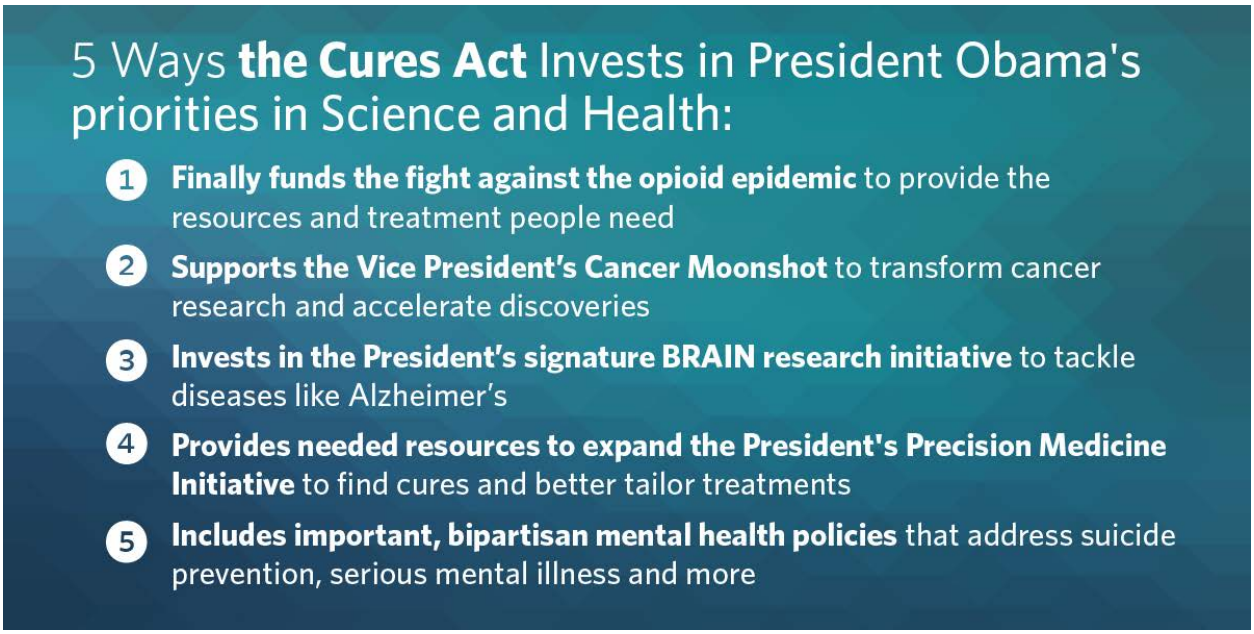
TIGER TIPS

RESOURCES FOR AUBURN RESEARCHERS

21st Century Cures Act

On December 13, 2016, President Obama signed into law the 21st Century Cures Act, bipartisan legislation that will go a long way toward bringing about medical breakthroughs needed to meet some of the biggest health challenges facing American today.[1]



In addition to the significant investments in innovative technologies and research that the Cures Act will make, the Act also includes additional actions toward reducing research regulatory burden that were recommended by the National Academies, National Science Board and others. The following is a brief description of each of these actions and the language included in the act for consideration and/or implementation:

Actions	21st Century Cures Act
Research Policy Board - A public-private entity recommended by the National Academies "to foster more effective conception, development and harmonization of research regulations." The NSB similarly recommended an interagency, intersector committee with stakeholder and OMB/OIRA representation.	Established by the Director of OMB. 10 or fewer federal members (OIRA, OSTP, HHS, NSF and others that support or regulate research). 9-12 representatives of academic or other non-profit research institutions or organizations with relevant expertise. Appointed through a formal process including nomination by members of the research community. The process would be established by the Secretary (in consultation with the Federal membership). This is likely in error, as in previous iterations the RPB was established by the HHS

[1] White House Blog, December 13, 2016

	Secretary due to HELP jurisdiction, now the OMB Director. 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. Not explicitly tasked with addressing prospective regulations and policies. Report to Congress and GAO evaluation. Sunsets 9/30/20.
Subrecipient Monitoring - reduce unnecessary or redundant oversight. Recommendations - National Academies - amend the Uniform Guidance (UG) to clarify applicability to Institutions of Higher Education (IHEs) only for project and performance monitoring. GAO - target higher risk subrecipients.	NIH Director directed to reduce administrative burden, including possible exemption where the subrecipient is subject to single audit and use of collaborative grant models or other structures allowing for multiple prime awardees.
Review Financial Conflict of Interest Policies - harmonizing policies and reducing burden. Recommendations: National Academies - Federal-wide policy to be developed by Congress and OSTP; NSB and GAO - evaluation of the 2011 revisions to the PHS COI regulations.	Within two years of enactment. Led by the HHS Secretary. Review to include the minimum threshold for reporting and just-in-time reporting.
Evaluation of Financial Reporting Procedures and Requirements - with the goal of minimizing burden.	Specific to HHS/NIH. Avoid duplication between HHS and NIH and minimize burden.
Review Animal Research Regulations - goal of reducing administrative burden. Recommendations - National Academies: OSTP to convene - goal of unified federal approach. NSB - engage all regulatory, independent and certification bodies.	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.
Clarify or Affirm Alternatives to Effort Reporting - Recommendations - NSB: OMB issue a memo of clarification indicating that the payroll certification method is acceptable to the Federal Government. National Academies: OMB affirm that IHEs may take advantage of the flexibility of the UG for documentation of personnel expenses.	Directs the HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses. It would be our understanding that the intent is that the HHS Secretary affirm the flexibility under the UG in documenting personnel expenses.

A link to the Act can be found here.