POLICY FORUM

RESEARCH REGULATION

Engage research institutions on research regulatory reform

Agencies should consult researchers and administrators on how to cut bureaucratic red tape

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Concerns about the growth of research regulations and reporting requirements and their impact on scientific productivity and international competitiveness have prompted many reports and recommendations over the past two decades (*1*–*6*). In the United States, investigators spend a considerable portion of their time on federally funded research engaged in associated administrative tasks (*7*). This takes time and effort away from research and can serve as a disincentive to seek grants or enter the field. Congress aimed to increase the efficiency of the federal investment in research and development and to reduce administrative burden on federally funded scientists through provisions of the 21st Century Cures Act (Cures Act, 13 December 2016) and the American Innovation and Competitiveness Act (AICA, 7 January 2017) (*8*, *9*). Addressing research regulatory burden in law and associated oversight may provide the relief that reports and recommendations alone have not generated. But more than a year and a half after enactment of these laws, under an administration that has eagerly expressed intent to reduce regulations and associated costs, we see limited progress, transparency, and engagement with the research institutions that accept federal awards. Here, we focus on U.S. efforts to address research regulatory reform and allow for more direct engagement by the stakeholder community in the regulatory process, similar to the efforts of other nations and the European Union (EU).

Academic institutions provide infrastructure, personnel, and other resources necessary to carry out most U.S. federally funded research, including roughly $5 billion in unreimbursed administrative costs and $1.4 billion in cost sharing associated with federal research and other awards in 2016 (*10*). Institutions are responsible for implementing federal regulations and requirements and for understanding the benefits and challenges, as well as what works and what does not. Active engagement between federal officials, investigators, and administrative staff from institutions could thus play a vital role in reducing regulatory inefficiency. But although institutions and investigators have the opportunity to provide written comments on proposed federal rules and policies, they have not had an opportunity to engage in real-time discussions on the development and reform of regulations, policies, and guidance that can drive up costs and redirect investigators from the conduct of research to the administration of federal awards. This is important because draft rules and policies may be issued as final policy with few changes and may be found inefficient or ineffective once implemented.

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ENGAGING RESEARCH INSTITUTIONS

In 2016, the U.S. National Academies of Sciences, Engineering, and Medicine called for a public-private forum for discussions on the regulation of ongoing and emerging federally funded research at academic research institutions. The Cures Act calls for the creation of such a forum through the establishment of a research policy board (RPB). The RPB would consist of federal members from departments and agencies that support or regulate scientific research, as well as nonfederal members from academic research institutions and affiliated nonprofit organizations. The RPB, which was to be established by the director of the Office of Management and Budget (OMB) by 13 December 2017, has not been created. The OMB Office of Information and Regulatory Affairs (OIRA) and other federal agency staff have indicated that a charter has been drafted and that at least some federal staff have been contacted regarding participation. We are unaware, however, of any efforts to select and engage nonfederal members or of any further progress and understand from agency staff that activities related to the establishment of the RPB have been at least temporarily suspended.

CONFLICTS, ANIMALS, AND FINANCES

The Cures Act seeks to address areas consistently identified as causing undue burden, including regulations and policies related to disclosure of financial conflicts of interest (FCOI), monitoring of subrecipients of grants by primary awardees, reporting of financial expenditures, and documentation of personnel expenses. The Cures Act requires the U.S. Department of Health and Human Services (HHS) to review regulations and policies related to disclosure of FCOI, including the minimum threshold, within 2 years of enactment. Revising and harmonizing existing federal FCOI regulations has the potential to reduce administrative burden, particularly if awardee institutions are engaged in identifying solutions. Yet as we approach the 18-month mark, although HHS and National Institutes of Health (NIH) staff have indicated that a review of the Public Health Service FCOI regulations is under way, discussions to date have remained internal to the agency. Revisions to the regulations in 2011 reduced harmonization across agencies, increased the reporting and review of low-level financial interests, and have been reported to be ineffective and unnecessarily burdensome (*11*).

The Cures Act directs the NIH, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture to review regulations and policies for the care and use of laboratory animals within 2 years of enactment and to make appropriate revisions to reduce administrative burden while maintaining the protection of animals used in research. This review should include input from experts as directed by the Cures Act and consider implementation of report recommendations, including those of the NIH's 1999 report on reducing regulatory burden (*1*). Agencies have conducted listening sessions and recently completed a 90-day public comment period (*12*) for reforming and coordinating regulations. However, the questions included in the request are somewhat narrow and hopefully not indicative of modest reforms.

The Cures Act calls on the NIH to reduce

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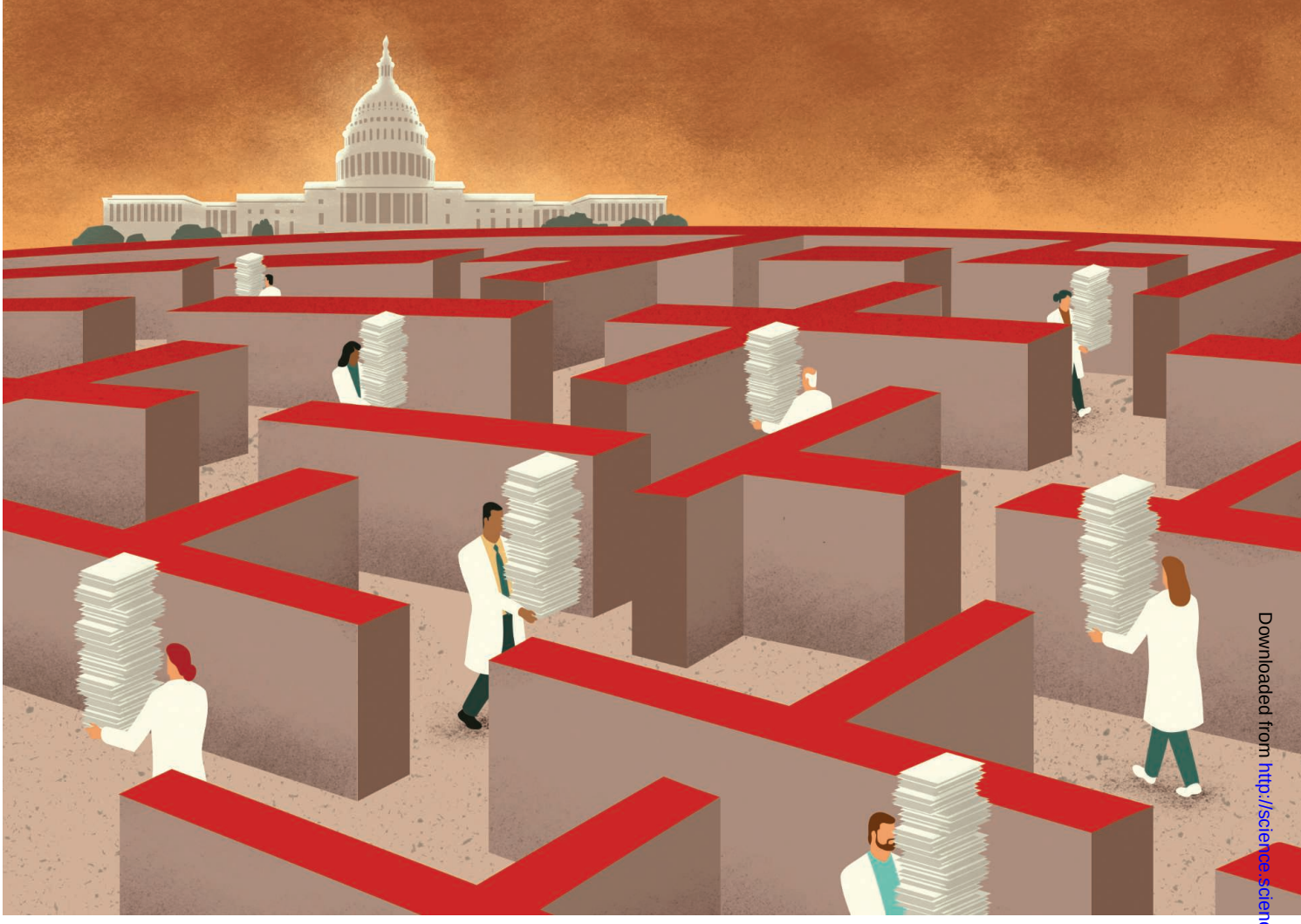

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burden associated with financial monitoring of subrecipients (other institutions or entities formally engaged in the research), including possible exemption from monitoring where subrecipients are subject to annual audit by federal regulations. There has been some discussion of the NIH and other federal agencies clarifying the role of subrecipient monitoring, potentially through terms and conditions of research awards. Recommended reforms put forward by the community for financial reporting more broadly have included elimination of the Federal Cash Transaction Report (FCTR), a quarterly report that is redundant under the modernized system because financial information on individual grants is available in real time. Although the FCTR was voluntarily eliminated by the National Science Foundation (NSF) for this reason, HHS has not made this change. We are unaware of any reforms to financial reporting taking place.

GRANT PROPOSALS AND MANAGEMENT

The AICA calls for a federal Interagency Working Group on Research Regulation to regularly review regulations and identify opportunities to streamline or eliminate regulations and processes to minimize burden. In carrying out these efforts, the working group is directed to consult with investigators, institutions, and other stakeholders. The AICA requires the working group to develop a government-wide uniform grant format and consider the use of preliminary proposals, simplified budgets, and greater use of "just-in-time" reporting when awards are made rather than meeting requirements at the proposal stage. The AICA also calls for a central database for biosketches, curriculum vitae, licenses, and publications; a central repository for assurances through which institutions obligate themselves to comply with regulations; and the review and simplification of progress reports.

Some of these functions have previously been carried out under the federal interagency Research Business Models (RBM) working group of the National Science and Technology Council. The RBM has previously developed a uniform progress report and made efforts to develop a centralized database, SciENcv (Science Experts Network Curriculum Vitae), that aims to enable federal researchers to more easily create and maintain biosketches and has been adopted by the NIH and, on a pilot basis, by the NSF.

In a 25 May 2018 report to Congress, the RBM indicated that it will execute the interagency responsibilities required under the AICA, which included annual reports beginning in January 2018 (*13*). The report provides an overview of previous efforts, as well as planned efforts, by the RBM. This includes pilot partnerships with Open Researcher and Contributor ID (ORCID) and CrossRef and the proposed use of individualized persistent researcher identifiers that would reduce the need for duplicative entries, consideration of mechanisms to streamline the grant application process, and consideration of how to harmonize FCOI policies across federal agencies (the latter not explicitly called for in the AICA).

Yet one critical element that this working group lacks is an active voice from representatives of the research community. Instead, federal agencies are reviewing their own regulations, policies, and processes to identify opportunities to reduce burden and are required only to "consult" with stakeholders. This consultation could simply take the form of traditional means such as requests for comment or attendance at widely attended meetings, although we would hope that the RBM would pursue more substantial engagement. This is very different from a public-private forum that allows for open engagement and dialogue

with the research community in identifying and mitigating federal regulatory burden. This is what the RPB, required under the Cures Act, would provide if it were to be established. Unlike the RBM, which includes only federal agency representatives, the RPB would include both federal and nonfederal representatives. Further, RPB meetings would be required by law to be public, whereas RBM meetings and deliberations are held privately.

The activities of the RBM and RPB would not be in conflict, but complimentary, each addressing different areas of research regulatory burden, one with considerably greater stakeholder engagement. The 2016 National Academies report (*5*) acknowledged the work of the RBM working group but also noted that, despite best efforts, federal requirements, forms, and processes continue to vary widely. The legislative language in the AICA mirrors many of the report recommendations on proposal preparation and progress reports. By contrast, the RPB called for in the report and in the Cures Act is directed to address regulatory and policy development and reform not typically addressed by the RBM and that would benefit from the kind of public-private entity proposed in the Cures Act.

The 25 May 2018 RBM report suggests that the RPB "would include a representative from RBM to ensure constructive coordination between these two bodies." An RPB would move the Unites States closer to the approach taken by the European Commission, which relies on a number of scientific and academic bodies to assist in consideration of technical, ethical, and practical application of standards before submitting proposed regulations to the EU Parliament (*14*).

SUBREGULATORY BURDEN

Although not addressed in the Cures Act or the AICA, another area that could be taken up is the issue of subregulatory burden. Although guidance can be welcome and critical, providing necessary details for implementation while maintaining a level of flexibility, agency requirements based on policies, procedures, award terms, and other materials can also substantially increase administrative burden. These measures, which, unlike regulations, generally do not undergo review by OIRA, have proliferated and can effectively serve as regulation, in many cases without input from the research community or adequate analyses of outcomes, such as costs, impact, and scientific implications. The OMB's 2007 Agency Good Guidance Practices bulletin sought to curb these practices, yet they persist. An example of this is the NIH Office of Laboratory Animal Welfare's interpretation of "should" statements as "must" statements in the *Guide for the Care and Use of Laboratory Animals* (*15*). Review of subregulations by the RPB and interagency working group and a restatement of the OMB bulletin would be helpful. This could be accompanied by a request for comment seeking feedback on burdensome federal guidance.

PULL BACK THE CURTAIN

The current approach of agencies working "behind a curtain" and previewing the product to the research community only at late stages is not productive. Agency staff often do not understand the operations of research institutions and are likely to miss the mark regarding the intended outcomes—and can also become wedded to their chosen approach. At the same time, research institutions may not be aware of statutory, legal, and other challenges. Congress has recognized the need for research regulatory reform that engages the community through the establishment of a review body composed of both federal agency staff and representatives from research institutions. This RPB would provide a ready forum for the open exchange of ideas and concerns before and during the formation or modification of regulations, policies, and guidance. Federal agencies and offices must be held accountable to establish and activate the RPB on a published timeline, address regulatory reform requirements, and submit associated reports to Congress as required by law. We also strongly urge the engagement of research institutions and investigators in agency-level reform efforts such as those being carried out by HHS as directed by the Cures Act and by the RBM under the AICA. Although the administration's intent to reduce regulations and associated costs has been well publicized, the regulation of research has not been a focus and considerable gains are yet to be made. ■

REFERENCES

1. NIH, "Initiative to reduce regulatory burden" (NIH, 1999); https://archives.nih.gov/asites/grants/06-17-2015/archive/grants/policy/regulatoryburden/index.htm.
2. National Science Board, "Reducing investigators' administrative workload for federally funded research" (NSB-14-18, NSF, 2014); www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.
3. Federation of American Societies for Experimental Biology, Association of American Medical Colleges, Council on Governmental Relations, National Association for Biomedical Research, "Reforming animal research regulations: Workshop recommendations to reduce regulatory burden" (FASEB, AAMC, COGR, NABR, 2017); www.faseb.org/Portals/2/PDFs/opa/2017/FASEB-Animal-Regulatory-Report-October2017.pdf.
4. National Research Council of the National Academies, "Research universities and the future of America: Ten breakthrough actions vital to our nation's prosperity and security" (The National Academies Press, 2012).
5. National Academies of Sciences, Engineering, and Medicine, "Optimizing the nation's investment in academic research: A new regulatory framework for the 21st century" (The National Academies Press, 2016).
6. Government Accountability Office, "Federal research grants: Opportunities remain for agencies to streamline administrative requirements" (GAO-16-573, GAO, 2016); www.gao.gov/assets/680/677949.pdf.
7. Federal Demonstration Partnership, "2012 Faculty Workload Survey: Research report" (FDP, 2012); https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.
8. 21st Century Cures Act, Pub. L. No. 114-255 (2016); www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf.
9. American Innovation and Competitiveness Act, Pub. L. No. 114-329 (2017); www.congress.gov/114/bills/s3084/BILLS-114s3084es.pdf.
10. National Center for Science and Engineering Statistics, "Universities report increased federal R&D funding after 4-year decline" (NSF 18-303, NSF, 2017); www.nsf.gov/statistics/2018/nsf18303/nsf18303.pdf.
11. Association of American Medical Colleges, "Implementing the regulations on financial conflicts of interest: Results from the AAMC Conflict of Interest Metrics Project" (Analysis in Brief, vol. 14, AAMC, 2015); www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf.
12. U.S. Department of Health and Human Services, *Fed. Reg.* **83**, 11221 (2018); www.gpo.gov/fdsys/pkg/FR-2018-03-14/pdf/2018-05173.pdf.
13. RBM Working Group Committee on Science, "Reducing federal administrative and regulatory burdens on research" (National Science and Technology Council, May 2018); www.whitehouse.gov/wp-content/uploads/2018/05/Reducing-Federal-Administrative-and-Regulatory-Burdens-on-Research.pdf.
14. The Royal Society, "UK research and the European Union: The role of EU regulation and policy in governing UK research" (The Royal Society, April 2016).
15. NIH, Office of Laboratory Animal Welfare, "Frequently asked questions"; https://olaw.nih.gov/guidance/faqs#3455.

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