

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

NIH-USDA-FDA Listening Session on Animal Research

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National Institutes of Health  
Office of Laboratory Animal Welfare

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

## What is it?

- Bipartisan legislation signed in December, 2016
- 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 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...



# 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 Director of the National Institutes of Health shall seek the input of experts, as appropriate.



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

The Director of the National Institutes of Health 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;**
- 2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and
- 3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.



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- 21<sup>st</sup> Century Cures Working Group convened in February 2017
- Working Group meets quarterly or as needed
- Public Request for Information (RFI) to be announced in early 2018 in Federal Register
- Listening sessions planned for 2018



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# What could NIH, USDA & FDA change to reduce burden on RESEARCHERS?



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