

Representing Over 110,000 Researchers

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National Academies of Sciences, Engineering and Medicine ATTN: Committee on Improving the Regulatory Efficiency and Reducing Administrative Workload to Strengthen Competitiveness and Productivity of U.S. Research Washington, DC 20001

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Question 1: Since the 2016 National Academies Report Optimizing the Nation's Investment in Academic Research, changes in federal regulations and policies for research have had impacts on U.S. R&D. Based on your experiences, which of the following research areas are in the greatest need of regulatory reform (multiple selections allowed):

Animal Research Grants Management Human Subjects Research Research Integrity Other: Duplicative and/or contradictory regulations

Question 2: When engaging in work to ensure compliance with federal regulations for your research, what have been some of your biggest challenges in the last 5-10 years?

In 2013, the National Science Foundation (NSF) issued a Request for Information (RFI) on behalf of the National Science Board's (NSB's) Task Force on Administrative Burdens to seek 1) comment from principal investigators (PIs) with federal research funding on federal agency and institutional requirements that contribute most frequently to their administrative burdens and 2) suggestions for how these burdens could be reduced or eliminated. Much of FASEB's response to that RFI – which synthesized perspectives of 1,324 individual respondents – continue to ring true today, and we encourage the Committee to review the summary report (https://tinyurl.com/FASEB-Admin-Burden). Comments from our community highlighted administrative burdens associated with grant preparation, submission, management, and funding; animal care regulations and oversight; variation in training requirements across agencies, states, and institutions; human subjects regulations/Institutional Review Board review; and inconsistent administrative policies or procedures. Reflecting on the 12 years that have passed since this effort, while there has been progress towards digitizing and even automating many of these processes, a key challenge that remains is inconsistency of forms, policies, and procedures across science agencies. Although the research community had hoped that the requirement within the 21st Century Cures Act to establish a Research Policy Board would create a forum for addressing these issues, this provision never came to fruition.

Full members: American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics • American Society for Investigative Pathology • The American Association of Immunologists • American Association for Anatomy • Society for Developmental Biology • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research • Society for the Study of Reproduction • Endocrine Society • Genetics Society of America • The Histochemical Society • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine • Society For Experimental Biology and Medicine • American Aging Association • Society for Leukocyte Biology • American Federation for Medical Research • Shock Society • Associate members: American Society of Human Genetics

Question 3: If you have the ability to change or streamline current research regulations, what would you most like to see happen? Why?

As noted in our response to the previous question, FASEB continues to hear complaints about the lack of consistent policies, procedures, and even standardized forms across federal agencies. This lack of consistency prompts institutions to implement strategies that add more administrative effort to ensure they have all information required to be compliant with all applicable funding agencies as well as state and local expectations. As a result, scientists continue to spend increasing amounts of their time addressing administrative issues rather than engaging in research activities. This is not an efficient use of individuals' time or federal resources.

FASEB acknowledges improved use of "just-in-time" documentation across federal agencies, leading to a reduction of administrative effort at the grant application stage and limiting the collection of detailed information, such as institutional approvals for animal use or human subjects research, for those applications of high scientific merit and likely to be funded. We strongly recommend agencies explore additional application components for which information could be collected via a just-in-time mechanism.