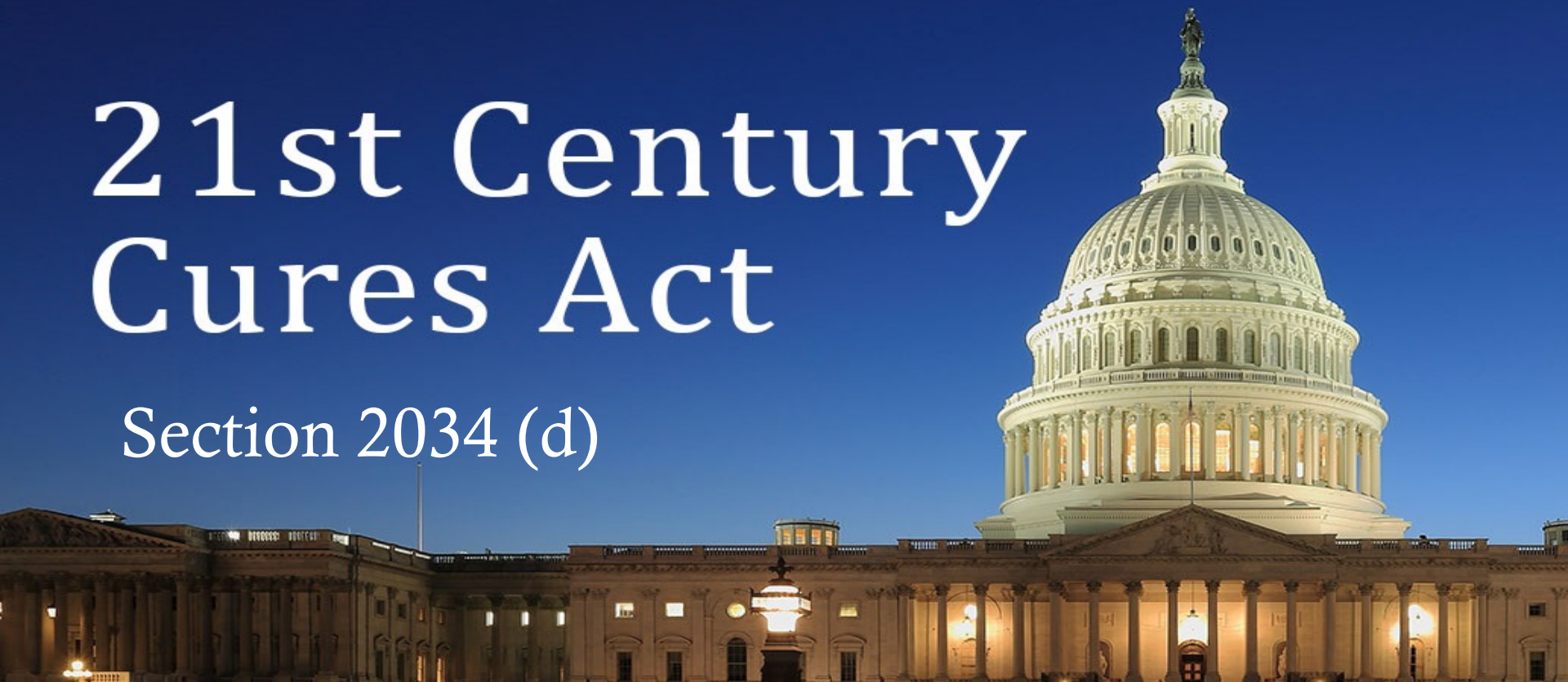


# 21st Century Cures Act

## Section 2034 (d)



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COGR – February 28, 2019

# 21<sup>st</sup> Century Cures Act

## What is it?

- Bipartisan legislation signed in December, 2016
- Intended to accelerate research and drug approval, address the opioid epidemic and mental illness
- Mandates federal efforts to reduce administrative burden for researchers
- Section 2034(d) assigns NIH as lead agency in cooperation with USDA and FDA to focus on animal care and use in research

# What Does it Ask?

## SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS.

(d) Animal Care And Use In Research.—Not later than 2 years after the date of enactment of this Act, the Director of the NIH, in collaboration with the Secretary of Agriculture and the FDA Commissioner, shall complete a **review of applicable regulations and policies** for the care and use of laboratory animals...

# What Does it Ask, cont.

...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 NIH Director shall seek the input of experts, as appropriate.

# 21<sup>st</sup> Century Cures Act - Details

The Director of NIH shall —

- 1) 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;**

# 21<sup>st</sup> Century Cures Act - Details

The Director of the National Institutes of Health shall —

- 2) **take steps to eliminate or reduce identified inconsistencies**, overlap, or duplication among such regulations and policies; and

# 21<sup>st</sup> Century Cures Act - Details

The Director of the National Institutes of Health shall —

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

# Working Group Actions

- Convened in February 2017
- Meets quarterly or as needed
- Held listening sessions in 2018
- Released Request for Information (RFI) for public comment in March 2018
- Analyzed over 19,000 responses
- Released draft report in December 2018 with 75 day public comment period



# Working Group Activities

- Reviewed reports, communications and surveys published from 2013-2018 that addressed investigator burden
- Held listening sessions and Q&A sessions with multiple stakeholders
- Analyzed suggested approaches from the RFI in development of draft report recommendations

# Documents reviewed

- Reforming Animal Research Regulations, FASEB, COGR, AAMC, NABR, 2017
- Optimizing the Nation's Investment in Academic Research, NAS, 2016
- Reducing Investigators' Administrative Workload for Federally Funded Research, NSF, 2014
- 2012 Faculty Workload Survey Research Report, FDP, 2014
- Findings of the FASEB Survey on Administrative Burden, FASEB, 2013

# Documents reviewed

- Revising the Requirements for Prompt Reporting under PHS Policy IV.F.3, 2017, NABR
- Animal Welfare Regulations Must Not Be Compromised to Comply with the Goals of the 21st Century Cures Act, 2018, HSUS and HSLF
- Rebuttal to Federation of American Societies for Experimental Biology's Reforming Animal Research Regulations, 2018, People for the Ethical Treatment of Animals.

# Recommended Steps to Reduce Burden

## *Inspections*

NIH and USDA will develop guidance to address flexibilities in how and by whom IACUC inspections are conducted. This includes:

- inspection of study areas if animals are in their natural environment and the area is prohibitive to easy access
- AAALAC site visits may be counted as one of the IACUC semiannual inspections

# Recommended Steps to Reduce Burden

## *Protocol Review*

- Enhance resources to streamline protocol review by use of DMR for low-risk activities and three-year de novo reviews
- Outline what is exempt from IACUC review
- Change Section 2.31(d)(5) to remove the requirement that IACUCs conduct continuing reviews not less than annually

# Recommended Steps to Reduce Burden

## *Reporting*

- USDA developed an online portal for submitting annual reports that will streamline data submission
- Annual reporting to both agencies on same reporting schedule through shared portal
- Regulatory change to eliminate need to renew USDA registration every 3 years

# Actions to Improve Coordination

## ***Guidance on Federal Standards***

- USDA will make any revised and future policies available for public comment
- USDA will add a statement in its policy manual that policies are clarifications of the AWA and Animal Welfare Regulations

# Actions to Improve Coordination

## *Agency Coordination*

- NIH and USDA will engage the Department of Defense and the Department of Veterans Affairs about harmonization to reduce administrative burden on investigators who receive support for research with animals from multiple federal agencies.



# Recommended Steps to Reduce Burden

## ***Reporting***

- Support the use of AAALAC program description elements in the OLAW Assurance
- Review and refine reporting requirements for reportable situations to OLAW

## ***Protocol Review***

- NIH to update guidance on non-pharmaceutical grade compounds

# Actions to Improve Coordination

## ***Guidance on Federal Standards***

- NIH provide a minimum of 60 day comment period for significant policy guidance
- NIH will review its disclaimer concerning current guidance and alternative approaches

# Actions to Improve Coordination

## *Training and Resources*

- NIH will simplify its sample animal study protocol form and pilot the revised protocol form through FDP
- NIH plans to consider other new website resources in coordination with USDA

# Actions to Improve Coordination

## *Training and Resources*

- Support industry-led training and resources to assist institutions in reducing administrative burden on investigators
- Support the efforts of the IAA to create a repository of IACUC best practices
- Support the efforts of the FDP to create CUSP as a repository for standard procedures used for research with animals

# In Summary

In the coming years, NIH, USDA, and FDA intend to make progress on the steps and actions described in this report and will identify additional areas to protect animal welfare while reducing unnecessary administrative burden on researchers.

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