Opinion: What the National Academies Report on Research Policy Overlooked

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The National Academies of Sciences, Engineering, and Medicine's new report, "Simplifying Research Regulations and Policies: Optimizing American Science[1]," offers a timely and much-needed blueprint to address the complexities of federal research regulations. With its emphasis on harmonization, a risk-tiered approach, and the integration of technology, the report accurately identifies a core issue discovered in 2020 through the Federal Demonstration Partnership[2]: that excessive and duplicative administrative tasks consume over 40% of a researcher's time, diverting vital resources away from scientific discovery. The National Academies' report offers an important first step toward creating a more efficient and productive research ecosystem.

However, in its attempt to address inefficiencies in federally supported academic research, the report's focus is too narrow. A truly comprehensive overhaul of medical research policy must go beyond federally funded work and research-specific regulations to address the broader operational issues that create the administrative and legal burdens. In addition to specific research regulatory rules, the National Academies report discusses financial conflict of interest, research misconduct, research asset management, and grant proposals. However, it overlooks critical factors such as domestic information security requirements for research data transfer and storage, staffing shortages in federal regulatory, oversight, and institutional research offices, and privacy policies at state and local institutions, among others. There is a complex ecosystem of root causes that must be holistically addressed for changes in federal research regulatory policy to truly have an impact.

Furthermore, while the report addresses financial conflicts of interest, it overlooks the more subtle, yet equally pervasive, "non-financial conflicts of interest" that can compromise research integrity. These include pressures related to career advancement, professional rivalries, institutional loyalties, or even ideological beliefs that can unwittingly influence study design or data interpretation.[3] The current research regulatory framework, which is heavily focused on financial disclosures, may not be equipped to address these more nuanced ethical concerns, which can pose an even greater threat to objectivity precisely because they are often unintentional and undisclosed.

The report's proposed solutions for harmonization, while laudable, are also primarily domestic. In today's globalized world, a purely U.S.-centric approach is insufficient. For over three decades, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[4] has brought together regulators and industry from the U.S., Europe, and Japan to create unified technical guidelines and standards. This collaboration aims to prevent the duplication of clinical trials, promote public health, and facilitate the mutual acceptance of clinical data across jurisdictions. The ICH framework already provides a powerful model for the "harmonization" the report calls for. A comprehensive strategy for U.S. research must actively champion and engage with these existing global harmonization efforts, rather than focusing solely on aligning federal agencies internally.

The most significant missing element in the report is the limited focus on industry-sponsored research. While federal agencies, especially the National Institutes of Health (NIH), provide essential support for many breakthroughs, most clinical trials are funded and run by industry. Recent studies reveal that the ratio of enrollments from industry versus NIH sponsorship is a notable 8.1 for all trials, and for adult trials alone, that number rises to 9.6[5]. Industry R&D spending on clinical trials often greatly exceeds government funding, making it the main force behind bringing new drugs to market. A report aimed at improving U.S. science, particularly in biomedicine, cannot ignore the sector that conducts most of this research. Any effective policy reform must involve industry policies to develop a unified framework that covers the entire research process. Also missing from the report is the need to close the gap of studies that are not subject to any U.S. regulation and that put study participants at risk.

The National Academies' report is a strong starting point, marking an important first step in a long-overdue discussion. It provides a valuable blueprint for streamlining administrative procedures and enabling researchers to focus on their work. However, to truly serve the public interest and maintain U.S. leadership in medical innovation, policymakers need to use this report as a foundation to build a broader vision—one that tackles the complexities of industry-sponsored research, a wider array of ethical dilemmas, the importance of international harmonization, and the vital role of patient experience and safety.

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[1] National Academies of Sciences, Engineering, and Medicine. 2025. Simplifying Research Regulations and Policies: Optimizing American Science. Washington, DC: The National Academies Press. https://doi.org/10.17226/29231

[2] Home - The Federal Demonstration Partnership, Accessed September 10, 2025, https://thefdp.org/

[3] Examples of Conflict of Interest in Research, Accessed September 10, 2025, https://www.infonetica.net/articles/examples-of-research-coi

[4] ICH Official web site : ICH, accessed September 10, 2025, https://www.ich.org/

[5] Patient Enrollment to Industry-Sponsored Versus Federally-Sponsored Cancer Clinical Trials - PMC, accessed Sep 10, 2025, https://pmc.ncbi.nlm.nih.gov/articles/PMC11575909/