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Federally Funded Academic Research Requirements: Background and Issues in Brief

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Summary

For decades, the federal government and academic research institutions have been partners in supporting American innovation, competitiveness, and economic growth. The federal government is the largest source of academic research and development (R&D) funding in the United States, providing funds through more than two dozen federal agencies, with the National Institutes of Health (NIH) and the National Science Foundation (NSF) providing the largest portions of federal R&D funding to U.S. colleges and universities.

As part of oversight of federal funding for academic research, Congress and federal agencies have established requirements through statutes, regulations, and guidance documents that U.S. universities and other research institutions must comply with when applying for, receiving, and reporting on the results of federal research grants. Such requirements seek to ensure transparency and effectiveness of federal funds, while helping to prevent waste, fraud, and abuse.

Academic research institutions broadly recognize the need for, and benefits from, federal regulations but have raised concerns that federal regulations and administrative requirements have produced unintended consequences, such as reducing research productivity and the return on federal investments. Surveys and assessment reports conducted over the past two decades have evaluated the benefits and challenges related to federal requirements for academic research. Among specific areas of concern frequently brought forth by researchers and academic administrators are the amount of time spent on completing administrative tasks compared to conducting research; the increasing number, and lack of harmonization, of requirements across federal funding agencies; the adequacy of stakeholder engagement in the review and modification of federal regulations; and the need for updated requirements for human subjects and animal research.

Legislation was enacted in the 114th Congress that addressed a number of the concerns, including the 21st Century Cures Act (P.L. 114-255), the American Innovation and Competitiveness Act (AICA, P.L. 114-329), and the National Defense Authorization Act for Fiscal Year 2017 (NDAA, P.L. 114-328). Enacted provisions addressed a subset of issues focused on specific agencies, including conflicts of interest disclosure, financial reporting, and subrecipient monitoring. Enacted provisions also addressed cross-agency efforts by directing the establishment of an advisory committee (Research Policy Board) with federal and non-federal stakeholders, as well as an interagency working group (WG) on federal research regulations.

The 115th Congress may conduct oversight as agencies work to implement the provisions enacted in the 114th Congress. Congress may further consider legislation to extend certain provisions more widely across the federal government. For current and potential future efforts to streamline and harmonize federal regulations, a central consideration will likely be ensuring that mechanisms to evaluate transparency and accountability of federal funds are not diminished.

Contents

Introduction 1
Background 1
Federal Research Grant Requirements 4
Executive Orders and Federal Statutes 4
Uniform Guidance 5
Agency Requirements 5
Reports and Assessments 6
Legislative Activities in the 114th Congress 7
21st Century Cures Act 7
American Innovation and Competitiveness Act 7
Other Selected Legislation 8
Congressional Hearings 8
Selected Issues for Congress 8
Federal Coordination and Stakeholder Engagement 8
Harmonizing and Streamlining Requirements 9
Standardized Forms 9
Proposal Preparation and Submission 10
Audits 10
Uniform Guidance Updates 10
Human Subjects and Animal Research 11
Concluding Observations 12

Figures

Figure 1. Federal Obligations to U.S. Universities and Colleges for Research and Development, FY2016 3

Tables

Table 1. Federal Obligations to U.S. Universities and Colleges for Research and Development, FY2016 3

Contacts

Author Information 13

Introduction

The federal government is the largest source of funding for academic research and development (R&D) at U.S. universities and colleges, obligating more than $28 billion in FY2016.[1] As part of oversight of federal funding for academic research, Congress and federal agencies have established requirements through statutes, regulations, and guidance documents that U.S. universities, colleges, and other research institutions must comply with when applying for, receiving, and reporting on the results of federal research grants.[2] Such requirements are implemented to ensure transparency and help prevent waste, fraud, and abuse.

Academic stakeholders generally recognize the need for oversight to ensure accountability, safety, and the integrity of the research enterprise. However, for more than a decade many have raised concerns that federal regulations and administrative requirements are having unintended consequences, such as reducing research productivity and the potential return on federal investments and discouraging students from pursuing careers in academic research.

This report contains background information and selected issues on federal regulations and administrative requirements related to federally funded academic research. It is not an exhaustive treatment of all federal regulations and administrative requirements related to federally funded academic research, but rather provides a general overview and discussion of select issues. Other CRS products provide additional information on the federal grants process and federal regulations and administrative requirements more broadly.[3]

Background

Academic research and development, particularly in science and technology, is widely considered to be an important contributor to American innovation, competitiveness, and economic growth. Federal funds provide more than half of the total amount U.S. universities and colleges spend on R&D each year. Institutional funds from U.S. universities and colleges are the next largest source of support, providing approximately one-quarter of the total R&D funds spent each year. Businesses, state and local governments, and nonprofit organizations, among others, provide the remaining sources of funding for academic R&D.[4]

Federal funds are provided through grants and other mechanisms by more than two dozen federal agencies. Over 90% of this funding comes collectively from the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA)

[1] National Science Foundation, National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development Fiscal Years 2014-2016, preliminary data, Table 10, at https://ncsesdata.nsf.gov/fedfunds/2014/html/FFS2014_DST_010.html.

[2] Federal funding for academic research is provided to institutions through various mechanisms, such as cooperative agreements, grants, and contracts. In this report, the term "grant" is used broadly to encompass all such mechanisms.

[3] For example, see CRS Report R44374, *Federal Grant Financial Reporting Requirements and Databases: Frequently Asked Questions*, by Natalie Keegan; CRS Video WVB00077, *Federal Grants Process*, by Natalie Keegan; and CRS Report R43726, *Delayed Federal Grant Closeout: Issues and Impact*, by Natalie Keegan.

[4] CRS analysis of data from the National Science Foundation, National Center for Science and Engineering Statistics, Higher Education Research and Development Survey Fiscal Year 2015, Table 2. In contrast to the Survey of Federal Funds for R&D, this survey data corresponds to the *academic fiscal year 2015*, which spans July 1, 2014, to June 30, 2015, for most institutions.

(**Table 1**). NIH alone provides U.S. universities and colleges with more than 60% of all federal funding for academic R&D (**Figure 1**).[5]

A 2012 survey by the Federal Demonstration Partnership (FDP) to "determine the impact of federal regulations and requirements on the research process" found that researchers spent on average 42% of their time on federally funded projects meeting administrative requirements rather than conducting research directly. According to the survey, "most respondents agreed that administrative workload associated with federally-funded research has increased in the past 5 to 6 years."[6]

Furthermore, a 2015 report by Vanderbilt University estimated the cost of compliance with federal research regulations across 13 U.S. universities and colleges at between 11% and 25% of each institution's research expenditures.[7]

Broadly, the academic community has indicated an interest in harmonizing federal regulations across agencies and eliminating some regulations. In a joint statement, the Association of American Universities, Association of Public and Land-grant Universities, and Council on Governmental Relations asserted the following:

> Minimizing administrative and compliance costs ultimately will provide a cost benefit to the Federal government and to university administrators, faculty, and students by freeing up resources and time to directly support educational and research efforts.[8]

A similar sentiment has been expressed by some Members of Congress. For example, in a 2016 subcommittee hearing, a few Members raised concern that federal laws, regulations, and reporting requirements are creating a situation where too much time and resources are spent on complying with federal requirements.[9] In a 2014 subcommittee hearing, the NSF Inspector General highlighted the importance of maintaining accountability in efforts aimed at reducing investigators' administrative workloads, stating:

> As accountability professionals, my office and the IG community are committed to striking the appropriate balance between reducing burden and maintaining proper accountability. To that end, we are focused on ways to ensure that that balance is maintained or strengthened, not diminished.[10]

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[5] CRS analysis of data from the National Science Foundation, National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development, Fiscal Years 2014-2016, preliminary data, Table 10, at https://ncsesdata.nsf.gov/fedfunds/2014/html/FFS2014_DST_010.html.

[6] Sandra L. Schneider et al., *2012 Faculty Workload Survey: Research Report*, Federal Demonstration Partnership, April 2014, p. 6. The FDP is a cooperative initiative among 10 federal agencies and 155 institutional recipients of federal funds (as of 2014) that began in the 1980s. Efforts to address "administrative burden" have been part of their working agenda since at least 2002; see "Evolution of the FDP," http://sites.nationalacademies.org/pga/fdp/index.htm.

[7] Vanderbilt University, *The Cost of Federal Regulatory Compliance in Higher Education: A Multi-Institutional Study*, October 2015. Accurately determining costs is difficult, however, as financial and time commitments may not be easily ascribed directly to one regulation or policy; for example, see American Council on Education, Report of the Task Force on Federal Regulation of Higher Education, *Recalibrating Regulation of Colleges and Universities*, 2015, pp. 10-11.

[8] Association of American Universities, Association of Public and Land-grant Universities, and Council on Governmental Relations, *Regulatory and Financial Reform of Federal Research Policy Recommendations to the NRC Committee on Research Universities*, January 21, 2011.

[9] U.S. Congress, House Committee on Science, Space, and Technology, Subcommittee on Research and Technology, *Academic Research Regulatory Relief: A Review of New Recommendations*, hearings, 114th Cong., 2nd sess., September 29, 2016.

[10] Testimony of NSF Inspector General Alison Lerner, in U.S. Congress, House Science Oversight Subcommittee and House Science, Education, and Technology Subcommittee, *Reducing the Administrative Workload for Federally Funded Research*, hearings, 113th Cong., 2nd sess., June 12, 2014.

Table 1. Federal Obligations to U.S. Universities and Colleges for Research and Development, FY2016

(in millions of dollars)

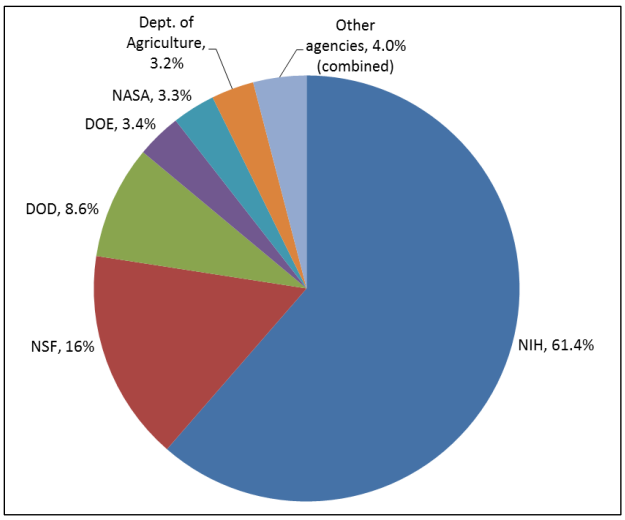
Federal Agency	Academic R&D Obligations	% of Total Federally Funded Academic R&D
National Institutes of Health	$17,533.3	61.4%
National Science Foundation	$4,582.8	16.0%
Department of Defense	$2,459.5	8.6%
Department of Energy	$971.2	3.4%
National Aeronautics and Space Administration	$931.8	3.3%
Department of Agriculture	$924.7	3.2%
Other Agencies (combined)	$1,156.3	4.0%
Total	**$28,556.7**	**100%**

Source: CRS analysis of data from the NSF National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development Fiscal Years 2014-16, preliminary data, Table 10, at https://ncsesdata.nsf.gov/fedfunds/2014/html/FFS2014_DST_010.html.

Notes: Totals may not add due to rounding. Totals to do not include funding to university-administered Federally Funded Research and Development Centers.

Figure 1. Federal Obligations to U.S. Universities and Colleges for Research and Development, FY2016

(in millions of dollars)



Source: Table 1.

Notes: Percentages may not add to 100% due to rounding.

Federal Research Grant Requirements

As described in a 2016 Government Accountability Office (GAO) report, federal research grants can be divided into several stages—pre-award, award, post-award implementation, and closeout—that are each associated with specific administrative requirements. For example, after a grant is awarded, grant recipients must meet a number of federal requirements associated with post-award implementation, including documenting personnel expenses and the purchase of research equipment and supplies, managing and reporting on the project's budget, and reporting on any subaward recipients.[11]

While this report focuses on federal requirements, academic institutions also develop internal policies for managing awards more broadly, including federal, state, and nonprofit awards. Requirements set by the institution facilitate compliance with federal regulations but may also add to the administrative workload. Institutional requirements vary depending on such factors as the size and focus of the institution and its research program, as well as the availability, or lack of, a sponsored research office.[12] The following subsections describe a selection of the overarching federal laws, regulations, and guidance pertaining to academic research awards.

Executive Orders and Federal Statutes

Since at least the 1970s, a number of executive orders (E.O.s) have sought to ensure coordinated and efficient federal regulations broadly.[13] E.O. 12866, Regulatory Planning and Review (1993), directed agencies to establish principles and processes that supported a variety of objectives, including those to "enhance planning and coordination with respect to both new and existing regulations." E.O. 13563, Improving Regulation and Regulatory Review (2011), and E.O. 13610, Identifying and Reducing Regulatory Burdens (2012), reaffirmed and built upon the 1993 E.O., including calling for greater agency coordination and harmonization of rules in order to reduce redundant, inconsistent, or overlapping requirements; and agency plans for retrospective analyses of existing rules.[14] Recently, President Trump signed an E.O. requiring that, for every one new regulation issued by a federal agency, two existing regulations be identified for elimination.[15]

Additionally, various legislative efforts have sought to minimize the impacts of federal grant requirements and monitoring efforts specifically. The Single Audit Act of 1984 (P.L. 98-502), as amended by the Single Audit Act Amendments of 1996 (P.L. 104-156; 31 U.S.C. 7501-7507), established uniform audit requirements for federal grant recipients as part of an effort to clarify interpretation of audit guidance among agencies and associated offices of the inspector general (OIGs). The single audit concept focuses on reviewing a federal grant recipient's internal controls rather than looking closely at specific expenditures of a grant award. The Federal Financial

[11] U.S. Government Accountability Office, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, GAO-16-573, June 2016, pp. 7-8.

[12] Sponsored research offices generally have dedicated staff that facilitate the various stages of the grant process for researchers across the institution.

[13] Early examples include E.O. 12044, Improving Government Regulations (1978) and E.O. 12291, Federal Regulatory Review (1981).

[14] See CRS Report RS20846, *Executive Orders: Issuance, Modification, and Revocation*, by Todd Garvey, for a broad discussion of executive orders, including more detail about E.O.s concerning the regulatory process.

[15] White House, Office of the Press Secretary, "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," January 30, 2017, at https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling.

Assistance Management Improvement Act of 1999 (P.L. 106-107) included provisions to simplify reporting requirements and required the Office of Management and Budget (OMB) to coordinate a common application and reporting system for grants. Subsequently, Grants.gov was created in 2003, through which grant-seekers can find and apply for discretionary funding opportunities from federal agencies. The Digital Accountability and Transparency Act of 2014 (DATA Act, P.L. 113-101) included requirements that OMB and the Department of the Treasury standardize data element definitions and design "a pilot for developing recommendations to reduce recipient reporting burden." GAO reports that, while steps are being taken, more work is needed to fully implement the DATA Act's requirements.[16]

Uniform Guidance

In 2013, OMB consolidated and streamlined numerous circulars pertaining broadly to federal awards into a final guidance document, called the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (commonly referred to as the Uniform Guidance or UG).[17] The UG is meant to provide a "government-wide framework for grants management" and "reduce administrative burden for non-federal entities receiving federal awards while reducing the risk of waste, fraud and abuse."[18] UG coverage includes budget preparation and management, subrecipient monitoring,[19] documentation of personnel expenses, and thresholds and procurement standards for competitive bidding procedures. To comply with the UG as implemented in December 2014, federal agencies are responsible for developing requirements for grant applicants and recipients of their program awards, with consultation from OMB's Office of Information and Regulatory Affairs (OIRA).

Agency Requirements

The UG provides broad guidance for federal grants, but federal agencies may vary in how they implement it and may have additional agency- or program-specific requirements. These may include variations with conflict of interest forms, biographical information forms (commonly called "biosketches"), and personnel work reporting (called "effort reporting").

In some cases, in addition to standard forms used across federal agencies, supplemental agency-specific forms are also required. For example, Standard Form 424 Research and Related is a government-wide application form, but many agencies require an additional form to be submitted through either Grants.gov or an agency-specific website (e.g., FastLane for NSF). Disparities in agency processes and requirements are among the top concerns for academic grant recipients, as described in subsequent sections of this report.

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[16] Testimony of GAO Director of Financial Management and Assurance Paula M. Rascona, in U.S. Congress, House Subcommittee on Government Operations, *DATA Act Implementation Check-In*, hearings, 114th Cong., 2nd sess., December 8, 2016.

[17] Circulars include instructions or information issued by OMB to federal agencies. The final guidance superseded and updated guidance from numerous OMB Circulars, including A-21, A-87, and A-122 (pertaining to cost principles); A-89 (catalogue of information on federal domestic assistance programs); A-102 (pertaining to the management of grants and cooperative agreements); A-110 (pertaining to administrative requirements); and A-133 (pertaining to audits).

[18] OMB, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," 78 *Federal Register* 78589, December 26, 2013. OMB set a one-year timeline for implementation after publishing the UG.

[19] "Subrecipient" refers to entities that obtain funding which was first awarded to a primary grant awardee and then passed on to a secondary recipient; primary recipients then monitor subrecipient compliance with federal requirements.

Reports and Assessments

Numerous evaluations have looked at the impacts of federal grant regulations on academic research. In 2016, the GAO and the National Academy of Sciences (NAS) each released reports evaluating federal regulations and administrative requirements placed on research grant recipients.[20] The GAO report concluded that some of the efforts by OMB and agencies to allow more institutional flexibility (e.g., expanded authorities for certain aspects of budget management and revised requirements for personnel documentation) had led to reduced administrative workloads and costs, though more could be done. The NAS report concluded that a new framework was needed "to ensure that regulatory requirements are justified, proportional to the problems being addressed, and harmonized across funding agencies so as to create a more effective and efficient partnership between funding agencies and research institutions."

Additionally, in 2014, the National Science Board (NSF's governing body) released a report examining administrative workload of federally funded investigators, which asserted a "consensus that some of these [administrative and compliance] requirements are interfering with the conduct of science out of proportion with the accepted need to ensure accountability, transparency, and safety."[21] And as previously discussed, the Federal Demonstration Partnership released reports from survey findings in 2012 and 2005 indicating a substantial portion of a researcher's time is spent addressing administrative tasks.

Collectively, these reports offer recommendations to issues that are long-standing. For example, a 1999 report on the NIH Initiative to Reduce Regulatory Burden[22] highlighted multiple regulatory concerns that continued to be raised in the recent GAO and NAS reports. In 1999, the author concluded that a number of issues were "not new, often having been identified by other studies" and addressing them would require "sustained attention."[23]

Across these reports, stakeholders have cited a variety of areas as contributing to administrative workload and costs. These include grant proposal preparation, financial management, effort reporting and personnel management, monitoring of grant subrecipients, and progress reporting. Broadly, analysts and stakeholders have recommended that the federal government continue its work to reduce administrative workloads; assess, modify, and eliminate ineffective or duplicative requirements; and improve coordination and harmonization among agencies and between agencies and grant recipient communities. More specifically, recommendations have included

- creation of an overarching body and an administrator position at OMB for reviewing regulations and standardizing policies;
- wider use of preliminary proposals, and simpler, standardized progress reports;
- creation of a central database of investigator information;
- development of a standard grant form and a standard conflict of interest form that more narrowly targets areas of greatest risk for researchers;

[20] U.S. Government Accountability Office, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, GAO-16-573, June 2016; National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*, Washington, DC: The National Academies Press, 2016.

[21] National Science Board, *Reducing Investigators' Administrative Workload for Federally Funded Research*, Arlington, VA: National Science Foundation, 2014 (NSB-14-18).

[22] Mahoney, John D., *NIH Initiative to Reduce Regulatory Burden: Identification of Issues and Potential Solutions*, 1999, at https://archives.nih.gov/asites/grants/06-17-2015/archive/grants/policy/regulatoryburden/index.htm.

[23] Ibid., "Executive Summary" section.

- changes to effort reporting processes, and guidance on acceptable methods; and
- modifications to the threshold for requiring competitive bidding of purchases (e.g., laboratory equipment), requirements for monitoring award subrecipients, and audit processes.

Legislative Activities in the 114th Congress

Reflecting congressional concerns over the amount of time and resources spent complying with federal regulations and administrative requirements, legislation in the 114th Congress sought to streamline and reduce federal academic research requirements.

21st Century Cures Act

On December 13, 2016, the 21st Century Cures Act was signed into law (P.L. 114-255). Section 2034 of the act requires the Secretary of Health and Human Services (HHS) to implement a number of "measures to reduce administrative burdens" on researchers. Specifically, the Secretary of HHS is required to

- lead a review of regulations and policies related to the disclosure of financial conflicts of interest;
- implement measures to reduce administrative burdens related to subrecipient monitoring;
- evaluate financial reporting requirements to avoid duplication between department and agency level procedures (e.g., between HHS and NIH, which is an agency of HHS); and
- clarify the applicability of the requirements under the Office of Management and Budget (OMB) Uniform Guidance for management and certification systems that can be used in the documentation of personnel expenses.

The act also requires the Director of NIH, the Secretary of Agriculture, and the Commissioner of Food and Drugs to review regulations and policies related to the care and use of animals in research and to make revisions that will reduce administrative burdens on investigators while maintaining the integrity of research findings and the protection of research animals.

Additionally, the act requires the Director of OMB to establish an advisory committee—known as the "Research Policy Board" (RPB) and composed of both federal and nonfederal members—to make recommendations on the modification and harmonization of regulations and policies across research funding agencies to minimize administrative burdens while maintaining effective oversight of federally funded research.

American Innovation and Competitiveness Act

On January 6, 2017, the American Innovation and Competitiveness Act (AICA) was signed into law (P.L. 114-329). Title II of the act contains a number of provisions to address administrative requirements related to academic R&D. Specifically, the act

- requires the Director of OMB to establish an interagency working group that is responsible for reviewing administrative requirements imposed on federally funded researchers and recommending ways to minimize regulatory burden, including through the development of a uniform grant format and a centralized database for investigator biosketches;

- requires the NSF Inspector General to conduct an audit of NSF's policies and procedures related to subrecipient monitoring; and
- increases the micro-purchase threshold for procurement activities—below which supplies or services can be acquired without soliciting competitive bids—from $3,500 to $10,000 for research grants awarded by NSF, NASA, and the National Institute of Standards and Technology.

Other Selected Legislation

On December 23, 2016, the National Defense Authorization Act for Fiscal Year 2017 was signed into law (P.L. 114-328). Section 217 of the act raises the micro-purchase threshold for grants, cooperative agreements, and contracts awarded to universities and other research institutions from *all* federal agencies to $10,000 from $3,500.

On May 19, 2015, the House passed H.R. 1119, the Research and Development Efficiency Act, which would have established an interagency working group responsible for reviewing and making recommendations on how to harmonize, streamline, and eliminate duplicative federal academic R&D regulations and reporting requirements (later enacted as part of AICA).

On June 24, 2016, Representative Daniel Lipinski introduced H.R. 5583, the University Regulation Streamlining and Harmonization Act of 2016, which included a number of provisions to address concerns over federal academic R&D regulations. Some provisions of H.R. 5583 were similar to those enacted in the 21st Century Cures Act and the AICA, including the establishment of a Research Policy Board and an interagency working group tasked with developing a central database of researcher information. H.R. 5583 also included a number of provisions not addressed in previous legislation such as requiring the President to appoint an Associate Administrator for Academic Research Enterprise from within OMB's OIRA and exempting prime grant-receiving institutions from monitoring subrecipients under certain conditions.

Congressional Hearings

As part of its oversight on federally funded academic R&D, the House Committee on Science, Space, and Technology held a hearing entitled "Academic Research Regulatory Relief: A Review of New Recommendations" on September 29, 2016. The hearing raised concerns about the amount of time researchers spent complying with federal requirements and the need to minimize requirements while maintaining transparency and accountability into federal spending.

Selected Issues for Congress

Legislation passed in the 114th Congress builds on prior efforts to address issues and recommendations regarding regulatory requirements for federally funded academic research. This section discusses potential areas of congressional interest.

Federal Coordination and Stakeholder Engagement

Two overarching, related areas of concern for many stakeholders have been federal coordination of regulations across agencies, and effective stakeholder engagement. Though previous efforts have been made to improve coordination among agencies that fund academic research—as through the Research Business Models working group and the Federal Demonstration Partnership—researchers and administrators cite variation in agency requirements as an ongoing concern. The recently enacted Research and Development Efficiency Act (§201 of the AICA)

establishes an interagency working group (WG), coordinated through OMB and the Office of Science and Technology Policy (OSTP). The WG is to broadly focus on reviewing research regulations and "reducing administrative burdens on federally funded researchers." As a 2012 GAO report noted, the federal government employs a variety of interagency collaborative mechanisms, and careful consideration of a variety of issues, including leadership, resources, and participants, may help determine the group's ultimate effectiveness.[24]

In addition to interagency efforts, nonfederal stakeholders have called for more effective ways for them to engage in the regulatory process. The WG created through the AICA calls for consultation with academic researchers from outside the federal government, though the details of such engagement are not specified. Further, the 21st Century Cures Act mandates that OMB forms the Research Policy Board (RPB) that includes both federal and nonfederal members. Thereby, the RPB has the potential to provide an additional mechanism for academic stakeholders to work directly with federal agencies to review policies, make recommendations, and establish best practices moving forward. The WG and RPB appear to be complementary in their mandates; however, Congress may consider additional statutory requirements for these two bodies to work together. Additionally, the effectiveness of the RPB and WG has yet to be seen, and congressional oversight may be important in ensuring the entities achieve their intended purposes.

Finally, a third overarching coordination and outreach mechanism proposed in legislation but not enacted was the creation of an Associate Administrator of Academic Research Enterprise within OMB's OIRA. Congress may consider whether requiring such a position would enhance the functions of the RPB and WG, would be unnecessary, or whether these determinations are better left to OMB's discretion.

Harmonizing and Streamlining Requirements

Academic stakeholder groups have recommended several actions to reduce the amount of time and resources that academic institutions spend on complying with the range of requirements, including standardizing forms, streamlining the grant proposal process, revising audit approaches, and updating certain UG policies.

Standardized Forms

Researchers have argued that reducing variations among agency forms that require similarly focused information could streamline the grant process without forfeiting important information. For example, many agencies require biographical information (e.g., experience, publications, and accomplishments) from researchers for grant applications in what are commonly referred to as "biosketches." However, these forms may vary in required categories, length, and formatting, though their overall goal is to evaluate researcher qualifications, as one might from a resume.

Additionally, researchers have called for the use of a standard grant proposal form. However, using only one standard form may prove challenging, as the information necessary to evaluate a proposal may vary widely depending on the type of funding, research area, and scope of projects among agencies with diverse missions (e.g., plant ecology research compared to clinical trials of new drugs). Opportunities for streamlining may exist at the applicant level, such as allowing research grant applications to be re-uploaded, modified to reflect current program priorities, and resubmitted on Grants.gov, rather than requiring researchers to re-input all information.

[24] Government Accountability Office (GAO), *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, GAO-12-1022, September 2012, at http://www.gao.gov/assets/650/648934.pdf.

Proposal Preparation and Submission

Researchers and administrative staff have consistently asserted that pre-award proposal preparation and submission require significant amounts of time and resources. To address concerns for both applicants and agency reviewers, reports have recommended the use of preliminary proposals. For some of its grants, NSF has already been requiring preliminary proposals—which are shorter and require less information than full proposals—for initial review. After this first review, a subset of applicants are invited or encouraged to submit more time-consuming full proposals. Based on initial assessments, the National Science Board reported no adverse impacts to proposal quality, funding rates, or numbers of submissions.[25] Subsequent reports on academic research regulations have recommended wider use of preliminary proposals, as well as "just-in-time" submissions[26] and simplified budgets. The WG mandated by the AICA is tasked with considering recommendations for standard grant proposals and changes to the proposal process, though specific changes were not required in the enacted provisions.

Audits

In conducting financial management of an individual grant, researchers and administrators have stated that uncertainties surrounding the audit process add to workload and costs.[27] Audit uncertainties purportedly lead universities to institute overly conservative policies in order to assuage audit and legal concerns. Assessment reports have made various recommendations to address the concerns while maintaining effective oversight by federal agency Inspectors General (IGs). For example, the NAS report recommended clarifying discrepancies between agencies and IGs when interpreting agency policy prior to conducting an audit, and revising the risk-based methodologies that IGs use to identify institutions for audits by accounting for the institution's prior compliance records. In response, the NSF and HHS IGs asserted that, in order to fulfill their mandates and maintain necessary independence from agencies, they must interpret policies objectively and continue to use innovative methods regardless of an institution's past performance.[28] Recommendations pertaining to the Single Audit Act from assessments by the GAO[29] and others might also help address researchers' concerns over individual audits, such as ensuring consistent auditor training requirements to improve uniformity and the quality of audits.

Uniform Guidance Updates

As highlighted in the GAO report, universities assert that the UG made some requirements more prescriptive (e.g., the micropurchase threshold, which was subsequently changed through the NDAA FY2017 legislation) but did not address other areas of concern, such as subrecipient

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[25] National Science Board, *Reducing Investigators' Administrative Workload for Federally Funded Research*, Arlington, VA: National Science Foundation, 2014 (NSB-14-18), p. 8.

[26] "Just-in-time" submissions generally refer to supplementary materials such as institutional approvals for studies involving human subjects or animals that can be submitted after full proposal review, just in time for the final approval.

[27] For example, see National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*, Chapter 6.

[28] Department of Health and Human Services, Office of the Inspector General, and National Science Foundation, Office of the Inspector General, *Optimizing the Nation's Investment in Academic Research, Part I*, April 29, 2016, at https://www.nsf.gov/oig/_pdf/Optimizing_the_Nations_Investment.pdf: a joint response to the National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*.

[29] GAO, *Single Audit Quality: Actions Needed to Address Persistent Audit Quality Problems*, GAO-08-213T, October 25, 2007.

monitoring requirements.[30] Specifically, the UG requires grantees to follow up on audit findings and ensure appropriate actions on deficiencies for all subrecipients, regardless of risk.[31] Universities contend that resources used to follow up on audits with low-risk subrecipients could be put to better use following up high-risk subrecipients.

The UG revisions did allow for institutional flexibility in the procedures used to track and document personnel expenses. These changes responded to concerns that the traditional effort reporting system—which tracks personnel expenses on grants using a person-based methodology—was difficult to measure and expensive to maintain. Prior to development of the UG, the Federal Demonstration Partnership had begun multiple pilot projects using payroll certification—a project-based methodology—to track such expenses. Universities have reported reduced time and costs associated with the personnel documentation requirements using payroll certification. IG audits reported that the pilot system "generally provided accountability over federal funds" at Michigan Technological University and that problems identified during George Mason University's audit were the result of "internal policies and procedures, and not as a result of inadequate design of pilot system controls."[32] A final, comprehensive assessment from the HHS and NSF IG offices for all four pilots, which includes pilots at the University of California (UC) Irvine and UC Riverside, is anticipated in 2017.

To assess UG implementation and determine future actions to revise the UG and improve administrative efficiency, OMB and the Council on Financial Assistance Reform (COFAR)[33] set forth administrative and audit metrics. These metrics, and required agency actions, are described in a 2014 OMB memorandum, M-14-17, "Metrics for Uniform Guidance (2 C.F.R. 200)." Per the memorandum, OMB and COFAR aim to have initial evaluations of UG impacts conducted in 2017. Congress may consider conducting oversight to track progress with UG implementation, subsequent proposed changes, and impacts to the UG from recent legislation.

Human Subjects and Animal Research

For research involving human subjects and animals, additional reviews are needed by Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs), respectively. The Federal Policy for the Protection of Human Subjects, originally promulgated in 1991 as the Common Rule, updated regulations to protect people who participate in federally funded research studies, either directly or through contributions of biological samples and personal information. On January 19, 2017, HHS released a final rule updating the Common Rule to "modernize, simplify, and enhance" oversight.[34] This update did not include expansions to

[30] U.S. Government Accountability Office, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, GAO-16-573, June 2016, pp. 20-24.

[31] Ibid, p. 24.

[32] NSF, Office of the Inspector General, *Labor Effort Reporting under the Federal Demonstration Partnership Pilot Payroll Certification at Michigan Technological University*, September 30, 2015, and *Labor Effort Reporting under the Federal Demonstration Project's Pilot Payroll Certification Program at George Mason University*, July 31, 2015.

[33] COFAR is an interagency group of executive branch officials tasked with coordinating federal financial assistance, including providing recommendations to OMB and best practices to agencies. Formed in October 2011, they worked with OMB to develop the UG. COFAR replaced two federal boards—the Grants Policy Council (established in 1999) and the Grants Executive Board (established in 2004).

[34] U.S. Department of Health and Human Services et al., "Federal Policy for the Protection of Human Subjects," 82 *Federal Register* 7149, January 19, 2016.

the informed consent process regarding biospecimens, but it did retain another much discussed provision to use a single IRB review for studies that span multiple institutions.[35]

While it is too early to determine the potential impact on "facilitating valuable research and reducing burden, delay, and ambiguity for investigators" intended by the Common Rule revisions, Congress may direct studies to aid in understanding how the changes do or do not improve research grant efficiency while maintaining protections for health and privacy.

Oversight of research animal care and use is governed by multiple laws and policies, including the Animal Welfare Act (7 U.S.C. 2131 et seq.) and the Health Research Extension Act (42 U.S.C. 201 et seq.). These acts require the establishment of standards for animal research and the formation of institutional IACUCs to evaluate and certify institutional compliance. Individual agencies may have additional regulatory and policy requirements.[36] The NAS study asserted that "the complexity of the [oversight] system creates problems such as contradictions in process and redundancy in reporting." To address some of these concerns, the 21st Century Cures Act directed NIH, USDA, and the U.S. Food and Drug Administration to review and streamline regulations and improve coordination. Stakeholders have recommended additional actions, such as development of a federal-wide Assurance system,[37] which Congress may consider. Further, Congress may broadly consider the potential impacts of any proposed changes on agencies' abilities to evaluate the welfare of animals used for federally funded research.

Concluding Observations

The amount of time and costs associated with regulations and requirements for federally funded academic research are of ongoing concern to scientists and administrators. Legislation passed by the 114th Congress to address many of the long-standing issues raised in recent reports has had broad support from the scientific community, though challenges and uncertainties remain. Academic institutions can help maximize federal efforts to streamline and harmonize requirements by working to improve their own internal policies and procedures.

As prior assessments have noted, no one regulation or policy is the major cause of stakeholder concern; rather, it is the cumulative impact across a range of requirements. Congressional oversight may be an important part of monitoring the progress of implementing the provisions enacted in the 114th Congress in a holistic way and evaluating their overall effectiveness. Further, Congress may broadly consider the appropriate balance between supporting the nation's academic research enterprise through efforts to streamline regulations and maintaining mechanisms for oversight, transparency, and accountability. Forthcoming assessments from such efforts as the revised Common Rule, final guidance from payroll certification pilot programs, and OMB review of UG components, may help to inform any future efforts to optimize federal research policies.

[35] A detailed discussion of updates to the Common Rule are beyond the scope of this brief report; for additional information, see CRS In Focus IF10380, *Updating the Common Rule in an Era of Big Health Data*, by C. Stephen Redhead.

[36] See National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*, pp. 105-116, for a table of oversight principles, statutes, and policies by agency.

[37] Ibid., p. 115.

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