Research Regulatory Reform: Recent Legislation and the New Administration

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Discussants

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Recent Legislation

21st Century Cures Act
• Signed into law December 13, 2016
• Sets in motion many of the recommendations made by the National Academies Committee on Federal Research Regulations and Reporting Requirements, including the Research Policy Board.

American Innovation and Competitiveness Act
• Signed into law January 6, 2017
• Interagency Working Group to reduce research regulatory burden; micropurchase threshold; specific provisions addressing pre-award and other requirements.

National Defense Authorization Act
• Signed into law December 23, 2016
• Creates a $10,000 or higher micropurchase threshold.
Executive Actions

Regulatory Freeze
• Mandatory 60 day review of new and pending regulations by the new administration

Interim Guidance on Reducing Regulations and Controlling Regulatory Costs
• Two existing regulations to be repealed for every new rule

Federal Hiring Freeze
• Retention
• Reallocation of resources
• Intergovernmental Personnel Act
Subrecipient Monitoring - NIH Director directed to reduce administrative burden

- Possible exemption where the subrecipient is subject to single audit
- Use of collaborative grant models or other structures allowing for multiple primes
- OMB FAQs anticipated.

Safe Harbor for Pass-through Entities and their Subrecipients (2 CFR 200.331)

Q: If a pass-through entity confirms that a proposed subrecipient has a current Single Audit report submitted in the Federal Audit Clearinghouse and has not otherwise been excluded (e.g., debarred or suspended) from receipt of Federal funding, can the pass-through entity rely on the subrecipient’s cognizant or oversight agency for audit to follow-up and issue management decisions?

A: Yes. The current guidance is intended to provide a Safe Harbor for pass-through entities and their subrecipients subject to a Single Audit. No additional subrecipient audit review by the pass-through entity is expected when the conditions outlined above exist. However such reliance does not eliminate the obligation of the pass-through entity to issue subawards that conform to agency and award specific requirements and to manage risk through life-of-the-subaward monitoring activities, such as monitoring of programmatic performance and invoices.
Cures Agency Specific Provisions – HHS/NIH

Review Financial Conflict of Interest Policies – Review by the HHS Secretary within two years of enactment
• Review to include the minimum threshold for reporting and just-in-time reporting.

Evaluation of Financial Reporting Procedures
• Avoid duplication between HHS and NIH and minimize burden

Clarify or Affirm Alternatives to Effort Reporting
• HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses.
Privacy Protection for Human Research Subjects
• Certificates of Confidentiality
• To be implemented within 6 months. Per NIH, COCs will issue automatically.

Data Sharing
• Allows the NIH Director to require grant recipients to share the data that is generated from NIH-funded research.

Clinical Trials Database
• HHS Secretary to consult with agencies and other stakeholders to receive recommendations related to enhancements to the clinical trial registry.
Cures Agency Specific Provisions – HHS/NIH/FDA

Protection of Human Research Subjects
• Requires the HHS Secretary to harmonize differences between the Common Rule and the Federal Food Drug and Cosmetic Act.

Informed Consent Waiver or Alteration for Clinical Investigations
• Provides the FDA the flexibility to waive or alter informed consent requirements for clinical trials with minimal risk, similar to the Common Rule.

Review of Animal Research Regulations
• 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.
AICA and NDAA increase the micropurchase threshold to $10,000 with the opportunity for higher thresholds.

- AICA applicable only to NSF, NASA and NIST.
- NDAA applicable to all agencies but must be renewed annually.
- OMB to address in the anticipated Federal Register notice.
Research Policy Board and Interagency Working Groups

Research Policy Board

• OMB to establish the board
• 10 or fewer federal members (OIRA, OSTP, HHS, NSF and others that support or regulate research) and 9-12 representatives of academic or other non-profit research institutions/organizations.
• Appointed through a formal process including nomination by members of the research community
• 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.
Interagency Working Group on Research Regulations

- Charged with reviewing existing regulations and making recommendations for eliminating, streamlining or improving regulations and processes and to refocus on performance-based goals.
- Directed to consult with stakeholders. Report to Congress after one year and annually for three.
  - Unified Grant Format
  - Preliminary Proposals
  - Simplified Budget Proposals
  - Greater use of just-in-time
  - Centralized Researchers Profile Database
  - Centralized Assurances Repository

Research Business Models Subcommittee

- Research Performance Progress Report
- SciENcv
- Other Federal efforts
Regulatory Freeze

Implications for:

• Department of Labor Overtime Rule
• Updates to the Uniform Guidance
• Department of Education’s Final Rule on Open Licensing Requirements for Competitive Grant Programs
  o Joint association letter expressing serious concerns about the rule.
• Federal Policy for the Protection of Human Subjects (Common Rule)
Interim Guidance on Reducing Regulations and Costs


• When an executive department or agency proposes a new rule it must identify at least two existing regulations to repeal as a means to fully offset the costs of the new regulation.
• The total incremental cost of all new regulations, including those repealed, must not be greater than zero.
• “New significant guidance or interpretive documents will be addressed on a case-by-case basis”
• To the extent feasible, regulatory actions should be eliminated before or on the same schedule as the new regulatory action they offset.”
2017 Outlook

115th Congress
• Funding
• Oversight

Trump Administration
• Funding
• Executive Orders

Executive Agencies
• Regulations