ICARE

Interagency Collaborative Animal Research Education

# OLAW CONVERSATIONS

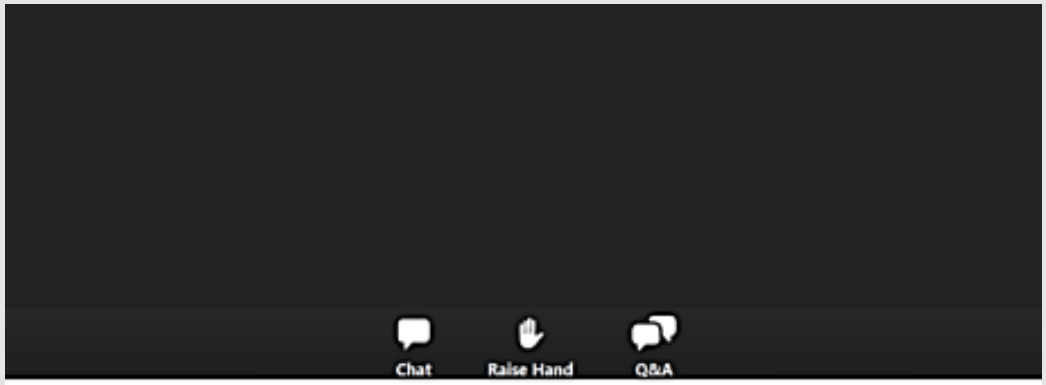
## 21st Century Cures Community Q&A

Thursday, March 31, 2022

NIH National Institutes of Health

*Office of Laboratory Animal Welfare*

# Today's session




**Troubleshooting tip when trying to speak after raising hand!**
Zoom controls vary by device. If you are still muted after the host unmutes you, try looking for the speaker icon in the top right, turning off subtitles under the CC icon, or an audio settings menu on the bottom left of your screen.

- Session will **not** be recorded
- Slide PDFs and certificates **will** be sent to attendees
- 3 ways to interact:
    - Raise hand feature
    - Chat box
    - Q and A feature.
        - There is a checkbox in the Q and A feature that provides the option to submit questions anonymously

# *21st Century Cures Community Q&A*

March 31, 2022

**Patricia Brown, VMD, MS**
**Robert Gibbens DVM**


# Objectives:

1. Review the timeline of the 21st Century Cures Act (21st CCA)

2. Summarize OLAW and USDA's updated guidance and rule changes

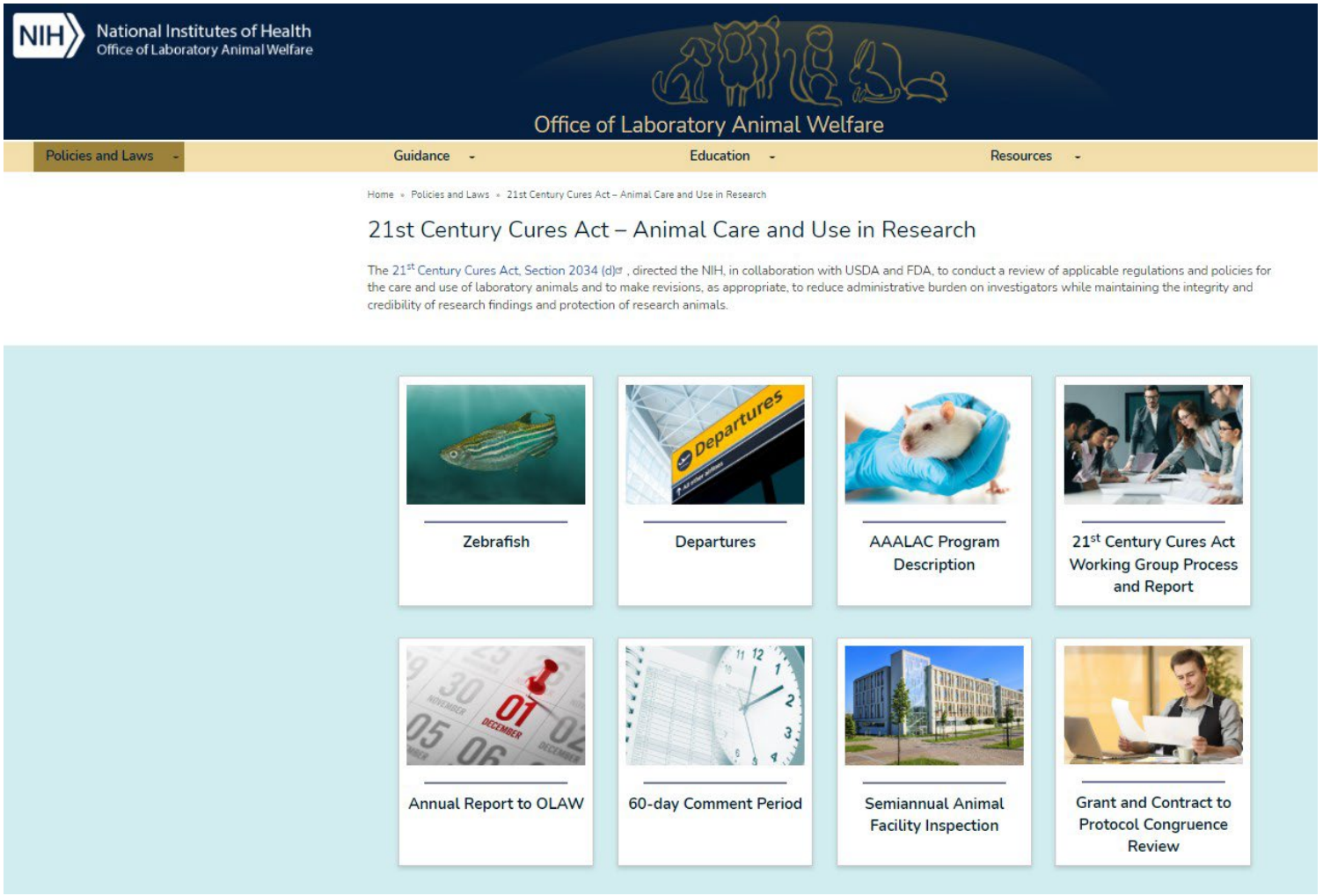
3. Answer your questions for each new guidance or rule!

# Agency Actions Timeline

# OLAW Home Page


https://olaw.nih.gov/home.htm

# 21st Century Cures Act Landing Page

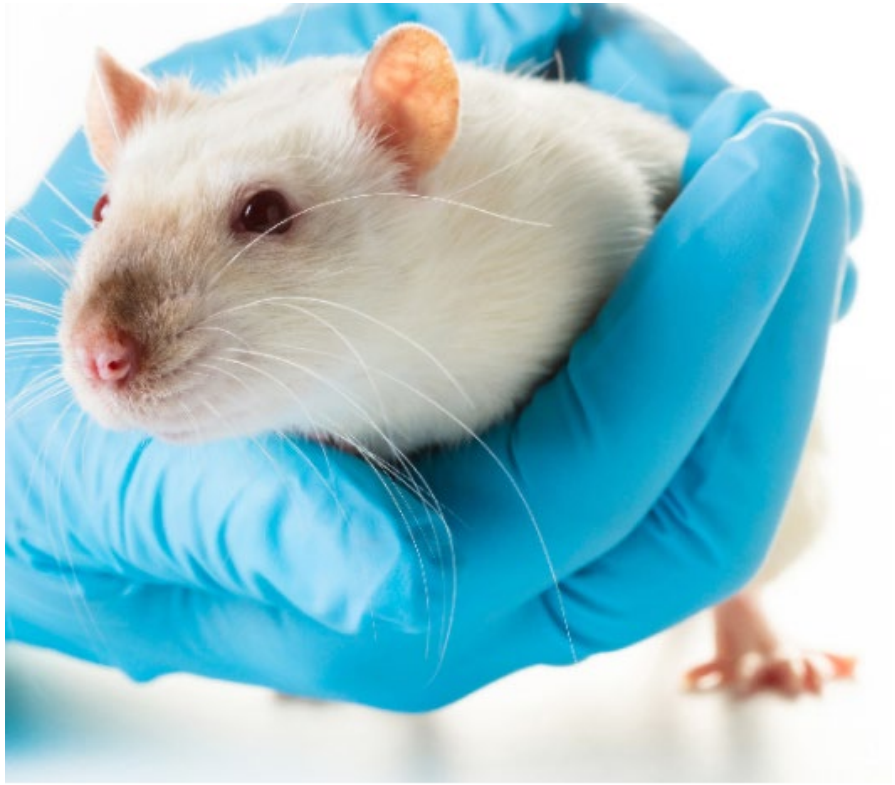



https://olaw.nih.gov/policies-laws/21st-century-cures-act


# Updated Guidance & Rules

1. AAALAC PD in Assurance
2. Semiannual Facility Inspections
3. Grant & Contract to Protocol Congruence
4. USDA: Modifications to §2.30
5. USDA: Modification to §2.31(d)(5)
6. USDA: Modification to §2.36(a)

# AAALAC Program Description

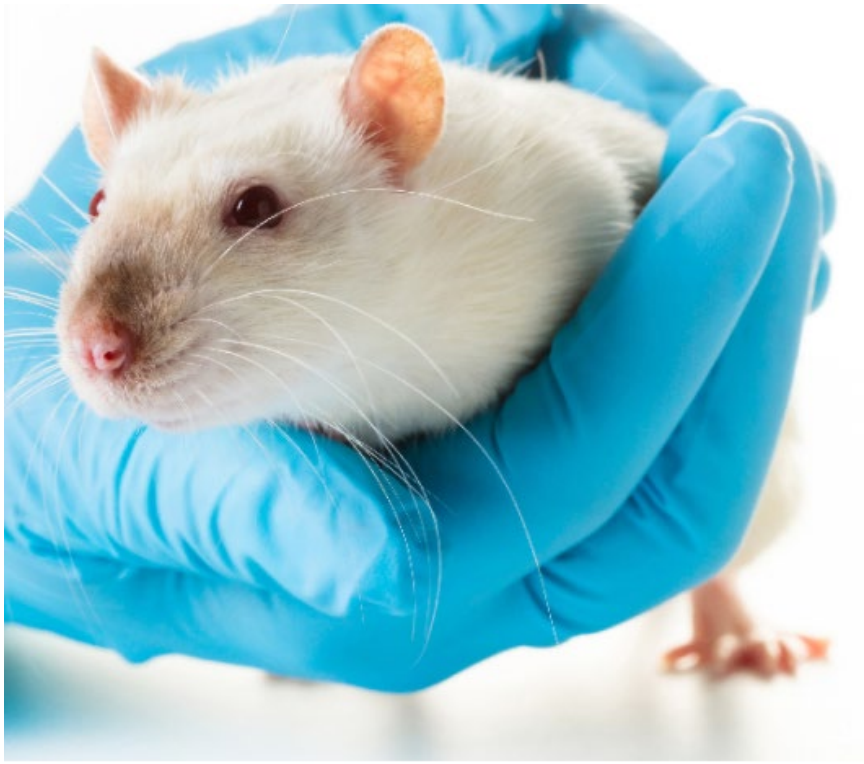


NOT-OD-21-130 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-130.html

https://olaw.nih.gov/policies-laws/21st-century-cures-act/AAALAC-Program-Description

# Applicable AAALAC Sections

- Post-Approval Monitoring
- Occupational Health and Safety of Personnel
- Training, Education, and Continuing Educational Opportunities
- The Role of the IACUC



# Semiannual Facility Inspections

NOT-OD-21-164 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-164.html

https://olaw.nih.gov/policies-laws/21st-century-cures-act.htm/Semiannual-Facility-Inspections

# Semiannual Facility Inspections: Flexibilities

| | NIH and USDA | NIH | USDA |
|---|---|---|---|
| Who | No IACUC member should be involuntarily excluded. | As few as 1 qualified individual/ad hoc consultant (need not be an IACUC member or institutional employee) | Subcommittees of at least 2 members (additional ad hocs OK) |
| When | 30-day flexibility (provided no forward drift year to year) | | |
| Where | | All animal facilities (as defined by PHS Policy) including satellite facilities and surgical areas, but discretion allowed for other areas | All animal facilities (as defined in AWRs), including animal study areas, but excluding free-living wild animals in their natural habitat |

# Semiannual Facility Inspections: Flexibilities

| | NIH and USDA | NIH | USDA |
|---|---|---|---|
| **How** | Remote options available | Videos, photographs, written descriptions, or other appropriate remote methods | Live feed is the only remote option |
| | IACUCs may assign specific facility inspections to subcommittees, but biased evaluations should be avoided | | |
| | Staggered inspections (facilities inspected over time), provided each animal area inspected at least every 6 months | | |
| | Inspections may be announced or unannounced | | |
| | OLAW Checklist optional | | |

# Semiannual Facility Inspections: Flexibilities

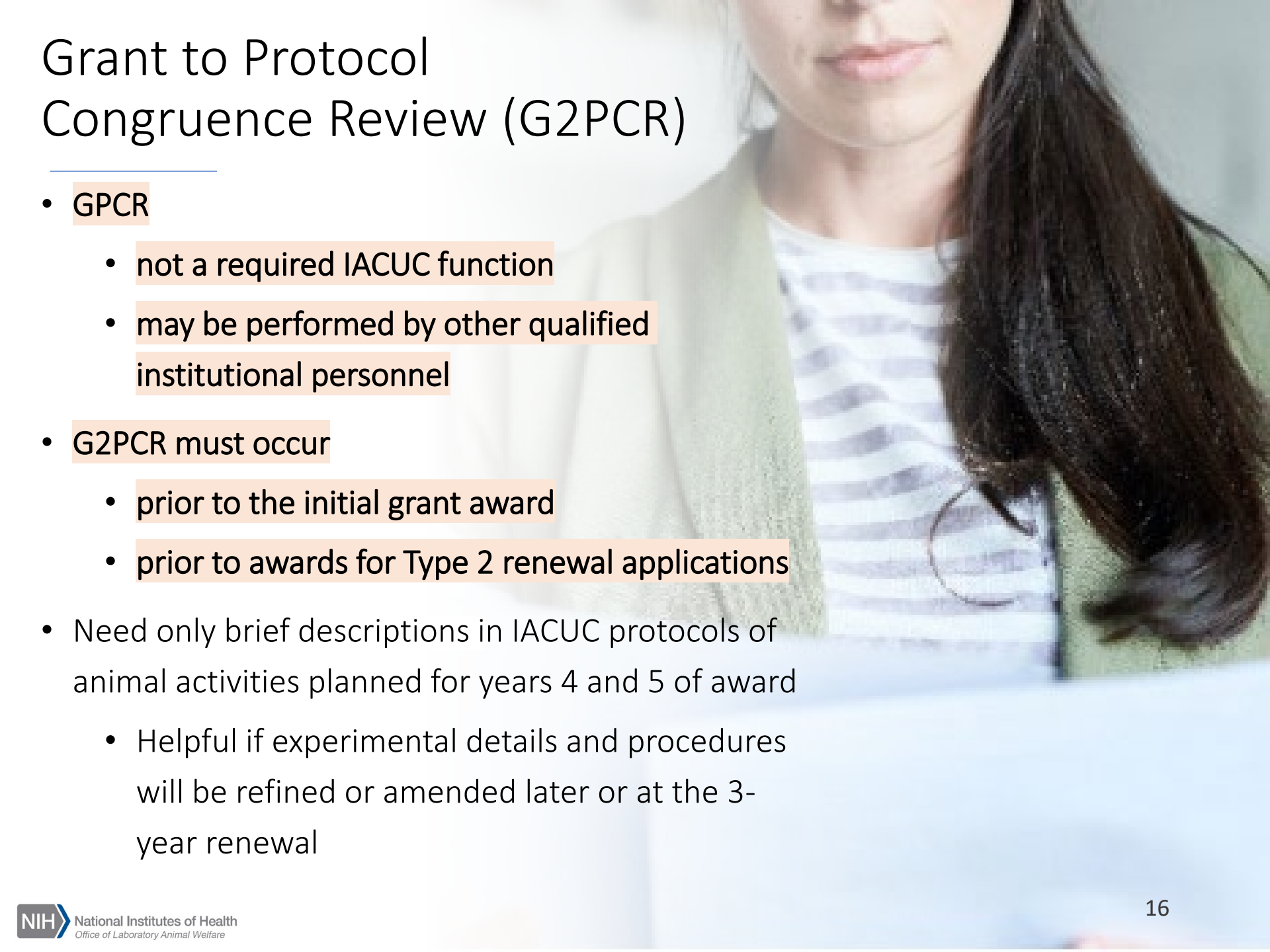
| | NIH and USDA | NIH | USDA |
|---|---|---|---|
| How | AAALAC site visit may be used provided it meets the requirements of the PHS Policy and AWRs for the report contents AND the subsequent inspection is conducted no later than six months from when the site visit occurred | When using an AAALAC site visit, the subsequent report to the IO must:<br>• comply with PHS Policy IV.B.3<br>• be endorsed by the IACUC as an official IACUC report and submitted by the IACUC to the IO. | When using an AAALAC site visit:<br>• site visit must correspond with the time of scheduled semiannual inspection<br>• all required areas must be addressed<br>• at least 2 IACUC members must participate<br>• all IACUC members must be given opportunity to participate<br>• report must include departures (with descriptions and reasons), and be signed by majority of members (digital OK) |

# Grant and Contract to Protocol Congruence

NOT-OD-22-005 https://grants.nih.gov/grants/guide/notice-files/not-od-22-005.html

https://olaw.nih.gov/policies-laws/21st-century-cures-act/grant-and-contract-to-protocol-congruence-review/Grants-to-Protocol-Congruency

# Grant to Protocol Congruence Review (G2PCR)



- GPCR
  - not a required IACUC function
  - may be performed by other qualified institutional personnel
- G2PCR must occur
  - prior to the initial grant award
  - prior to awards for Type 2 renewal applications
- Need only brief descriptions in IACUC protocols of animal activities planned for years 4 and 5 of award
  - Helpful if experimental details and procedures will be refined or amended later or at the 3-year renewal

# More on G2PCR

- If IACUC review is delayed because the animal activities won't occur until a year or later in the award period, the NIH grants manager will issue a Notice of Award indicating that no funds may be drawn from the grant for animal activities until a valid IACUC approval date is provided.

- NIH Grants Policy requires the PI to obtain approval for certain changes in scope of the research that may involve the animal activities. IACUC review and approval of those changes is required but further congruence review is not required.

# How to conduct GPCR

- No requirement to do a side-by-side comparison of an entire application and the IACUC protocol
- Comparison of key elements of the grant (e.g., research strategy and Vertebrate Animals Section) to the protocol may reduce burden by minimizing the need to review multiple sections of the grant application for congruence
- A one-to-one relationship between the grant and approved protocol is not required, and more than one protocol may be associated with one grant and vice versa.

USDA United States Department of Agriculture

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United States Department of Agriculture (USDA)
Animal and Plant Health Inspection Service (APHIS)
Animal Care (AC)



https://www.comeseeourworld.org/onprc-rhesus-in-shelter-housing/
Photo Credit: Oregon National Primate Research Center/OHSU

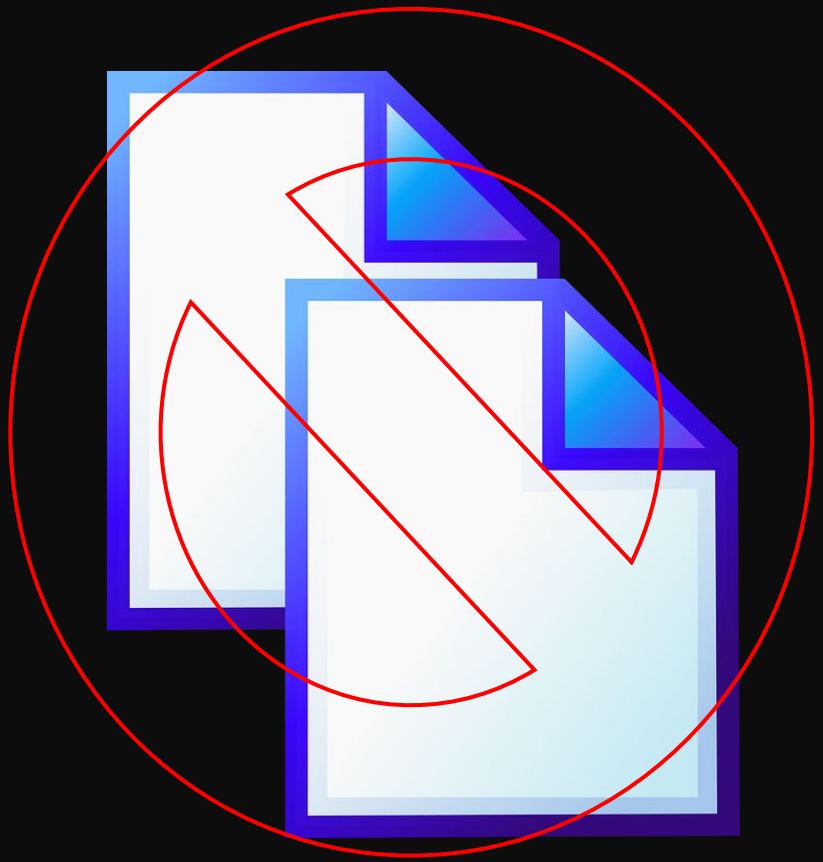
# AWA Research Facility Registration Updates, Reviews, and Reports Regulation



USDA United States Department of Agriculture

# 21st Century Cures Act: Remove Duplicative and Unnecessary Information Requirements

- AC's regulation implemented to be in compliance with the 21st Century Cures Act
- USDA to make revisions to reduce administrative burden on the research community, while maintaining integrity of research findings and protection of research animals.
- Approximately 1,100 registered facilities use animals to conduct research, teaching, testing, and experimentation.



CC0 https://pixabay.com/vectors/document button duplicate copy 35941/

USDA United States Department of Agriculture

# Modifications to §2.30

- Removed the requirement for research facilities to update registration every 3 yrs.
- Clarified conditions for cancellation
- Eliminated inactive status
  - A facility can no longer request inactive status
    - A facility will either be registered or unregistered

USDA United States Department of Agriculture

# Easing Registration

https://www.freestock.com/free-photos/casual-guy-carrying-books-633847
Image used under license from Freestock.com

# What Do You Think?

A facility with a cancelled registration is still required to apply for registration 10 days before beginning regulated activity.

A. True
B. False

# Review of Animal Activities


CC0 Public Domain https://pxhere.com/en/photo/1432977

- Modification to §2.31(d)(5)
- Old Requirement:
  - Continuous review of animal activities **not less than annually** after IACUC approval
- New Requirement:
  - IACUC **complete** review of animal activities **every 3 years**
  - Complies with 21st Century Cures Act to reduce burden by harmonizing with the Public Health Service (PHS) Policy

# What Do You Think?

USDA's "Research Rule" went into effect on December 27, 2021. The most recent complete or continuous review of a protocol using rabbits was done on December 30, 2020. By what date does the AWA require the next complete review of that protocol?

- A. 30-Dec-2021
- B. 30-Dec-2022
- C. 30-Dec-2023
- D. 30-Dec-2024
- E. Never, since protocols no longer expire

# Annual Report Signatures

- Modification to §2.36(a)
- No longer require CEO or IO to sign annual report
  - Expedites processing
  - Facilities are left to their own discretion to designate signatories

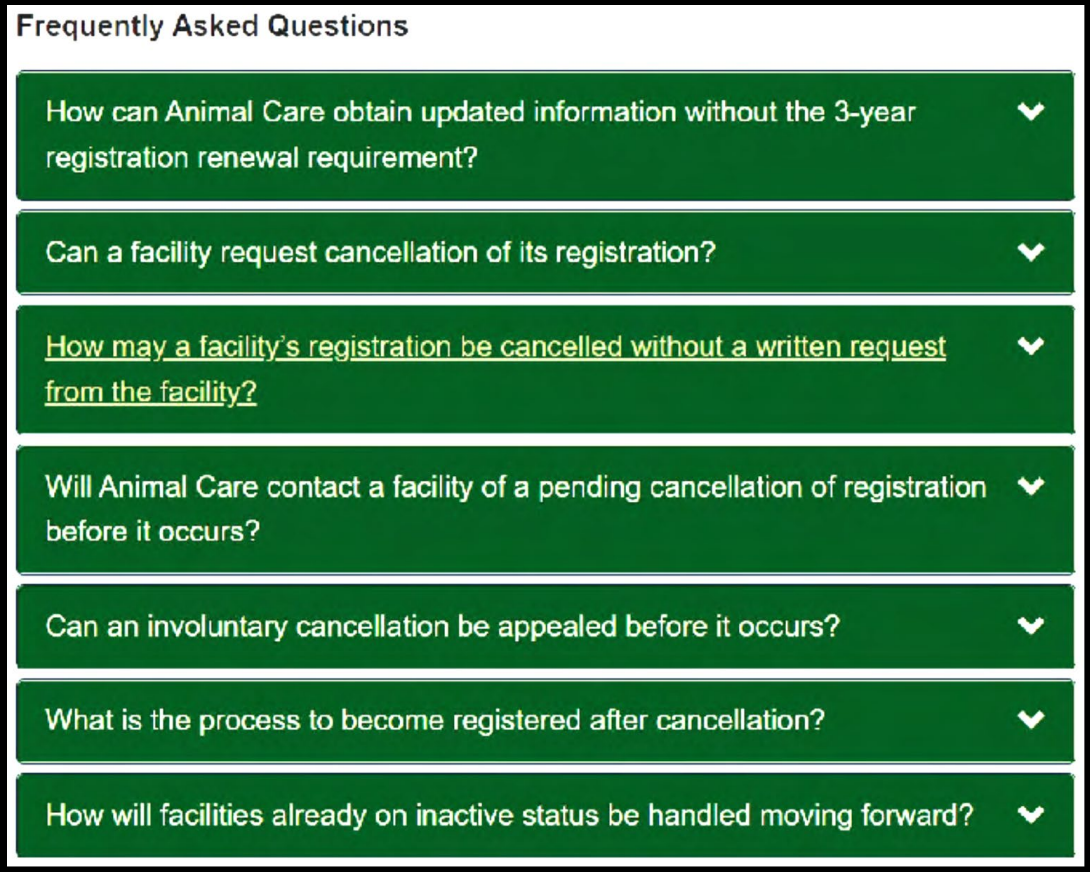
# What Do You Think?

A signatory that is not the CEO or IO, does not assume the responsibility of those positions when they sign the Annual Report.

a. True
b. False

USDA United States Department of Agriculture

# New FAQs!




www.aphis.usda.gov/aphis/ourfocus/animalwelfare/awa/new-research-rule/faqs

USDA United States Department of Agriculture

# What Do You Think?

In FY22 The House Agriculture Appropriations Subcommittee directed USDA APHIS Animal Care to eliminate the use of teachable moments or any similar program that obscures findings during inspections.

A. True
B. False

# Teachable Moments


- Ensure regular consistent, thorough, unannounced inspections
- Act swiftly when facilities fail to comply
- Require that inspection reports identifying violations, noncompliances be shared with relevant local, state, and federal agencies
- **Document failure to allow access for inspection and each failure to comply with animal welfare standards**
- **Ensure that there is no use of teachable moments**
- **Teachable moments to be phased out by October 1, 2022**

https://www.congress.gov/congressional-report/117th-congress/house-report/82/1?s=5&r=182

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Thank you!

Next Session: TBD

NIH National Institutes of Health

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