

# 21st Century Cures Act

## Next Steps



Patricia Brown, NIH, OLAW

Betty Goldentyer, USDA, APHIS, Animal Care

Brianna Skinner, FDA

December 5, 2019

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## 21st Century Cures Act NIH Actions

Patricia Brown, VMD, MS, DACLAM  
Director, Office of Laboratory Animal Welfare, NIH



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## Objectives

- Describe the history and key elements of the 21st Century Cures Act with potential impact on animal programs and IACUCs
- Evaluate proposed actions by NIH to change policies and guidance to reduce administrative burden on researchers

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## 21<sup>st</sup> Century Cures Act What is it?

- Comprehensive legislation in December 2016
- Intended to advance biomedical research from basic research to advanced clinical trials of new therapies
- 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

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## 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...

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## 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.

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## 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;**

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## 21<sup>st</sup> Century Cures Act: Details, cont.

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

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## 21<sup>st</sup> Century Cures Act: Details, cont.

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.

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## Working Group Timeline

- Convened in February 2017
- Reviewed relevant regulations and policies in 2017
- Held listening sessions in 2018
- Released Request for Information (RFI) for public comment in March 2018
- Released draft report in December 2018
- Final report published August 2019

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## Working Group Activities

Reviewed applicable regulations and policies based on reports, surveys and communications from 2013-2018 that addressed investigator burden

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## 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

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## Documents Reviewed, cont.

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

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## More Working Group Activities

- Analyzed the 19,000 public comments received from the RFI
- Developed the draft report incorporating the key issues identified from the RFI
- Refined the final report to include input from public comments on draft report

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# 21st Century Cures Act



Find the final report and more at:

<https://olaw.nih.gov/21st-century-cures-act.htm>



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## NIH Steps to Update Guidance

- Flexibilities in semiannual inspections
- Use of DMR for low-risk activities and use of VVC for significant changes
- What is exempt from IACUC review
- Options for IACUC review for non-pharmaceutical-grade substances
- Reporting noncompliance
- Departures from the *Guide*

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## NIH Steps to Improve Coordination

- Annual reporting on same schedule as USDA – not for 2019 report
- Change instructions for Domestic Assurance to support use of AAALAC Program Description elements
- 60-day comment period for policy and guidance changes
- Update OLAW disclaimer on policy guidance

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## NIH Steps to Improve Coordination, cont.

- Review grant-protocol congruence guidance
- Engage with DoD and VA to harmonize
- Support industry-led training and resources:
  - Training IACUCs to reduce burden (ICARE, IACUC 101, SCAW, PRIM&R, IAA BP)
  - CUSP through FDP
  - Universal IACUC protocol through FDP
  - IACUC common practices through IAA
- Update OLAW website resources

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## 21<sup>st</sup> Century Cures Act USDA APHIS Actions

Betty Goldentyer, DVM  
USDA, APHIS, Animal Care



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## Objectives

Evaluate proposed actions by USDA APHIS to change policies and guidance to reduce administrative burden on researchers

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## USDA Steps to Reduce Burden

### *Inspections*

USDA will develop guidance to address flexibilities in how and by whom IACUC inspections are conducted, including:

- 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

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## USDA Steps to Reduce Burden, cont.

### ***Protocol Review***

- Enhance resources to streamline protocol review by use of DMR for low-risk activities and 3-year complete 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

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## USDA Steps to Reduce Burden, cont.

### ***Reporting***

- USDA developed an online portal for submitting annual reports with user input that has streamlined 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

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## USDA Steps to Improve Coordination

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

- USDA will make significant policies and significant revisions to new policies available for public comment
- USDA will include a statement in its policies to explain that policies are clarifications of the AWA and Animal Welfare Regulations, which are the only legally binding requirements

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## USDA Steps to Improve Coordination, cont.

### Agency Coordination

NIH and USDA will engage the DoD and VA to develop options for harmonizing requirements to reduce administrative burden on investigators who receive support for research with animals from multiple federal agencies

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

Brianna Skinner, DVM, MPH  
FDA, OCET, Office of the Commissioner



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## Objectives

Evaluate proposed actions by FDA to assist USDA and NIH in changes to policies and guidance to reduce administrative burden on researchers

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## FDA Steps to Reduce Burden

FDA's rulemaking with respect to part 58, GLP for Nonclinical Laboratory Studies is still ongoing. Any comments made in response to the 21<sup>st</sup> Century Cures Act RFI regarding the subject of the GLP rulemaking may be taken under advisement as finalization of the proposed rule is considered.

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## FDA Steps to Reduce Burden, cont.

NIH OLAW will review and update the guidance on non-pharmaceutical-grade substances to further clarify the options for IACUC review. The agency will enlist the expertise of the FDA in the effort and seek public comment on the updated guidance.

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## Implementation

- Begin within the next 2 years
- Public engagement throughout the process

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## Evaluation of Steps to Reduce Burden

Following the implementation of policy and regulatory changes in the next 2 years, the agencies plan to evaluate the outcome of the efforts to reduce administrative burden while maintaining scientific integrity and animal welfare.

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What did you like in the  
Report on Reducing Burden?



Audience Input

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## 21st Century Cures Act

Next Steps



Questions?

Submit to the chat box in the GoToMeeting control panel

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### Question 1

Did the recommendations made in the 21<sup>st</sup> CCA report consider programs that used diverse animal species including wildlife, USDA-covered species, and lab rodents?

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### Question 2

How will you engage with stakeholders while implementing 21<sup>st</sup> CCA action items?

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### Question 3

How do you intend to evaluate the agencies' ongoing efforts to reduce administrative burden?

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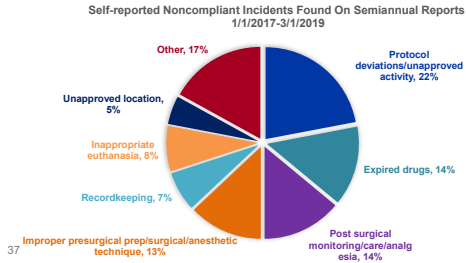
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### Question 4

In the final report, OLAW indicated that animal welfare would be negatively impacted by reducing semiannual inspections to annual rather than semiannual. It was cited that "approximately 7% of the self-reported noncompliant incidents were identified during semiannual inspections." What percent of the 7% cited actually involved animal welfare?



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### Question 5

When can we stop conducting the annual continuing reviews?

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### Question 6

When will the USDA Policy Manual be reposted?

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**Question 7**

At what stage of review are the GLP rules?

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**Question 8**

When will the next version of the GLP rules be available for public review?

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**21st Century  
Cures Act**

Next Steps

**Questions?**

Submit to the chat box in the GoToMeeting control panel

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## Next OLAW Webinar

### Building a Research Occupational Health Program



Ted Myatt, Sc.D.  
University of Rhode Island

March 12, 2020

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