ASSOCIATION OF AMERICAN UNIVERSITIES

Recent Legislative Actions Taken Reducing Research Regulatory Burden*

(Updated as of December 19, 2016)

21st Century Cures

National Defense Authorization Act

American Innovation and Competitiveness Act

*List is based upon: COGR. *Matrix of Recent Legislative Actions Taken to Reduce Regulatory Burden*. 2016

21st Century Cures –

(Passed House and Senate. Signed by President Obama on December 13, 2016.)

- **Research Policy Board (SEC. 2034):** The act calls on the Director of OMB to create a new Research Policy Board (RPB) with 10 or fewer federal members (OIRA, OSTP, HHS, NSF and others that support or regulate research) and 9 -12 representatives from academic or other non-profit research institutions or organizations with relevant expertise. RPB members are to be appointed through a formal process including nominations by members of the research community. 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. The RPB is not explicitly tasked with addressing prospective regulations and policies. The Act requires a report to Congress and GAO evaluation of the RPB's effectiveness. The provision sunsets September 230, 2020.

- **Subrecipient Monitoring (SEC. 2034):** The Act directs that NIH Director to reduce administrative burden, including possible exemption where the sub-recipient is subject to single audit and use of collaborative grant models or other structures allowing for multiple prime awardees. This appears to apply only to NIH awards.

- **Review Financial Conflict of Interest (COI) Policies (SEC. 2034):** The Act requires a review of COI within two years of enactment of the legislation to be led by the HHS Secretary. The minimum threshold for reporting and just-in-time reporting are to be specifically examined as a part of the review.

- **Evaluation of Financial Reporting Procedures (SEC. 2034):** Specific to HHS/NIH. Avoid duplication between HHS and NIH and minimize burden.

- **Review Animal Research Regulations (SEC. 2034):** Within two years of enactment, the NIH, USDA and FDA are charged with identifying and eliminating inconsistent, overlapping or unnecessarily duplicative regulations and policies and improving coordination relating to animal research requirements.

- **Clarify or Affirm Alternatives to Effort Reporting (SEC. 2034):** The act directs the HHS Secretary to clarify the applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses. It is our understanding that the intent is that the HHS Secretary affirm the flexibility under the existing OMB uniform guidance in documenting personnel expenses.

National Defense Authorization Act –

(Passed House and Senate. Conference report language adopted by Senate. Presented to President on Dec 14.)

- **Increases the Micro-Purchase Threshold (SEC. 217):** A provision in the Act will increase the threshold from the current level contained in OMB's uniform guidance to $10,000 or a higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings, institutional risk assessment, or State law.

American Innovation and Competitiveness Act –

(Passed Senate and House. President expected to sign.)

- **Interagency Working Group on Research Regulations (SEC. 201):** The act calls on the OMB, in coordination with OSTP, for to establish a new interagency working group on research regulations. This group will be 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 universities. The act directs the new working group to consult with stakeholders and requires that an annual report be provided to relevant congressional committees for the first four years of the working group existence. Specific areas of regulatory reform called out to be examined in this provision include:

    - ***Unified Grant Format*** - consider a simplified, unified grant format for use by all agencies.
    - ***Increased use of preliminary proposals***
    - ***Simplified Budget Proposals***
    - ***Greater Use of Just-in-time***
    - ***Create a Centralized Researchers Profile Database*** - establish a centralized database for bio-sketches, CVs, licenses, and related documents to be utilized for all grant proposals "to the extent practicable. Consider incorporating existing databases.
    - ***Create a Centralized Assurances Repository*** - for all assurances required for federal grants.
    - ***Review and Simplify Progress Reports*** - consider limiting reports to performance outcomes.

    It remains to be seen how this new group will work with the new Research Policy Board (RPB) established by the CURES act, however, this group can easily be created as a vehicle to help provide support to that newly established Board.

- **Micro-purchase threshold for procurement solicitations by research institutions (SEC. 207):** Increases the threshold from the current level contained in OMB's uniform guidance from $3,5000 to $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. This provision only applies to NSF, NIST and NASA whereas the provision included in the National Defense Authorization Act applies to all federal agencies.