21st Century Cures Act: Implications for the FDP

Richard Seligman, California Institute of Technology

David W. Robinson, Oregon Health & Science University

Reducing Administrative Burden

The 21st Century Cures Act was signed into law by President Obama on December 13, 2016

The Act contains 18 Titles and is over 400 pages in length and aims to

"To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes."

In particular alignment with the FDP mission and vision is **Section 2034: Reducing Administrative Burden for Researchers**

Within this section are a number of directives and considerations related to the following areas:

- Conflict of Interest
- Subrecipient Monitoring
- Financial Reporting
- Animal Care and Use in Research
- Documentation of Personnel Expenses
- Establishment of Research Policy Board

Conflict of Interest

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall:

A. 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;

B. make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants; and

C. confer with the Office of the Inspector General about the activities of such office related to financial conflicts of interest involving research funding agencies.

In updating policies under paragraph (1)(B), the Secretary shall consider:

A. modifying the timelines for the reporting of financial conflicts of interest to just-in-time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

B. ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term “investigator” for purposes of the regulations and policies described in subparagraphs (A) and (B) of paragraph (1); and

C. updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

Subrecipient Monitoring

The Director of the National Institutes of Health shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate

- an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that:
    A. the subrecipient is subject to Federal audit requirements pursuant to the Uniform Guidance of the Office of Management and Budget;
    B. the primary awardee conducts, pursuant to guidance of the National Institutes of Health, a pre-award evaluation of each subrecipient's risk of noncompliance with Federal statutes and regulations, the conditions of the subaward, and any recurring audit findings; and
    C. such exemption does not absolve the primary awardee of liability for misconduct by subrecipients;

- the implementation of alternative grant structures that obviate the need for subrecipient monitoring, which may include collaborative grant models allowing for multiple primary awardees.

Financial Reporting

The Secretary of Health and Human Services, in consultation with the Director of National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients

Animal Care and Use in Research

Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall 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 while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall:

I. identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

II. take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

III. take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

Documentation of Personnel Expenses

The Secretary of Health and Human Services shall clarify the applicability of the requirements under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

Establishment of a Research Policy Board

Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the "Research Policy Board" (referred to in this subsection as the "Board"), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements

The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

i. The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.
ii. The Director of the Office of Science and Technology Policy.
iii. The Secretary of Health and Human Services.
iv. The Director of the National Science Foundation.
v. The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates:

i. nomination by members of the nonprofit scientific research community, including academic research institutions; and
ii. procedures to fill membership positions vacated before the end of a member's term.

Activities of the Research Policy Board

The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include:

i. providing thorough and informed analysis of regulations and policies;
ii. identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;
iii. making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;
iv. creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and
v. conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances.

Activities of the Research Policy Board

Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

The Board shall terminate on September 30, 2021

Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board's activities with respect to the responsibilities described in paragraph

National Defense Authorization Act 2017

The National Defense Authorization Act 2017 was signed into law by President Obama on December 23, 2016

The Act contains 55 Titles and is over 950 pages in length and aims to:

"To authorize appropriations for fiscal year 2017 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes."

In particular alignment with the FDP mission and vision is **Section 217: Increased micro-purchase threshold for research programs and entities.**

This section raises the threshold for Micro-purchases to $10,000 or higher, consistent with clean audit findings, institutional risk assessment, or State law

American Innovation and Competitiveness Act

The American Innovation and Competitiveness Act was passed on December 16, 2016 and was signed into law by President Obama on January 6, 2017.

The Act contains 6 Titles and is 70 pages in length and aims to:

"To invest in innovation through research and development, and to improve the competitiveness of the United States"

In particular alignment with the FDP mission and vision is **Title II – Administrative and Regulatory Burden Reduction**

Within this section are a number of directives and considerations related to the following areas:

- Establishment of an Interagency Working Group for the purposes of reducing administrative burdens on federally funded researchers (Section 201)
- Within 1 year the NSF IG prepare and submit to the appropriate committees of Congress
- an audit of the Foundation's policies and procedures governing the monitoring of pass-through entities with respect to subrecipients (Section 206)
- Raise the micro-purchase threshold for NSF, NASA and NIST to $10,000 (Section 207)

Research Administrative Burden is being Acknowledged

In Title II, Section 201 a number of findings are listed to support the establishment of the aforementioned Interagency Working Group that are worth highlighting to the members of the FDP:

> (b)(2) Substantial and increasing administrative burdens and costs in Federal research administration, particularly in the higher education sector where most federally funded research is performed, are eroding funds available to carry out basic scientific research.
>
> (b)(4) Progress has been made over the last decade in streamlining the pre-award grant application process through the Federal Government's Grants.gov website.
>
> (b)(5) Post-award administrative costs have increased as Federal research agencies have continued to impose agency-unique compliance and reporting requirements on researchers and research institutions.
>
> (b)(6) Researchers spend as much as 42 percent of their time complying with Federal regulations, including administrative tasks such as applying for grants or meeting reporting requirements.

It is the sense of Congress that:

> (c)(1) administrative burdens faced by researchers may be reducing the return on investment of federally funded research and development; and
>
> (c)(2) it is a matter of critical importance to United States competitiveness that administrative costs of federally funded research be streamlined so that a higher proportion of federal funding is applied to direct research activities.

Questions? Comments?