

Non-HHS Research Regulatory Reform

- The Executive Office of the President (EOP) and Office of Management and Budget (OMB) should consolidate oversight under one federal agency or office with one set of regulations, policies, guidance documents and reporting requirements for research misconduct; conflict of interest; export controls (currently State, Commerce and Treasury); data sharing/public access; and Health and Safety/Occupational Health. The latter includes oversight from OSHA, NIOSH, and OLAW (for animal research); CDC and APHIS (select agents); NIH (rDNA); the National Center for Import and Export (APHIS, the importation of human or nonhuman-primate material that is produced in tissue culture or is a potential or actual zoonotic pathogen); DOT (transportation of hazardous materials); DOE, EPA, and DEA (controlled substances); NRC and others.
- OMB should quickly begin the process of standing up the Research Policy Board mandated by section 2034 of the [21st Century Cures Act](#) (Cures Act), *Reducing Administrative Burden for Researchers*. The language in the Cures Act directs OMB to establish the new Board and the process by which members of the Board will be appointed within one year of enactment. Per the National Academies report *Optimizing the Nation's Investment in Academic Research*, “the regulatory regime (comprising laws, regulations, rules, policies, guidance, and requirements) governing federally funded academic research should be critically reexamined and recalibrated.” As directed by the Cures Act, the Board, consisting of federal and non-federal members--including university representatives and university affiliated non-profit organizations with relevant expertise--will advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and harmonize them. As conceived by the National Academies, the Board would also prospectively advise on proposed rules, policies and guidance.
- The EOP and OMB, Office of Information and Regulatory Affairs (OIRA) should develop a robust process for the promulgation of sub-regulatory federal rules and policies that would require the public have at least 60 days to comment on the merits and impact of any proposed policy, guidance document, or frequently asked question (FAQ) before it is issued. Agencies are currently regulating through policy with no statutory or regulatory basis and through guidance material that is not subject to public comment and OIRA oversight. OIRA should take an active role in ensuring that final regulations, policies and significant guidance include material changes recommended in comments received from the regulated community. Guidance documents should also clearly indicate that they are guidance only and have no legal basis for enforcement and should not be incorporated by reference as “requirements” in terms and conditions of an award or contract. Federal policies and significant guidance should be subject to regulatory planning and retrospective review.

- Eliminate Duplicative Administrative Reviews by Pass-through Entities (Subrecipient Monitoring). The Uniform Guidance has added prescriptive administrative requirements (e.g., implied need to document on a transaction-by-transaction basis the determination of subrecipient/contractor relationship and detailed risk assessment and monitoring requirements) to an already burdensome process of issuing subawards to other universities and research organizations for collaborations on federally funded projects. With subrecipient monitoring, the “Prime” recipient is expected to monitor the business practices and internal controls of the subrecipient. This may be necessary for subrecipients that do not meet the threshold for Federal Single Audit (\$750K in 2 CFR 200). It is unnecessary for subrecipients that have completed a Federal Single Audit.

OMB should modify the Uniform Guidance to clarify that where a subrecipient has a current Single Audit report, and has not otherwise been excluded (e.g., debarred or suspended) from receipt of federal funding, prime recipients can rely on the subrecipient’s auditors and cognizant or oversight agency for audit for routine audit follow-up and management decisions, and thus no separate audit review or management decision by the pass-through entity is required. Such reliance does not eliminate the obligation of the prime recipient to issue subawards that conform to agency and award-specific requirements and to manage risk through ongoing subaward monitoring (e.g., monitoring of technical progress and expenditures, and adherence to award terms and conditions). Modifications via FAQs or other guidance are suboptimal and, to the extent this is the route OMB takes, should be linked to the guidance in a more formal way, for example, through the compliance supplement.

- Agencies should establish a mechanism for review of policies and guidance that consistently create compliance challenges, to identify the cause of the challenges and to work with stakeholders in identifying alternatives.
- Agencies should develop pilot projects through the Federal Demonstration Partnership for major new regulations and policies to assess their effectiveness prior to implementation and to ensure they are not adding unnecessary burdens.
- Develop a common federal portal for grants submission, progress reporting, invoicing/cash draw downs, publication requirements and final reporting (e.g., financial, equipment) with a single set of rules, forms and due dates (potentially using NSF policy and guidelines as a model).
- Consider having all regulations, policies and major guidance sunset after a set period of time (e.g., 5 years). To be renewed, the government would have to seek comments and demonstrate benefits or cost efficiencies accrued based on data from stakeholders.
- Eliminate the requirement to resubmit the Federal Financial Report (FFR) for small dollar credits (e.g. <\$100 or \$500 or possibly 0.1% of award amount). Allow universities to instead accumulate all ending and post award debits and credits to federal awards over a period of time (e.g., quarterly or annually) and refund net credits directly to the U.S. Treasury, or reimburse the U.S. Government through some other mechanism, which could save hundreds of dollars or more per award.

- Federal agencies should adopt performance-based measures for grants. If a progress or final report is accepted by the agency, then the personnel effort devoted to the project was sufficient and appropriate to achieve its objectives and time and effort reporting and salary certification unnecessary.
- Establish a central federal database for biosketches, CVs, licenses, and related documents for all grant proposals.
- Develop standard forms and processes across agencies.
- Require all federal agencies to adopt common research terms and conditions under, and to adhere to, the OMB Uniform Guidance.
- Federal agencies should eliminate quarterly financial reports once they have transitioned to subaccounts.
- As recommended by the National Science Board, agencies should modify proposal requirements to include only those essential to evaluating the merit of the proposed research and making a funding determination. This can be achieved through:
 - Preliminary proposals
 - Broadening just-in-time submission
 - Simplifying budget requirements
- Eliminate/rescind the Department of Education (ED) Final Rule on Open Licensing Requirements for Competitive Grant Programs. The rule undermines the ability of ED grant recipients to partner with the private sector to commercialize materials and technologies developed with ED funding. Lack of incentives for private investment erodes the ability to provide for value-added further development, refinement, and effective marketing and distribution of the materials and technologies. Premature release of untried materials may lead to modifications without the necessary validation by the original developers, which could lead to undesirable outcomes as well as reputational risks. No evidence has been provided by ED of the need or problem that the open licensing requirement would address. Additional information can be found [here](#).
- Modify the Conflict of Interest in Procurement Rule, 2 CFR 200.112. OMB should make a technical correction to the UG, removing “selection of a subrecipient” to clarify that the intent of the regulations is to address conflicts that might arise around how a non-Federal entity expends funds under a Federal award and not to address individual financial interests. Further, OMB should work with agencies to harmonize policies such that they are consistent with the intent of the Uniform Guidance. Additional information can be found [here](#).
- Eliminate the OMB/CASB Disclosure Statement (DS-2). The DS-2, which was designated to be rescinded under the initial, 2013 version of the Uniform Guidance (2 CFR Part 200), is a document setting forth an institution’s accounting practices with regard to federal funds that requires approval by the institution’s cognizant agency for indirect costs. It is a

transposition of accounting policies and practices that are already documented elsewhere, usually on an institution's website or within policy manuals that are readily available to auditors. Cognizant agencies cannot keep up with requests for approval and necessary changes are delayed. It is now a burden both for universities and the government that has far outlived any usefulness. It is rarely requested at audit, yet IGs insist it is a critical tool to mitigate waste, fraud, and abuse. All other recipients of federal funds, including State, Local, and Tribal governments and nonprofits, are excluded from this requirement. The lack of value of the DS2 has clearly been demonstrated by the fact that it has not yet been updated for the Uniform Guidance.

- Delay implementation of the National Archives and Records Administration (NARA) Controlled Unclassified Information Final Rule. A FAR clause is anticipated sometime this year. DFARS implementation requires contractor compliance by December 2017. It would be helpful to have at least a year after FAR implementation to comply with the NARA rule and to get a further delay for DFARS until December 2018.
- Eliminate the Department of Education Requirement for an Annual Compliance Audit of Title IV Student Aid Programs. ED included this requirement in the draft version of the 2017 Compliance Supplement. Appropriately, it has since been eliminated. There is no good basis to require an annual audit when a grantee is deemed low-risk. However, ED's position (per an August 5, 2016 Notice) still indicates that an annual audit is required, despite this requirement being inconsistent with the Higher Education Act of 1965, the Single Audit Act of 1984, and most recently, the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (2 CFR Part 200).
- Eliminate the Service Contract Act Reporting Requirements. The FY 2010 Omnibus Funding bill included a requirement that agencies submit annual inventories to OMB of service contracts based on their Federal Activities Inventor Reform (FAIR) Act inventories. Two new implementing clauses were added to the FAR (52.204-14 and 15) requiring reporting of direct labor hours expended in performing the services, effective 1/30/2014. Agencies began requiring contractors to submit this information in late 2015 (there is an annual October 31 due date). R&D contracts with universities, while excluded from Service Contract Act wage rate requirements, are considered service contracts for purposes of agency FAIR Act inventories. For universities the requirement is burdensome and not useful. Universities can only report estimates, since their payroll systems are not set up on a labor hour basis. There also are potential audit concerns. Research contracts with universities should be excluded from the labor hour reporting requirements.
- Eliminate redundant reports on inventions (currently reported in progress reports, paper final invention reports and iEdison). The government should utilize the USPTO database (or if not feasible, iEdison) to quantify federally funded inventions/patents and institutions should not be required to separately report discoveries that may not be patentable.