Research Regulatory Reform: Recent Legislation and the New Administration

Council on Governmental Relations Meeting
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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.

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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- Two existing regulations to be repealed for every new rule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

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Cures Agency Specific Provisions – HHS/NIH

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 passthrough 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.

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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.

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Cures Agency Specific Provisions – HHS/NIH

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.

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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.

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Micropurchase Threshold

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.

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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.

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Research Policy Board and Interagency Working Groups

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

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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
  - Joint association letter expressing serious concerns about the rule.
- Federal Policy for the Protection of Human Subjects (Common Rule)

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Interim Guidance on Reducing Regulations and Costs

January 30, 2017 Executive Order "Reducing Regulation and Controlling Regulatory Costs": "Regulatory Cap for Fiscal Year 2017"

- 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."

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2017 Outlook

115th Congress

- Funding
- Oversight

Trump Administration

- Funding
- Executive Orders

Executive Agencies

- Regulations

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Questions?

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