

441 G St. N.W.
Washington, DC 20548

February 3, 2021

Chairman
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
House of Representatives

Federal Research Grants: OMB Should Take Steps to Establish the Research Policy Board

Federally funded research projects play a key role in advancing science and innovation in the United States. In fiscal year 2020, the Trump Administration requested \$139 billion for research and development funding.¹ In accordance with laws, regulations, and policy guidance, agencies must implement a variety of administrative requirements that allow for oversight of federal research funding. Some requirements were established or strengthened in response to cases of researchers improperly spending funds or out of concerns about the integrity of the research being conducted. Others were established to meet broader policy objectives, such as increasing access to research data and results.²

Organizations that have studied administrative requirements have raised concerns about the workload and costs for researchers and universities to comply with these requirements and their effect on researchers' ability to efficiently conduct research.³ For example, the National Science

¹The data reflect fiscal year 2020 funding levels proposed by the President's *Budget of the United States Government, Fiscal Year 2020* (released Mar. 11, 2019). National Science Foundation National Center for Science and Engineering Statistics, *Federal R&D Funding, by Budget Function: Fiscal Years 2018–2020*, NSF 20-305 (Alexandria, Va.: December 2019).

²University administrators and researchers must comply with certain requirements when developing and submitting grant applications and with others as part of the terms and conditions of any awards they receive. For example, agencies generally require that applicants provide biographical sketches describing their professional accomplishments when submitting grant proposals, and require that grantees document the personnel expenses (e.g., researcher salaries) and the purchases (e.g., equipment and supplies) charged to a grant.

³We have previously reported on agencies' reimbursement of administrative and other indirect costs associated with university research. See GAO, *University Research: Policies for the Reimbursement of Indirect Costs Need to Be Updated*, [GAO-10-937](#) (Washington, D.C.: Sept. 8, 2010). We reported that federal agencies reimburse universities for their administrative costs up to a cap established in Office of Management and Budget guidance, and universities pay the remainder. In 1991, OMB established a cap of 26 percent of modified total direct costs—all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards and subcontracts up to the first \$25,000 of each subaward or subcontract. The cap on administrative costs is still in place and can be found in Appendix III to 2 C.F.R. part 200.

Board reported in 2014 that the administrative workload placed on federally funded researchers is more than what is needed to ensure accountability, transparency, and safety.⁴ Similarly, according to a 2016 report by the National Academies of Sciences, Engineering, and Medicine, regulatory activities related to research have grown dramatically in scale and sophistication in recent decades, resulting in researchers spending additional time, energy, and resources complying with administrative requirements.⁵

In a June 2016 report, we identified common factors that add to researchers' administrative workloads and costs for complying with selected requirements, including variation in agencies' implementation of requirements and increased prescriptiveness of certain requirements.⁶ We made a total of nine recommendations related to identifying and pursuing opportunities to streamline administrative requirements on research grants to universities.⁷

Legislation enacted in 2016 authorizes the establishment of an advisory committee responsible for making recommendations on modifying and harmonizing regulation of federally funded research to reduce administrative burden. Specifically, the 21st Century Cures Act requires the Office of Management and Budget (OMB) to establish, within 1 year of the act's enactment, an advisory committee to be known as the Research Policy Board (the Board), that will provide the federal government with information on the effects of regulations related to federal research requirements.⁸ The Board is to consist of both federal and non-federal members and include not more than 10 members from federal agencies, including officials from OMB, the Office of Science and Technology Policy (OSTP), the Department of Health and Human Services (HHS), the National Science Foundation (NSF), and other departments and agencies that support or regulate scientific research, as determined by the OMB Director.⁹ Non-federal members are to include not fewer than nine and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise, selected through a formal process to be established by the Director of OMB,

⁴National Science Board, *Reducing Investigators' Administrative Workload for Federally Funded Research*, NSB-14-18 (Mar. 10, 2014). The National Science Board establishes the policies of the National Science Foundation within the policy framework set forth by the President and Congress, and serves as an independent policy advisory body to the President and Congress on science and engineering research and education issues.

⁵National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century* (Washington, D.C.: National Academies Press, 2016).

⁶GAO, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, [GAO-16-573](#) (Washington, D.C.: June 2016).

⁷In this report, we recommended that the Department of Energy, the National Aeronautics and Space Administration, the Department of Health and Human Services, and the National Science Foundation coordinate through the Office of Science and Technology Policy's Research Business Models Working Group to identify additional areas where they can standardize requirements and report on these efforts. As of February 2020, this recommendation had been implemented by these agencies who noted several efforts to identify areas for standardizing administrative requirements for federal research grants including participating in interagency working groups, convening a group of experts, and issuing reports. See [GAO-16-573](#) for additional information.

⁸Pub. L. No. 114-255, § 2034(f), 130 Stat. 1033, 1060-62 (2016) (enacted Dec. 13, 2016).

⁹OSTP was established in 1976 to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technical issues of national concern, including but not limited to the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources. Presidential Science and Technology Advisory Organization Act of 1976, Pub. L. No. 94-282, tit. II, 90 Stat. 459, 463-68. OSTP also leads interagency science and technology policy coordination efforts and assists OMB with an annual review and analysis of federal research and development in budgets.

in consultation with federal members. The statute directs the Board to make recommendations regarding the modification and harmonization of regulations and policies with similar purposes across research funding agencies to ensure that the administrative burden of such policies and regulations is minimized while maintaining responsible oversight of federally funded research.

According to the act, activities of the Board may include:

- providing thorough and informed analysis of regulations and policies;
- identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;
- making recommendations with respect to efforts within the federal government to improve coordination of regulation and policy related to research;
- creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and
- conducting ongoing assessment and evaluation of regulatory burden, including the development of metrics, periodic measurement, and identification of process improvements and policy changes.

The act includes reporting requirements for the Board and specifies that the Board shall terminate on September 30, 2021.¹⁰

The 21st Century Cures Act also includes a provision for GAO to conduct an independent evaluation of the Board's activities and submit its results to Congress by December 2020.¹¹ This report examines the steps OMB has taken to establish the Board as required by the 21st Century Cures Act. Enclosure I provides information about other OMB efforts to modify and harmonize regulations and policies in federal research.

To determine the steps OMB has taken to establish the Board, we reviewed written responses from OMB officials knowledgeable about the status of the Board and its activities. The act also requires the Board to include members from HHS, NSF, and OSTP, and we collected and reviewed additional information from most of these agencies on the status of OMB's establishment of the Board.¹²

In addition, we reviewed the 21st Century Cures Act and other laws related to the Board and its establishment. We reviewed relevant reports on issues related to administrative burden, including our prior reports and others issued by the National Science Board; the National Academies of Sciences, Engineering, and Medicine; and the Council on Government Relations. We also reviewed related documents such as memoranda and final guidance published in the *Federal Register* and received written responses from OSTP officials on coordination efforts

¹⁰Pub. L. No. 114-255, § 2034(f)(5)-(6), 130 Stat. at 1062.

¹¹Pub. L. No. 114-255, § 2034(f)(7), 130 Stat. at 1062 (providing that GAO shall submit its report not later than four years after enactment of the 21st Century Cures Act). In accordance with § 2034(f)(7), we provided a draft report containing the results of our review to Congress on December 10, 2020.

¹²NSF declined to comment on the establishment of the Board by OMB, noting that they could not comment on OMB's plans or discussions related to the Board. Therefore, we did not collect or review information from NSF on the status of OMB's establishment of the Board.

with OMB related to modification and harmonization of regulations and policies with similar purposes across research funding agencies.¹³

We conducted this performance audit from February 2020 to January 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

OMB Has Not Established the Research Policy Board, Citing Issues with Full Agency Participation

As of January 2021, OMB had not established the Board as required by the 21st Century Cures Act. In October 2020, OMB stated that it had not established the Board because of issues with HHS's and other federal agencies' full participation in the Board's work related to developing or implementing a modified approach to certain policies involving the indirect costs related to research projects.¹⁴ Approximately 15 months after the enactment of the act, in March 2018, OMB sent a letter to Congress expressing concerns with HHS's ability to participate on the Board.¹⁵ The letter stated that, to carry out the activities identified in the statute, "the Board would necessarily delve into issues related to compliance burden and indirect cost reimbursement to entities that receive federal funding for research," and that a specific provision within another statute could, if continued in future bills, "complicate or even possibly prohibit HHS from participating in major elements of the Board process."

In general, OMB explained that the statutory provision cited in its letter prohibits HHS from using funds to develop or implement a modified approach to indirect cost policies.¹⁶ The Further

¹³Guidance for Grants and Agreements, 85 Fed. Reg. 49,506 (Aug. 13, 2020) (codified at Title 2 of the Code of Federal Regulations).

¹⁴Indirect costs are costs not directly attributable to a specific project but are necessary for the general operation of an organization receiving an award. Such costs can include depreciation on buildings and equipment; the costs of operating and maintaining facilities; and general administration and expenses, such as salaries and expenses for management, personnel administration, and accounting. GAO, *National Science Foundation: Actions Needed to Improve Oversight of Indirect Costs for Research*, [GAO-17-721](#) (Washington D.C.: Sept. 28, 2017). OSTP suggested using "facilities and administrative costs" in place of "indirect costs" throughout the report to alleviate potential confusion. While OMB's *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, commonly referred to as the "Uniform Guidance," refers to "indirect (facilities & administrative (F&A)) costs" both in the definitions section and throughout the guidance, see generally 2 C.F.R. pt. 200, we use "indirect costs" because it is the term used in the statutory language serving as the basis for concerns discussed in this report.

¹⁵Letter from OMB Director Mick Mulvaney to the Honorable Lamar Alexander (Mar. 13, 2018). In that letter, OMB also cited funding for the Board as an issue. While OMB has not received an appropriation specific to establishing the Board, it explained to us in July 2020 and October 2020, that NIH subsequently received funding that could be used to support the activities of the Board. Specifically, the Further Consolidated Appropriations Act, 2020, provided about \$2.2 billion to NIH to carry out the responsibilities of its Office of the Director, and identified establishing, operating, and supporting the Board as purposes for which its appropriation is available. Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2565 (2019). In October 2020, OMB explained to us that these funds are sufficient to establish, operate, and support the Board. NIH officials had stated in August 2020 that no funds have been used for purposes related to the Board.

¹⁶Continuing Appropriations Act, 2018 and Supplemental Appropriations for Disaster Relief Requirements Act, 2017, Pub. L. No. 115-56, div. D, § 138, 131 Stat. 1129, 1146 (2017). The act states "None of the funds appropriated in this Act may be used to develop or implement a modified approach to [provisions relating to indirect costs in part 75 of

Consolidated Appropriations Act, 2020, included similar language and expands the prohibition referenced by OMB to any department or agency.¹⁷ (We refer to this statutory prohibition on the use of funds as the “indirect cost provision” in the rest of this report.) Furthermore, the OMB letter stated that, without representation of a major research agency such as the National Institutes of Health (NIH), which is part of HHS, “OMB would not be equipped to meet the statutory goals of the Board.” OMB noted to us in October 2020 that HHS agreed with its position.

In October 2020, however, HHS stated in written responses to us that the indirect cost provision would not prohibit NIH’s participation on the Board and that the department was not aware of any other appropriations law provision that would prohibit such participation. According to HHS, as a federal advisory committee, the Board is to provide advice and recommendations to government officials on whether current regulations and policies are administratively burdensome, and what changes, if any, may help to reduce such burden. HHS noted that the Board does not have authority to develop or implement a modified approach for applying HHS’s indirect cost rate provisions to current HHS and NIH grant awards.¹⁸ Therefore, according to HHS, HHS’s or NIH’s participation on the Board would not be subject to the funding restriction in the indirect cost provision. We have no basis to disagree with HHS’s position.

The 21st Century Cures Act does not specifically direct the Board to examine issues related to indirect costs, and we identified other issues related to harmonizing and streamlining administrative requirements as well as reducing administrative burden that may fall within the scope of the Board’s activities. For example, the act specifies five activities that the Board may conduct, which include creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and conducting ongoing assessment and evaluation of regulatory burden, including the development of metrics, periodic measurement, and identification of process improvements and policy changes.

In June 2016, we found that selected universities and stakeholder organizations identified common factors that add to their administrative workload and costs for complying with selected requirements such as detailed pre-award requirements for applicants to develop and submit documentation for grant proposals, and increased prescriptiveness of certain requirements.¹⁹ Other federal and non-federal organizations have also commented on issues related to administrative burden in federal research that the Board could examine. For example, in 2014, the National Science Board identified common areas associated with high administrative workload, including financial management; the grant proposal process; reporting on progress,

title 45, Code of Federal Regulations], or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.”

¹⁷Pub. L. No. 116-94, div. A, tit. II, § 224, 133 Stat. at 2582 (2019). The act states “None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to [provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations], or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.” The Consolidated Appropriations Act, 2021 continues this provision. Pub. L. No. 116-260, div. H, tit. II, § 224, 134 Stat. 1182 (2020).

¹⁸45 C.F.R. pt. 75 (providing uniform administrative requirements, cost principles, and audit requirements for HHS awards, including provisions regarding indirect costs).

¹⁹[GAO-16-573](#).

time, and effort; and personnel management.²⁰ The Board could consider examining these or other issues related to streamlining and harmonizing regulations and reducing administrative burden in federally funded research in accordance with the 21st Century Cures Act.²¹

In October 2020, OMB agreed that the Board, if established, could conduct some activities that would address provisions of the 21st Century Cures Act without addressing indirect costs. OMB further stated, however, that in its view, such an approach from a both a policy and practical perspective “would have limited value given stakeholder interest in discussing indirect costs as part of reducing administrative burden of research policy and regulation.”

By not having established the Board, OMB is missing opportunities for the Board to provide information on the effects of regulations related to requirements for federally funded research, and to make recommendations to harmonize and streamline such requirements. The act required that OMB establish the Board within 1 year of the act’s enactment and that the Board submit its first required report to Congress and other entities containing recommendations within 2 years of enactment and once thereafter. Therefore, with less than 1 year before the Board is set to terminate on September 30, 2021, OMB may not have sufficient time to establish a functioning Board. Without action from Congress to pass legislation that would extend the Board’s authorization period, the Board, if established, would have limited time to fulfill its mission and develop recommendations to harmonize and streamline research requirements.

Conclusions

The 21st Century Cures Act requires OMB to establish the Research Policy Board to provide the federal government with information on the effects of regulations related to federal research requirements. However, as of January 2021, OMB had not established the Board. As a result, OMB may not have sufficient time to establish a functioning Board before it is set to terminate on September 30, 2021. In the absence of action by Congress to pass legislation that would extend the Board’s authorization period, the Board, if established, would likely have insufficient time to complete its work, including the development of recommendations to harmonize and streamline research requirements.

OMB explained it has not established the Board because it believes a statutory provision prohibits HHS and other agencies from taking action on issues that could implicate certain indirect cost provisions. However, HHS officials stated that this statutory provision would not prohibit NIH’s participation on the Board.²² Furthermore, the 21st Century Cures Act does not specifically require the Board to examine indirect cost policies, and there are several other issues that the Board could consider examining under its mandate. By not having established

²⁰National Science Board, *Reducing Investigators’ Administrative Workload for Federally Funded Research*.

²¹OSTP’s Joint Committee on the Research Environment (JCORE) also has ongoing efforts to reduce administrative burden on researchers through coordinating administrative requirements. In May 2019, the National Science and Technology Council established JCORE to examine key areas related to federally funded research. JCORE conducts its work through four subcommittees whose goals are to (1) ensure rigor and integrity, (2) coordinate administrative requirements, (3) strengthen research security, and (4) foster a safe, inclusive, and equitable research environment. According to OSTP, each subcommittee consists of approximately two dozen members from OMB, and federal science, foreign affairs, and security agencies. See enclosures I and II for additional detail.

²²As indicated earlier in the report, we have no basis to disagree with HHS’s position.

the Board, OMB is missing opportunities for the Board to provide information and to make recommendations to harmonize and streamline requirements for federally funded research.

Matter for Congressional Consideration

Congress should consider extending the period of authorization for the Research Policy Board, giving OMB additional time to establish the Research Policy Board and complete its statutory mission under the 21st Century Cures Act. (Matter for Consideration 1)

Recommendation for Executive Action

The Director of OMB should establish the Research Policy Board as mandated by the 21st Century Cures Act and report to Congress on the Board's activities. (Recommendation 1)

Agency Comments and Our Evaluation

We provided a draft of this report to OMB, HHS, and OSTP for review and comment. The agencies' comments are summarized below:

- In its emailed comments, OMB did not state whether it agreed or disagreed with our recommendation to establish the Board and report to Congress on its activities. The agency reiterated its position that the indirect cost provision significantly limits HHS's ability to participate on the Board and the Board's ability to meet its goals, thus preventing establishment of the Board. We maintain that the evidence in this report shows the need for our recommendation. Specifically, HHS stated in its written responses that the indirect cost provision would not prohibit NIH's participation on the Board and that the department was not aware of any other appropriations law provision that would prohibit such participation. Further, the 21st Century Cures Act does not specifically direct the Board to examine issues related to indirect costs, and we identified other issues related to harmonizing and streamlining administrative requirements as well as reducing administrative burden that may fall within the scope of the Board's activities. Without action, OMB is missing opportunities for the Board to provide information and to make recommendations to harmonize and streamline requirements for federally funded research.
- OSTP provided technical comments in an email, which we incorporated as appropriate.
- HHS told us in an email that they had no comments on the draft report.

We are sending copies of this report to the appropriate congressional committees, the Director of OMB, the Secretary of HHS, and the Director of OSTP. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or neumannj@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report include Farahnaaz Khakoo-Mausel (Assistant Director), Douglas G. Hunker (Analyst-in-Charge), Virginia Chanley, Joseph Cook, Louise Fickel, Christopher Pacheco, Amy Pereira, and Danielle Novak.

A handwritten signature in black ink, appearing to read "John Neumann", with a long horizontal flourish extending to the right.

John Neumann
Managing Director, Science, Technology
Assessment, and Analytics

Enclosures (2)

Enclosure I: Information on OMB Actions to Modify and Harmonize Regulations and Policies in Federally Funded Research

OMB has taken actions to harmonize and modify regulations and policies in federal research and to minimize administrative burden. These actions include participating in activities initiated by the Office of Science and Technology Policy's (OSTP) Joint Committee on the Research Environment (JCORE),²³ and issuing final guidance for grants and agreements.

OSTP JCORE Activities. OMB has participated in activities initiated by OSTP's JCORE. For example, OMB's Office of Financial Management and Office of Information and Regulatory Affairs are members of JCORE's subcommittee on coordinating administrative requirements and are engaged in efforts to reduce administrative burden on researchers, according to OSTP officials. OSTP officials also noted that OMB coordinated with it and other agencies on proposed changes to its *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (Uniform Guidance) and other efforts through this subcommittee.²⁴ Enclosure II provides a comparison of JCORE's actions with the potential activities that the Research Policy Board could undertake as identified in the 21st Century Cures Act.

Final Guidance. In January 2020, OMB issued proposed updates to its guidance for grants and agreements intended to reduce recipient administrative burden, provide direction on implementing new statutory requirements, and improve federal financial assistance management, transparency, and oversight.²⁵ In August 2020, OMB published the final guidance in the *Federal Register*, which became fully effective in November 2020.²⁶ OMB's guidance includes the following:

- **Providing flexibility to increase micro-purchase thresholds.** OMB incorporated prior guidance explaining the process for institutions of higher education, related or affiliated nonprofit entities, nonprofit research organizations, and independent research institutes to request an increase in the micro-purchase threshold into its Uniform Guidance, and extending this flexibility to all non-federal entities.²⁷ Micro-

²³In May 2019, the National Science and Technology Council established the Joint Committee on the Research Environment (JCORE) to examine key areas related to federally funded research. JCORE conducts its work through four subcommittees whose goals are to (1) ensure rigor and integrity, (2) coordinate administrative requirements, (3) strengthen research security, and (4) foster a safe, inclusive, and equitable research environment. According to OSTP, each subcommittee consists of approximately two dozen members from OMB, and federal science, foreign affairs, and security agencies.

²⁴In December 2013, OMB consolidated its grants management circulars into a single document—the Uniform Guidance—to streamline its guidance, promote consistency among grantees, and reduce administrative burden on non-federal entities, as well as to strengthen oversight of federal funds to reduce risk of waste, fraud, and abuse. This guidance became effective on December 26, 2014, and can be found at 2 C.F.R. part 200.

²⁵Guidance for Grants and Agreements, 85 Fed. Reg. 3766 (proposed Jan. 22, 2020) (to be codified at Title 2 of the Code of Federal Regulations).

²⁶Guidance for Grants and Agreements, 85 Fed. Reg. 49,506 (Aug. 13, 2020) (codified at Title 2 of the Code of Federal Regulations). Specified provisions in the guidance became effective prior to November 2020.

²⁷Micro-purchases are the acquisition of property or services, the aggregate dollar amount of which cannot exceed a certain amount, known as the micro-purchase threshold. Section 217 of the National Defense Authorization Act for Fiscal Year 2017 set the micro-purchase threshold at \$10,000 for institutions of higher education, or related or affiliated nonprofit entities, nonprofit research organizations or independent research institutes and allowed for

purchases allow for recipients to make purchases below a certain threshold without soliciting competitive price or rate quotations, if the non-federal entity considers the price to be reasonable. This approach ultimately saves the non-federal entity time and money.

- **Standardizing terminology.** OMB revised and clarified the definitions for selected terms, such as period of performance, budget period, and renewal.
- **Eliminating references to non-binding guidance.** OMB revised its guidance to prevent agencies from imposing non-binding guidance on federal awardees that has not gone through the appropriate public notice and comment process through inclusion in the terms and conditions of federal awards.

request and approval of a higher threshold amount in certain circumstances. Pub. L. No. 114-328, div. A, tit. II, sub. B, § 217, 130 Stat. 2000, 2051-52 (2016).

Enclosure II: Examples of OSTP Activities Related to Potential Activities Identified in the 21st Century Cures Act for the Research Policy Board

This enclosure provides examples of activities taken by the Joint Committee on the Research Environment (JCORE) consistent with, but not specifically in response to, the potential actions of the Research Policy Board as described in the 21st Century Cures Act (see table 1).

Table 1. Examples of the Office of Science and Technology Policy’s (OSTP) Activities Related to Potential Activities Identified in the 21st Century Cures Act for the Research Policy Board

21st Century Cures Act provision	OSTP activities ^a
(A) Provide thorough and informed analysis of regulations and policies.	According to an OSTP official, the Joint Committee on the Research Environment (JCORE) has analyzed regulations and policies in the following areas: (1) financial conflict of interest, (2) agency application requirements and use of measures such as preliminary proposals, (3) estimated budgets with limited details, and (4) just-in-time submission of application requirements to reduce administrative burden. As of May 2020, JCORE had not issued a public report on the findings of its analyses, according to an OSTP official.
(B) Identify negative or adverse consequences of existing policies and make actionable recommendations regarding possible improvement of such policies.	In November 2019, JCORE issued a request for information on actions that federal agencies can take to maximize the quality and effectiveness of the American research environment. According to an OSTP official, comments received identified the need for coordination, and modification of some requirements to reduce administrative burden related to financial conflicts of interest regulations and policies. Generally, JCORE has sought to take action based on existing findings and recommendations—such as those from the National Academies, National Science Board, and others—rather than seeking to make recommendations, according to an OSTP official.
(C) Make recommendations with respect to efforts within the federal government to improve coordination of regulation and policy related to research.	In November 2019, the White House hosted a summit to discuss JCORE’s progress. Key recommendations from the summit included: <ul style="list-style-type: none"> • establishing common forms and systems for compliance to decrease administrative workload and • limiting federal grant application initial reviews to establishing the merit of the proposed research. • reviewing compliance requirements “just in time” by agency staff after favorable merit review.
(D) Create a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices.	In November 2019, the JCORE summit brought together more than 100 people from industry, academia, and the federal government to inform the work of this joint committee across these key areas of work. Summit attendees had the opportunity to participate in breakout sessions on transparency, integrity, workload, and coordination.
(E) Conduct ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.	As noted above, JCORE has analyzed regulations and policies in several areas. An OSTP official stated that while they did not use specific metrics to evaluate regulatory burden, necessary metrics could be introduced.

Source: GAO analysis of section 2034(f)(3) of the 21st Century Cures Act and OSTP information. | GAO-21-232R

^a“OSTP activities” reflects activities that OSTP identified as being consistent with, but not specifically carried out in response to, section 2034(f) of the 21st Century Cures Act. See Pub. L. No. 114-255, § 2034(f), 130 Stat. 1033, at 1060-62 (2016).

(104123)

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through our website. Each weekday afternoon, GAO posts on its [website](#) newly released reports, testimony, and correspondence. You can also [subscribe](#) to GAO's email updates to receive notification of newly posted products.

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <https://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#).
Subscribe to our [RSS Feeds](#) or [Email Updates](#). Listen to our [Podcasts](#).
Visit GAO on the web at <https://www.gao.gov>.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact FraudNet:

Website: <https://www.gao.gov/fraudnet/fraudnet.htm>

Automated answering system: (800) 424-5454 or (202) 512-7700

Congressional Relations

Orice Williams Brown, Managing Director, WilliamsO@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800, U.S. Government Accountability Office, 441 G Street NW, Room 7149, Washington, DC 20548

Strategic Planning and External Liaison

Stephen J. Sanford, Acting Managing Director, spel@gao.gov, (202) 512-4707, U.S. Government Accountability Office, 441 G Street NW, Room 7814, Washington, DC 20548

