goals, expand its scope, and clarify that "collection of information" explicitly includes third-party disclosures. This legislative action directly overrode the Supreme Court's decision in *Dole v. United*

Steelworkers[7], highlighting a deliberate congressional intent to expand the Act's reach.

A key observation about the PRA's design is its inherent dual mandate: to "minimize paperwork burden" and to "maximize the potential use of the information collected." It also aims to "ensure maximum utility and quality of Federal information [1]." When these goals are applied to federal scientific research, tension arises. The lengthy approval process, while ostensibly meant to lessen public burdens, usually creates a new, significant administrative burden for agencies seeking to conduct scientific research. This bureaucratic obstacle can have a chilling effect, discouraging studies that could produce high-quality, helpful information.[2] This outcome conflicts with the Act's "utility and quality" goal by emphasizing strict procedural compliance over the substantive results of information collection.

The development of the Act also reflects a deliberate legislative choice to move beyond a narrow focus on "paperwork" and adopt a broader definition of "information collection." Although the Act is known as the "Paperwork Reduction Act," its legal definition of "collection of information" is intentionally broad, including "facts or opinions by or for an agency, regardless of form or format."[1] This definition explicitly encompasses "surveys, permits, questionnaires, and reports," and specifically mentions "research studies and focus groups with the same set of questions or tasks."[1]

2. PRA's Voluntary Collection Application to Scientific Research

Contrary to the idea that voluntary participation should exempt research from PRA, the Act's current regulatory interpretation clearly states that "voluntary collections are not automatically exempt."[1] Federal agencies confirm that PRA clearance is needed for federally sponsored data collections involving 10 or more non-federal respondents using identical questions, regardless of whether participation is voluntary or mandatory. This broad scope applies to many scientific studies, all of which fall under the PRA's strict requirements. Science is an international competition, and the PRA hinders the ability of US federally funded researchers to collect information from the public, effectively tying their hands.

While the PRA measures burden in "burden hours"[1], the real cost of applying PRA to scientific research goes much beyond these direct measures. It involves significant opportunity costs, including delayed or missed research, reduced scientific flexibility within federal agencies, and the risk of less well-informed public policy choices. These wider, strategic costs are hard to quantify as "burden hours" but are a notable setback to government efficiency and societal advancement. The argument should shift strategically from just "burden hours" to the broader, more strategic costs of PRA use in scientific research, highlighting that the current approach hinders the PRA's own goals of maximizing utility and enhancing government performance.

The mandatory clearance process for such information collections is lengthy, usually taking six to nine months[8]. This process includes several steps: internal agency review, publication of two Federal Register notices for public comment (a 60-day and 30-day period), and final approval by OIRA.[3]

The Act treats data collection the same whether it is voluntary or mandatory. What is unique

about scientific research is that there are mechanisms in place to oversee the collection tools and to give approvals to the research. Most scientific studies involving the public must also disclose the purpose of the research, declare the time commitment of the individual, and, in most cases, obtain the consent of the person from whom the information is collected. Due to these existing policies, the PRA is a redundant and often unhelpful process for scientific research.

The administrative burden and lengthy approval times for PRA clearance are not just procedural inconveniences; they pose a significant obstacle. The Act has been criticized for "counterintuitively inhibit[ing] federal agencies from activities that could improve public information gathering, such as surveys and user research".[9] This creates a direct causal link: the PRA's bureaucratic overhead actively discourages agencies from conducting valuable research, even when that research would ultimately benefit the public or enhance government operations. This results in a chilling effect, impeding the government's ability to collect essential data for evidence-based policymaking, program evaluation, and scientific progress, directly opposing the PRA's own goal of "maximizing the potential use of the information collected".[1]

3. Distinguishing Scientific Research from Service-Seeking or Compliance-Driven Collections

Scientific and public-benefit research has its primary purpose in the advancement of knowledge, understanding complex phenomena, or improving public welfare through insights derived from data, rather than administrative processing, enforcement, or a direct *quid pro quo* for government services. While scientific research findings may *inform* government services or policy, the act of collecting the research data itself is typically not directly linked to a respondent seeking a specific government service or fulfilling a regulatory mandate.

The core of this argument lies in the "public good" versus "regulatory compliance" dichotomy. While the PRA aims to minimize burden, it also has goals related to maximizing information utility and improving government performance.[1] Research, especially scientific research, often contributes to the *public good* through knowledge generation and societal advancement, even if it does not directly relate to a specific government service or regulatory requirement. The current PRA framework, by treating all "collections" similarly, fails to adequately distinguish between information collected for regulatory control or service delivery and information collected for broader societal benefit through scientific inquiry.

4. The Case for Exempting Scientific Research

A. Legislative Intent

Despite the 1995 reauthorization's expansion of the "collection of information" definition, the foundational intent of the PRA, particularly the original 1980 Act, was to mitigate burdens associated with mandatory reporting and recordkeeping requirements. This is evidenced by the focus on tax forms and regulatory compliance in its legislative history.[1] The Supreme Court's decision in *Dole v. United Steelworkers*, before its legislative override, interpreted the Act as applying to information collected "by or for the use of a federal agency," reinforcing the idea of agency-centric data acquisition for its own regulatory or administrative functions. This aligns

with the contention that the PRA was intended for data collections where government services are being sought or regulatory compliance is mandated.

While Congress intended to broaden the *scope* of "information collection", it may not have fully considered the specific implications for *voluntary scientific research* as distinct from regulatory reporting or service applications. This framing suggests that the current application to voluntary research is an overreach or an unintended consequence of broadly worded legislation, making a compelling case for legislative or regulatory refinement.

B. The Unique Nature of Scientific and Public-Benefit Research

Research conducted or sponsored by federal agencies often serves specific goals, such as advancing scientific knowledge, guiding public policy, improving public health, or protecting the environment. Such research usually uses rigorous methods (e.g., statistical surveys, qualitative interviews) and undergoes thorough ethical and methodological reviews. For example, research involving human subjects is typically overseen by Institutional Review Boards (IRBs), which ensure participant safety, informed consent, and data security. This process addresses many concerns that PRA aims to mitigate, such as burden, privacy, and utility. Applying the full PRA clearance process in addition to existing IRB review creates redundant bureaucratic hurdles without adding proportional value. This is a clear case of “regulatory overlap” that increases administrative burdens on researchers and agencies. Such redundancy weakens the justification for applying PRA to scientific research, reinforcing the view that existing, specialized oversight mechanisms are sufficient and better suited to ensure quality and protect respondents in this context.

This was acknowledged in the 21st Century Cures Act legislation, which added a specific exemption: "The PRA shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health".[10] This exemption is contingent on the program systematically analyzing project outcomes and publicizing the results.[8] This demonstrates that Congress *can* and *has* legislated specific exemptions for voluntary research when it serves a clear public benefit (systematic analysis, public dissemination). The conditions attached to the NIH exemption (systematic analysis, publicization) can be framed as adequate safeguards against potential abuse, addressing concerns about data quality and utility. This existing statutory exemption provides a powerful legal and policy precedent that can be leveraged as a template or a strong argument for why similar voluntary research across other federal agencies, particularly those focused on scientific inquiry and public benefit, should also be exempt. It suggests that the *type* and *purpose* of the research, rather than just its "voluntary" nature, is a valid and recognized basis for exemption.

C. Existing Precedent

A significant precedent exists in the 21st Century Cures Act, which added a specific exemption: "The PRA shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health".[4] This exemption is contingent on the program systematically analyzing project outcomes and publicizing the results. This demonstrates that Congress *can* and *has* legislated specific exemptions for voluntary research when it serves a

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5. Policy Implications and Recommendations for Reform

To address the challenges identified, a multi-pronged approach encompassing both legislative and administrative reforms is recommended.

Legislative Amendment (Preferred and most robust for long-term clarity):
A legislative amendment to 44 U.S.C. §3502(3) should be pursued to explicitly exempt "voluntary information collections conducted for the primary purpose of scientific research, program evaluation, or user experience improvement, where the intent is knowledge generation and public dissemination, and where the collection is subject to equivalent ethical or methodological review (e.g., Institutional Review Board (IRB) approval, rigorous peer review, or established agency scientific integrity processes)." This change would expand the existing NIH exemption to all federal agencies, providing consistent treatment for similar research activities. It would clearly define the scope of the exemption, addressing concerns about ambiguity and ensuring that quality and ethical standards are maintained through alternative oversight mechanisms. Congress has already considered exempting voluntary information collections that are conducted to develop or improve digital services or in conjunction with an agency's use of agile software development practices, which provides a foundation for this broader proposal.

Regulatory Reinterpretation/Guidance by OIRA (Immediate and Flexible Relief):
Meanwhile, as Congress considers action, OIRA should issue new, comprehensive guidance based on the precedent set by the usability testing memo. This guidance should clarify that a broader range of scientific research activities are exempt from PRA clearance. It should especially highlight research authorized by a recognized ethical review board (e.g., IRB) or through a registered Human Research Protection Plan with a Federalwide Assurance.

Advocating for a multi-pronged approach—pushing for legislative change while urging OIRA to use its existing authority to provide administrative relief and streamline processes for scientific research—is the most pragmatic and effective strategy.

IV. Conclusion

The Paperwork Reduction Act, while vital for managing federal information burdens in specific circumstances, has, through its broad application, inadvertently created significant impediments to valuable scientific research initiatives. The core contention that PRA should not apply to scientific research, given its distinct nature from compliance or service-seeking data collection, is supported by an analysis of the Act's original intent and the disproportionate administrative

burden it imposes.

Eliminating the PRA requirement for scientific research collections would directly support key priorities of the current administration, particularly those focused on deregulation, streamlining government processes, and fostering evidence-based policymaking.

The administration has articulated a clear policy to significantly reduce regulatory burdens and costs on American citizens and businesses. Furthermore, exempting scientific research from PRA requirements would significantly advance the administration's commitment to evidence-based policymaking. The Foundations for Evidence-Based Policymaking Act of 2018[11] (commonly known as the Evidence Act) mandates that federal agencies modernize their data management practices and develop systematic plans for using evidence to inform policy decisions.

Such reforms are crucial not only to alleviate unnecessary bureaucratic hurdles but also to foster innovation, accelerate knowledge generation, and ultimately enhance the government's efficiency and effectiveness in serving the public interest.

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