

Recent Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate. Signed into law Dec. 13) Link to PDF	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 16.) Link to PDF	National Defense Authorization Act (Passed House and Senate. Conference report language adopted by Senate on Dec. 8) Link to PDF
<p>Research Policy Board A public-private entity recommended by the National Academies "to foster more effective conception, development and harmonization of research regulations." The NSB similarly recommended an interagency, intersector committee with stakeholder and OMB/OIRA representation.</p>	<p>Established by the Director of OMB. 10 or fewer federal members (OIRA, OSTP, HHS, NSF and others that support or regulate research). 9-12 representatives of academic or other non-profit research institutions or organizations with relevant expertise. Appointed through a formal process including nomination by members of the research community. The process would be established by the Secretary (in consultation with the Federal membership). This is likely in error, as in previous iterations the RPB was established by the HHS Secretary due to HELP jurisdiction, now the OMB Director. The board is charged with coordinating and improving regulations and policies; discussing policy and regulatory gaps and challenges; and ongoing assessment of regulatory burden. Expert subcommittees can be formed as needed. Not explicitly tasked with addressing prospective regulations and policies. Report to Congress and GAO evaluation. Sunsets 9/30/20.</p>	<p style="text-align: center;">Not addressed.</p>	<p style="text-align: center;">Not addressed.</p>

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Interagency Working Group on Research Regulations	Not addressed.	To be established by OMB in coordination with OSTP. 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 IHEs. Directed to consult with stakeholders, an improvement over the existing research business models (interagency) working group. Requires a report to congressional committees annually for the first four years.	Not addressed.
Subrecipient Monitoring - reduce unnecessary or redundant oversight. Recommendations - National Academies - amend the UG to clarify applicability to IHEs only for project and performance monitoring. GAO - target higher risk subrecipients.	NIH Director directed to reduce administrative burden, including possible exemption where the subrecipient is subject to single audit and use of collaborative grant models or other structures allowing for multiple prime awardees.	Not addressed.	Not addressed.

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<p>Micropurchase Threshold - Increase to \$10,000 with the opportunity for higher thresholds.</p> <p>Recommendations - National Academies. GAO - target higher risk purchases.</p>	Not addressed.	<p>\$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with audit findings, institutional risk assessment, or State law. Applicable only to NSF, NASA and NIST.</p>	<p>\$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with <u>clean</u> audit findings, institutional risk assessment, or State law. Grants, cooperative agreements, and contracts for <u>all</u> federal agencies.</p>
<p>Review Financial Conflict of Interest Policies - harmonizing policies and reducing burden - Recommendations: National Academies - Federal-wide policy to be developed by Congress and OSTP; NSB and GAO - evaluation of the 2011 revisions to the PHS COI regulations.</p>	<p>Within two years of enactment. Led by the HHS Secretary. Review to include the minimum threshold for reporting and just-in-time reporting.</p>	Not addressed.	Not addressed.
<p>Evaluation of Financial Reporting Procedures and requirements with the goal of minimizing burden.</p>	<p>Specific to HHS/NIH. Avoid duplication between HHS and NIH and minimize burden.</p>	Not addressed.	Not addressed.

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Review Animal Research Regulations - goal of reducing administrative burden. Recommendations - National Academies: OSTP to convene - goal of unified federal approach. NSB - engage all regulatory, independent and certification bodies.	Within two years of enactment. NIH, USDA and FDA are charged with identifying and eliminating inconsistent, overlapping or unnecessarily duplicative regulations and policies and improving coordination.	Not addressed.	Not addressed.
Clarify or Affirm Alternatives to Effort Reporting - Recommendations - NSB: 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.	Directs the HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses. It would be our understanding that the intent is that the HHS Secretary affirm the flexibility under the UG in documenting personnel expenses.	Not addressed.	Not addressed.

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Unified Grant Format - Recommendations - National Academies	Not addressed.	Working group to consider a simplified, unified grant format for use by all agencies.	Not addressed.
Preliminary Proposals - Recommendations: NSB and GAO	Not addressed.	Consideration by interagency WG	Not addressed.
Simplified Budget Proposals - Recommendations - NSB; GAO	Not addressed.	Consideration by interagency WG	Not addressed.
Greater Use of Just-in-time - Recommendations - NSB and Academies reports	Not addressed.	Working Group to consider.	Not addressed.
Create a Centralized Researchers Profile Database - Recommendations - National Academies	Not addressed.	WG to establish a centralized database for biosketches, CVs, licenses, and related documents. Consider incorporating existing databases. To be utilized for all grant proposals "to the extent practicable."	Not addressed.

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<p>Create a Centralized Assurances Repository</p> <p>- Recommendations - National Academies: "similar to the Single Audit Clearinghouse of the FDP."</p>	Not addressed.	For all assurances required for federal grants.	Not addressed.
<p>Review and Simplify Progress Reports - Recommendations - NSB. National Academies: single uniform format.</p>	Not addressed.	Consider limiting reports to performance outcomes. The RBM working group has created the Research Performance Progress Report, a unified federal progress report. Potential for further simplification and limiting to performance outcomes.	Not addressed.

Reports cited include the National Science Board report "Reducing Investigators' Administrative Workload for Federally Funded Research;" The National Academies Report "Optimizing the Nation's Investment in Academic Research;" and the GAO report "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements"