

**REDUCING INVESTIGATORS'
ADMINISTRATIVE WORKLOAD
FOR FEDERALLY FUNDED RESEARCH**



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EXECUTIVE SUMMARY

The past two decades have witnessed increasing recognition that the administrative workload placed on federally funded researchers at U.S. institutions is interfering with the conduct of science in a form and to an extent substantially out of proportion to the well-justified need to ensure accountability, transparency and safety. A 2005 Federal Demonstration Partnership (FDP) survey of investigators found that principal investigators (PIs) of federally sponsored research projects spend, on average, 42 percent of their time on associated administrative tasks. Seven years later, and despite collective Federal reform efforts, a 2012 FDP survey found the average remained at 42 percent.ⁱ

In December 2012, the National Science Board (NSB, Board) convened a Task Force on Administrative Burdens (Task Force).ⁱⁱ The Task Force issued a request for information (RFI) to identify which Federal agency and institutional requirements contribute most to PIs' administrative workload and conducted a series of roundtable discussions with faculty and administrators. The most frequently reported areas associated with high administrative workload were financial management; the grant proposal process; progress and other outcome reporting; human subjects research and institutional review boards (IRBs); time and effort reporting; research involving animals and institutional animal care and use committees (IACUCs); and personnel management. Other areas frequently addressed were subcontracts, financial conflict-of-interest (COI), training, and laboratory safety and security.

Investigators and institutions acknowledge their responsibility to ensure transparency, accountability and safety in the conduct of federally funded research and, thus, that rules and regulations are necessary. However, they also mentioned an array of areas where those rules and regulations could be eliminated, streamlined, or harmonized across agencies to significantly reduce unnecessary regulatory burden. Further, there is a perception that we have lost focus on the science and introduced requirements that are not necessary for the assessment of merit and achievement, accountability, or the protection of research subjects. These requirements often come at considerable cost to investigators and institutions and yield a loss of valuable research time, particularly when not harmonized across Federal agencies. Investigators and institutions perceive a lack of consideration for the cost and benefit of new regulations, suggesting that the cost is often far greater than the benefit, and that there were no means to assess their effectiveness. Once implemented, regulations are not easily modified or eliminated.

Investigators at many institutions suggested that a culture of overregulation has emerged around Federal research, which further increases their administrative workload. This overregulation was associated with a perceived increase in auditing practices and resulting institutional concerns about liability. Increased Federal reporting and compliance requirements, coupled with insufficient reimbursement of costs associated with federally funded research and a resulting decline in institutional administrative support at some universities, are reported to have added significantly to the faculty workload in tracking information, gathering administrative data, and preparing reports at the expense of performing research.

Many of the issues raised have been highlighted in previous surveys and reports for more than a decade. Failure to address these issues has resulted in wasted Federal research dollars. At a time of fiscal challenges and with low funding rates at many Federal agencies, it is imperative that these issues are addressed so that researchers can refocus their efforts on scientific discovery and translation. The Board offers several key, overarching, recommendations and a series of policy actions aimed at modifying and streamlining those requirements that are essential to ensure the proper performance of federally funded research.

I. FOCUS ON THE SCIENCE

Investigators' administrative workload could be reduced significantly if requirements that are not critical to a proposals merit review were postponed until the proposal has been positively reviewed and is being considered for funding. Administrative work could be reduced further if progress reports were streamlined and focused solely on performance outcomes. The Board strongly encourages the National Science Foundation (NSF) Director and other Federal agencies funding scientific research to focus the peer-review process and post-award oversight on merit and achievement.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board recommends that agencies modify proposal requirements, so that they only include those essential to evaluating the merit of the proposed research and making a funding determination. This can be achieved through use of these or other mechanisms:
 - Preliminary proposals
 - Broadening just-in-time submission
 - Simplifying budget requirements
- B | Annual progress reports should be limited to research outcomes, reported in simplified formats and commensurate with the size of the award. Additional data requests should be limited to only what is essential for assessment of performance and compliance.
- C | The Board advises the NSF Director to fully review and consider the agency-specific comments received in response to the Board's RFI, as well as consideration of piloted modifications to the proposal process, and to report to the Board on review and progress within six months of the publication of this report.

II. ELIMINATE OR MODIFY INEFFECTIVE REGULATIONS

In a number of areas, investigators and institutions have identified regulations that are ineffective or inappropriately applied to research time and again in surveys and reports. Effective action should be taken to eliminate or modify these requirements to avoid further waste of Federal research dollars and to accelerate the pace of scientific discovery and innovation.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board proposes that the Office of Management and Budget (OMB) identify appropriate means by which the piloted payroll certification approach for time and effort reporting can be used by universities and accepted by auditors and Inspectors General (IGs). Once resolved, a Memo of Clarification should be issued indicating that the payroll certification method is acceptable to the Federal Government.
- B | The Board supports a number of recently proposed reforms to regulations governing human subjects research, including:
 - Encouraging the use of a single IRB for multi-site studies.
 - Eliminating continuing review for all expedited/minimal-risk protocols.
 - Expansion and clarification of current exemption categories.

Further, the Board endorses the Association for the Accreditation of Human Research Protection Programs (AAHRPP) recommendation to declare all research involving minimal risk as eligible for review using the expedited procedure. The Board further recommends eliminating the requirement that IRBs review grant proposals and the requirement to submit IRB approved research protocols for review by agency IRB or peer review panel.

- C | An evaluation of the regulations, policies, guidance, best practices and frequently asked questions

(FAQs) of all regulatory, independent, and certification bodies governing animal research should be considered to identify policies and guidance that increase investigators' administrative workload without improving the care and use of animals.

- D | Proper balance between protection against COI and encouragement of university/industry partnership is needed to facilitate sound investment of Federal funding in innovative activities. The Board recommends an evaluation of recent changes to Public Health Services (PHS) COI regulations to assess cost and effectiveness and impact on entrepreneurial activities. The Board does not recommend adoption of the PHS COI regulations by other Federal agencies.
- E | The Board recommends re-examining safety and security requirements, or aspects of these requirements that target industry, but are also applied to research settings. Based on this examination, appropriate alternatives should be identified and implemented.

III. HARMONIZE AND STREAMLINE REQUIREMENTS

Despite efforts on the part of OMB, Federal agencies and groups such as the Research Business Models Working Group (RBM) and FDP, a substantial lack of consistency and standardization remains within and among agencies in all aspects of grant management (i.e., regulations, policies, guidelines, and reporting requirements; terms and conditions; oversight; forms and formatting; electronic research administrative systems; and training). This lack of consistency comes at a high cost to investigators and institutions and must be addressed.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board urges Federal agencies to accelerate efforts to harmonize and streamline the grant proposal and submission processes and post-award requirements.
- B | The Board recommends that a mechanism be established to ensure uniform and consistent audit practices based clearly and directly on regulatory requirements. The Board further urges agencies and institutions to consider requiring receipts and justifications only for larger purchases.ⁱⁱⁱ Audits that focus on larger expenditures, outcomes, and infrastructure for compliance and risk management, would significantly reduce investigators' workload while maintaining necessary oversight.
- C | To address the recommendations in this and other reports and to properly develop and implement new requirements affecting investigators and institutions, the Board recommends that a permanent high-level, inter-agency, inter-sector committee be created, with stakeholder and OMB/Office of Information and Regulatory Affairs (OIRA) representation. Stakeholders, either in concert with agencies as part of a committee or through a forum such as the National Academies, should create a priority list of regulations and policies that should be eliminated, modified, or harmonized to reduce the administrative workload of PIs and institutions. Implementation of the changes identified could occur, in part, through the recommended inter-agency, inter-sector committee.

IV. INCREASE UNIVERSITY EFFICIENCY AND EFFECTIVENESS

University resources and the ability of institutions to manage Federal grants and comply with regulations vary widely, and this variance has real implications for investigators. Dissemination of effective practices and models can create efficiencies that reduce PIs' administrative workload. For research subject to IRB and IACUC review, effective practices and institutional assistance can result in significant time savings.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board recommends that institutions communicate the origin of compliance requirements to researchers and avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so.
- B | The Board recommends that Federal agencies collaborate with research institutions, and organizations representing investigators and institutions to identify and disseminate model programs and best practices (e.g., for financial management and IRB/IACUC review) that could be adapted for use at other institutions. This effort could be aided by the recommended inter-agency, inter-sector committee.
- C | The time and effort involved in protocol preparation, revision, and review could likely be reduced if IRB and IACUC staff provided researchers with knowledgeable assistance in the preparation and modification of these protocols. The Board recommends that universities review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high-quality protocols that protect research subjects.