

Reform Area	Statutory Requirements/Actions	Federal Actions to Date
<p>Research Policy Board A public-private entity recommended by the National Academies (NAS) "to foster more effective conception, development and harmonization of research regulations." The National Science Board (NSB) similarly recommended an interagency, intersector committee with stakeholder and Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) representation.</p>	<p>Section 2034(f) of the 21st Century Cures Act directed OMB to establish a research policy board within one year of enactment (by December 2017).</p>	<p>OMB published a Statement of Administration Policy (SAP) dated August 15, 2018, regarding appropriations for DOD, and Labor, Health and Human Services, Education, and related agencies, for FY19. The SAP indicates that "The Administration is disappointed that the bill does not authorize the use of NIH funding to establish and operate the 21st Century Cures Act Research Policy Board, as requested in the FY 2019 Budget." The SAP goes on to say that the indirect cost policy provision, "which prohibits changes to the method NIH uses to pay grantee institutions for administrative and facilities costs" "makes it difficult to address regulatory burden in a meaningful way. As a result, the Administration will not be able to establish the Research Policy Board as directed by the Congress."</p>
<p>Interagency Working Group on Research Regulations</p>	<p>Section 201 of the American Innovation and Competitiveness Act (AICA) directed OMB to create an interagency working group on research regulations in coordination with the Office of Science and Technology Policy (OSTP). The working group is charged with reviewing existing regulations and making recommendations for eliminating, streamlining, or improving regulations and processes with the goal of reducing burden on researchers and institutions of higher education (IHE). The Act requires a report to congressional committees annually for the first four years.</p>	<p>The existing Research Business Models (RBM) Working Group of the Committee on Science, National Science and Technology Council, was "reconvened" to execute the working group responsibilities required under the AICA. The working group issued the report Reducing Federal Administrative and Regulatory Burdens on Research on May 25, 2018 in response to provisions of the AICA.</p>

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<p>Financial Conflict of Interest (FCOI) Harmonizing policies and reducing burden - Recommendations: National Academies - Federal-wide policy to be developed by Congress and OSTP; NSB and the Government Accountability Office (GAO) - evaluation of the 2011 revisions to the PHS COI regulations.</p>	<p>Section 2034(a) of the 21st Century Cures Act directed the HHS Secretary to "lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest" and "make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers" within two years of enactment (by December 2018).</p>	<p>HHS has not published notices or requests for information on FCOI to date and may seek to address FCOI reform through the RBM as part of a harmonized, federal-wide effort. Per the May 25, 2018 RBM report, "RBM will examine the studies of the effectiveness of FCOI policies as well as the associated burdens and consider ways to harmonize requirements across agencies so as to reduce burdens."</p>
<p>Subrecipient Monitoring Reduce unnecessary or redundant oversight. Recommendations - National Academies - amend the Uniform Guidance (UG) to clarify applicability to IHEs only for project and performance monitoring. GAO - target higher risk subrecipients.</p>	<p>Section 2034(b) of the 21st Century Cures Act directed the National Institutes of Health (NIH) to "implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees" including possible exemption where the subrecipient is subject to single audit and through use of collaborative grant models or other structures allowing for multiple prime awardees. The Act did not establish a timeline for completing such measures.</p>	<p>NIH has indicated interest in addressing administrative burden associated with subrecipient monitoring through the RBM as part of a harmonized, federal-wide effort. Per the May 25, 2018 RBM report, "OMB's 2014 Uniform Guidance (2 CFR 200)21 (UG) aimed to reduce administrative burden associated with Federal awards while reducing the risk of waste, fraud, and abuse." "RBM has agreed to investigate the factors that have inhibited the intended effect of the UG language on sub-recipient monitoring. The committee will then offer recommendations about what can be done to clarify the intent and reduce unnecessary, duplicative monitoring activities..."</p>

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Financial Reporting	Section 2034(c) of the 21st Century Cures Act directs the HHS Secretary, in consultation with NIH, to evaluate financial expenditure reporting procedures and requirements for recipients of NIH funding and to take action to avoid duplication between department and agency procedures and requirements.	HHS has not published notices or requests for information related to financial reporting to date.
Animal Research Regulations Recommendations - National Academies: OSTP to convene - goal of unified federal approach. NSB - engage all regulatory, independent and certification bodies.	Section 2034(d) of the 21st Century Cures Act directs NIH, in collaboration with USDA and FDA, to complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators not later than two years after the date of enactment (December 2018).	NIH, USDA, and FDA published a draft report on December 7, 2018 on the agencies review of applicable regulations and policies, and recommendations for reducing administrative burden. The draft, which is open for public comment for 60 days, highlights efforts taken in support of the review, including listening sessions and a request for information.

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<p>Documentation of Personnel Expenses (Effort Reporting) Recommendations - NSB: that OMB issue a memo of clarification indicating that the payroll certification method is acceptable to the Federal Government. National Academies: OMB affirm that IHEs may take advantage of the flexibility of the UG for documentation of personnel expenses.</p>	<p>Section 2034(e) of the 21st Century Cures Act Directs the HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses.</p>	<p>On November 30, 2017 NIH issued a notice (NOT-OD-18-108) on Standards for Documentation of Personnel Expenses. In the notice, the agency clarifies "the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreement recipients." The notice indicates that "For records which meet the required standards, the non-Federal entity will not be required to provide additional support or documentation for the work performed, other than that referenced in 45 CFR 75.430 paragraph (i)(3)." It also indicates that "Cognizant agencies for indirect costs are encouraged to approve alternative proposals based on outcomes and milestones for program performance where these are clearly documented. Where approved by the Federal cognizant agency for indirect costs, these plans are acceptable as an alternative to the requirements for records of personnel expenses."</p>
<p>Unified Grant Format Recommendations - National Academies</p>	<p>Section 201 of the AICA calls for an interagency working group to "develop, to the extent practicable, a simplified, uniform grant format to be used by all Federal science agencies."</p>	<p>The May 25, 2018 RBM report describes earlier efforts to create a standard grant-application form in 2003 (the SF424RR), and subsequent efforts to identify common data elements and develop data standards; develop a modular approach to application forms; develop standard approaches and help text; refine approaches to electronic implementation; and hold training meetings and system improvement discussions.</p>

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<p>Preliminary Proposals, Simplified Budget Proposals, and Greater Use of Just-in-time Recommendations - NSB, NAS, and GAO</p>	<p>Section 201 of the AICA calls for an interagency working group to consider implementing these measures.</p>	<p>From the May 25, 2018 RBM report, "Several RBM member agencies have experimented with such innovations and have lessons to share from their experiences. RBM will explore these lessons and seek others about these approaches to reducing the burdens of initial applications. After assessing the available knowledge base, RBM will devise recommendations for how best to proceed with regard to streamlined grant applications and review."</p>
<p>Centralized Researchers Profile Database Recommendations - National Academies</p>	<p>Section 201 of the AICA calls for the establishment of a centralized database for biosketches, CVs, licenses, and related documents and to consider incorporating existing databases. To be utilized for all grant proposals "to the extent practicable."</p>	<p>From the May 25, 2018 RBM report, "RBM anticipates that it is best to avoid full-scale development of a stand-alone system, but, instead, to adapt existing workflows and systems that researchers are already using." The report describes "current Federal activities designed to promote a universally useful and used researcher profile system" including pilots with the Federal Demonstration Partnership; with ORCID (Open Researcher and Contributor Identification) to "expand the ORCID data model to include additional Curriculum Vitae fields"; and with "CrossRef and a coalition of funders to create a universal funding identifier." The report also notes the Science Experts Network Curriculum Vitae (SciENcv), a federal "electronic researcher-profile project that enables researchers to more easily create and maintain biosketches to be submitted with Federal grant applications and annual reports" at NIH, IES, and NSF. RBM is also seeking to "link every part of the research ecosystem through persistent identifiers."</p>

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<p>Centralized Assurances Repository Recommendations - National Academies: "similar to the Single Audit Clearinghouse of the FDP."</p>	<p>Section 201 of the AICA calls for an interagency working group to "establish a central repository for all of the assurances required for Federal research grants" and provide guidance on its use.</p>	<p>From the May 25, 2018 RBM report, "an interagency working group has developed a draft government-wide annual standard set of assurances for grant applicants and recipients. The intent is to establish a centralized service for the collection of and access to government-wide assurances that apply to grants, leveraging the Integrated Award Environment managed by the General Services Administration" "...it is anticipated that this service will be made available in Quarter 2 of Fiscal Year 2019. Once available and fully implemented, grant applicants will no longer make multiple assurances on their applications; they would only indicate that their institution's assurances are up to date in the centralized system." "RBM is following the progress of this project, will provide comments as appropriate during the public comment period, and will continue to track the project..."</p>
<p>Progress Reports Recommendations - NSB. National Academies: single uniform format.</p>	<p>Section 201 of the AICA calls for an interagency working group to "conduct a comprehensive review of the mandated progress reports for federally funded research" and develop a strategy to simplify them.</p>	<p>In January 2010, the RBM published the Research Performance Progress Report (RPPR), a standard performance report. At the time of the May 25, 2018 RBM report, USDA, DHS, Commerce (DOC), DOD, DOE, DOJ, EPA, the Department of Education's IES, NASA, NEH, NIH (and other PHS agencies), and NSF had adopted the RPPR which has since been updated.</p>

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<p>Micropurchase Threshold Increase to \$10,000 with the opportunity for higher thresholds. Recommendations - National Academies. GAO - target higher risk purchases.</p>	<p>National Defense Authorization Act - \$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings, institutional risk assessment, or State law. Grants, cooperative agreements, and contracts for all federal agencies. Applies to all federal agencies. Similar language in the AICA is applicable only to NSF, NASA and NIST.</p>	<p>OMB released memorandum M-18-18 on June 20, 2018, Implementing Statutory Changes to the Micro-Purchase and the Simplified Acquisition Thresholds for Financial Assistance. The memorandum "raises the threshold for micro-purchases under Federal financial assistance awards to \$10,000, and raises the threshold for simplified acquisitions to \$250,000 for all recipients" and implements an approval process for institutions seeking thresholds higher than \$10,000.</p>