21st Century Cures Act: Reducing Administrative Burden

FDP Virtual Meeting
Research Compliance Committee
May 11, 2022

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National Institutes of Health

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USDA-APHIS-Animal Care

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Objectives

1. Discuss 21st Century Cures Act (21CCA) history
2. Describe USDA and OLAW regulatory and policy updates under the 21CCA
3. Identify new opportunities for commenting on proposed guidance
21CCA Legislation

• Comprehensive bipartisan legislation passed in 2016

• Intended to advance biomedical research from basic research to advanced clinical trials and streamline drug approval process

• 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
Mandate

- Specific activities expected by Congress:
  1. Identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies
  2. Take steps to reduce identified regulations and policies
  3. Take actions, as appropriate, to improve coordination of regulations and policies

- The NIH, USDA, and the FDA, will complete a review of applicable regulations and policies for the care and use of laboratory animals 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
Agency Actions Timeline

- Working Group convened to review regulations and policies
- Final report published
- NIH issued:
  - 2 RFIs
  - 4 Guide Notices
  - USDA published final rule
- NIH issued:
  - 3 RFIs
  - 1 Guide Notice
  - Harmonize with DoD, VA, NSF and NASA
  - USDA issued proposed rule
- NIH issued: 1 RFI

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Final Report

- Describes the recommendations and decisions of the agencies

- Appendix 3 summarizes the responses to the draft report with Working Group analysis and Agency decisions

Regulatory Updates under 21st CCA: USDA-APHIS-Animal Care

May 2022 FDP RCC Meeting
May 11, 2022

Lance H. Bassage, II, VMD, DACVS
Director, National Policy Staff
USDA-APHIS-Animal Care
“AWA Research Facility Registration Updates, Reviews, and Reports”

Final Rule – December 27, 2021
AC’s regulatory changes were implemented to be in compliance with the 21st Century Cures Act.

Goal: 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.
Registration requirements: updates, duration, and cancellation

- Modification to § 2.30

- Removed the requirement for research facilities to update registration every 3 years

- Clarified conditions for cancellation
  - Submission of a written request to Deputy Administrator to cancel

- Eliminated inactive status
  - A facility can no longer request inactive status
  - A facility will either be registered or unregistered
Review of Animal Activities

- 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
Annual Report Signatures

• Modification to §2.36(a)

• No longer require CEO or IO to sign annual report
  
  o Expedites processing
  
  o Facilities are left to their own discretion to designate signatories
USDA-APHIS-Animal Care
Contact Us

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare

E-mail: animalcare@usda.gov

Phone: (970) 494-7478

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Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

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OLAW’s 21st CCA Webpage

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

60-day Comment Period

- OLAW provides a minimum of 60 days for comments to significant policy guidance including any new interpretations of the:
  - PHS Policy
  - Guide
  - AVMA Guidelines for the Euthanasia of Animals
- Focus on high-risk animal welfare concerns

In the report Reducing Administrative Burden for Researchers: Animal Care and Use in Research, OLAW committed to providing a minimum of 60 days for comments to significant policy guidance. This will include but is not limited to any new interpretations of the:

- PHS Policy
- Guide for the Care and Use of Laboratory Animals, or
- AVMA Guidelines for the Euthanasia of Animals.

Such guidance will focus on high-risk animal welfare concerns affecting institutions, IACUC functions, and updates to guidance as an outcome of the 21st Century Cures Act.

**Annual Reports**

The 21st Century Cures Act Working Group identified harmonizing the OLAW and USDA annual reporting schedules as an opportunity to decrease administrative burden. The reporting period for the Annual Report to OLAW has been harmonized with that of USDA. The reporting period is now October 1 – September 30 of each year and must be submitted to OLAW by December 1.

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**NOT-OD-20-109** Notice of Update to the Reporting Period of the Annual Report to OLAW (Released May 21, 2020)

Reporting harmonized with USDA

- **October 1 – September 30** of each year
- **Submitted to OLAW by December 1**

NOT-OD-21-130: Notice to Encourage Using AAALAC International Program Description Sections to Complete Parts of the OLAW Domestic Animal Welfare Assurance (Released June 4, 2021)

• The relevant sections of the AAALAC PD that institutions may incorporate into the Assurance include:

  ✓ Section 2.I.B.2. Post-Approval Monitoring
  ✓ Section 2.I.A.2.b. Occupational Health and Safety of Personnel
  ✓ Section 2.I.A.2.a. Training, Education, and Continuing Educational Opportunities
  ✓ Section 2.I.B.1. The Role of the IACUC

Semiannual Animal Facility Inspection

- **NOT-OD-21-164**: Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities (Released August 2, 2021)
  - Harmonizes with USDA
  - Describes 9 flexibilities for conducting semiannual facility inspections

### Semiannual Facility Inspections: Flexibilities

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

<table>
<thead>
<tr>
<th>How</th>
<th>Remote options available</th>
<th>Videos, photographs, written descriptions, or other appropriate remote methods</th>
<th>Live feed is the only remote option</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IACUCs may assign specific facility inspections to subcommittees, but biased evaluations should be avoided</td>
<td>Only employed in rare circumstances where the safety of the inspector is a legitimate concern</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Staggered inspections (facilities inspected over time), provided each animal area inspected at least every 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inspections may be announced or unannounced</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OLAW Checklist optional</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Semiannual Facility Inspections: Flexibilities

| 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:  
• comply with PHS Policy IV.B.3  
• be endorsed by the IACUC as an official IACUC report and submitted by the IACUC to the IO. | When using an AAALAC site visit:  
• site visit must correspond with the time of scheduled semiannual inspection  
• all required areas must be addressed  
• at least 2 IACUC members must participate  
• all IACUC members must be given opportunity to participate  
• report must include departures (with descriptions and reasons), and be signed by majority of members (digital OK) |
Grant and Contract to Protocol Congruence Review

Developed 2 guidance on October 18, 2021:

1. **NOT-OD-22-005** Notice of Clarification of Institutional Responsibilities Regarding NIH Grant to Protocol Congruence Review

2. **NOT-OD-22-006** Notice of Clarification of Offeror Responsibilities Regarding Contract to Protocol Congruence Review

- Describes: Requirement, Responsibility, Timing and Verification and Methods for Conducting Congruence Review

Institutional Responsibilities for Congruence Review

- Institution’s responsibility
- Prior to the initial award
- Institutions are free to devise a workable mechanism by developing and implementing an appropriate system of policies and procedures

OLAW Published RFIs
Zebrafish

- **NOT-OD-21-118**: Request for Information (RFI) on Flexibilities to Reduce Administrative Burden While Continuing to Apply the PHS Policy to Zebrafish Immediately After Hatching:
  - Closed August 9, 2021
- Developing guidance based on input to RFI

Departures from the *Guide*

The public identified departures from the *Guide for the Care and Use of Laboratory Animals* (Guide) as an area to reduce administrative burden.

In the report *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*, developed in response to the 21st Century Cures Act, OLAW committed to clarifying the guidance for the reporting requirements of departures from the *Guide*.

- **NOT-OD-20-161**: Request for Information (RFI) on Clarifying the Reporting Requirements for Departures from the Guide for the Care and Use of Laboratory Animals
  - Closed November 1, 2021
- Developing guidance based on input on the *Guide*:
  1. **Exceptions list**
  2. **Must Statements checklist**
  3. IACUC reporting requirements for departures from **must**, **should**, and **may** statements

NOT-OD-22-114: Request for Information (RFI) on Flexibilities for Conducting Semiannual Animal Program Review
(Released April 19, 2022)

- Closes August 1, 2022
- Harmonizes with USDA
- Describes 7 flexibilities for conducting semiannual program review

Future Steps

RFIs under development:

• Streamlining protocol review
• What is exempt from IACUC review
• Update current reporting noncompliance guidance (NOT-OD-05-034)

Options for IACUC review of non-pharmaceutical grade substances
More Steps to Improve Coordination

Engage

Engage with DoD, VA, NSF and NASA to harmonize

Support

Support industry-led training and resources:

- Training IACUCs to reduce burden (ICARE, IACUC 101, SCAW, PRIM&R)
- CUSP through FDP
- Universal Protocol Template through FDP
- IACUC best practices through IAA

Update

Update OLAW website resources
Efforts are ongoing

Public engagement throughout the process

Plans to evaluate the outcome of the efforts
OLAW Contacts

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• 301-496-7163

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• https://olaw.nih.gov

Twitter:
• @NIH_OLAW

ListServ or RSS feed:
• subscribe through OLAW webpage for news and announcements.

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ThoughtExchange Post session survey question:

What flexibilities, guidance, or efforts do you feel would be helpful for reducing administrative workload for researchers without compromising the data integrity and the welfare of animals?

The following question was included in the survey sent to you before the live session. We are asking this question again because we would like to find out if the live session had an effect on the perception of efforts to reduce administrative workload for researchers.
Questions?

Contact us at

olaw@od.nih.gov

301-496-7163
Agenda

• Compliance Unit Standard Procedure (CUSP) Sharing Site Project Update (*Aubrey Schoenleben & Sally Thompson-Iritani, University of Washington*)

• Universal Protocol Template (UPT) Update (*Bill Greer, University of Michigan*)

• Research Security Subcommittee Rebranding (*Doug Backman, University of Central Florida*)

• Building Research Compliance Committee and Subcommittee communities through our listservs!

• Discussion
CUSP Sharing Site: Project Update

Aubrey Schoenleben & Sally Thompson-Iritani, University of Washington
May 11, 2022
Goal: Create an online repository where participating institutions can share standard procedures used in animal care protocols.

A burden reducing initiative of the 21st Century Cures Act

CUSP = Compliance Unit Standard Procedure
Benefits

- Reduced administrative burden for researchers, IACUCs and IACUC staff.
- Support development of high quality animal care protocols.
- Provide consistency within and across institutions.
- Support knowledge sharing both within the animal welfare compliance community, and with the public.
Transition to more modern technology stack in progress!
First round of user testing completed in April.
18 testers, representing 15 institutions
Anticipate 2-3 rounds of testing in this phase.
Site Security

- Two-step process for site access: (1) User verifies email address; (2) Institutional representative confirms affiliation
- Multiple user roles
- Option to display/not display institution name on submitted procedures.
- Split server environment (database is hosted behind a firewall)
- Visibility into active browser sessions
- 2-factor authentication (future enhancement)
- Single sign-on provider to manage account access/passwords. (future enhancement)
Working Group Activities

**Education & Outreach**
*Chairs: Michelle Brot, Scott Bury*
- Creating one-pager for interested institutions
- Developing “More Information” section of Sharing Site
- Sharing progress at local and national meetings (e.g., SRAI, 21CCA WG, meeting, AALAS)

**Help Desk**
*Chairs: Elaine Kim, April Ripka*
- Creating help documentation and FAQs for site users
- Exploring solutions to make help videos (both end to end and task-specific guides)
- Starting to define roll out plan

**Quality Control**
*Chair: Eva McGhee*
- Close to finalizing user survey – will be sending to FDP Executive Committee for review
- Developing implementation plan for survey

**Technical Systems**
*Chairs: Mark Hnath, Cyndi Rosenblatt*
- Testing support
- Build out template for import/export of procedures.
- Develop template to support process for collecting and prioritizing enhancement requests.
Other Goals for this Quarter

- Finalize Terms of Service & Privacy Policy
- Continue to explore how CUSP can be used to support research with non-typical species (e.g., cephalopods).
- Define timeline for build completion and initial roll out.
Thank You!

Want to help? Email cusp@thefdp.org
Learn more on our webpage.
Universal Protocol Template (UPT) Update

Bill Greer, University of Michigan

Animal Subjects Subcommittee—May 11, 2022
1. Pandemic Derailing
2. In summary, how did we determine an UPT is needed?
3. Status Update
4. Next Steps
5. Estimated Timeline
6. Q/A
Derailed...

1. Face to face meetings eliminated
2. Community input compromised
3. Leadership survival
Derailed...

1. Face to face meetings eliminated
2. Community input compromised
3. Leadership
Derailed...

1. Face to face meetings eliminated
2. Community input compromised
3. Leadership survival
What made us think an UPT would be useful?

1. Through IAA the idea was imagined based on ~8 years of conversations with IACUC Administrators during portions of BP meetings *(Concepts and Philosophies)*

2. The IAA Project formalized a project in 2016 and formalized partnerships *(Specific goals)*

3. IAA held dedicated sessions to gather info & develop an UPT(2017 – 2018)

4. FDP and IAA partnered to establish a project dedicated to developing an UPT
What’s the objectives of the UPT?

1. Tailored to species most commonly used (i.e., mice and rats);

2. Only include information needed by the IACUC to conduct the review;

3. Provide as much information as possible to the PI (use check boxes); and

4. Keep it user friendly for all.
Disclaimer:

- Once the UPT is finalized and made available through the OLAW and IAA website, it can be used as a resource by any interested party.

- The use of the template *will not be mandated* by OLAW or the USDA.
Estimated Timeline

May – July 2022
Restart Group Discussions and finalize the UPT

October 2022
Initiate User evaluations and refine the UPT

December 2022
Final User input and refine the UPT

February 2023
Final UPT to OLAW to be provided as a resource

October 2022
Finalize the UPT

December 2022
Finalize the UPT

January 2023
Finalize the UPT
Questions/Thoughts
Other Research Compliance Committee Updates
The former Export Control Subcommittee has been rebranded to become the **Research Security Subcommittee**.

Consistent with recent changes in the regulatory landscape, many export control offices and staff at academic institutions are expanding their roles beyond traditional export compliance to include research security more broadly, and this rebranding recognizes this shift in our community.

The rebranding will allow this subcommittee to broaden its initiatives to best meet current and evolving needs.
Continuing Leadership and Co-Chair Opening

• Doug Backman, current Export Control Subcommittee Co-Chair, will remain as a Co-Chair.

• Call for a second Co-Chair disseminated via the FDP-Main listserv.
  • Application materials due by Friday, May 20th.
  • Please reach out to Melissa.Korf@hms.harvard.edu with any questions

• Interested in future Research Security Subcommittee initiatives and volunteer opportunities? Sign up for the new Research Security listserv!
Fostering community through our listservs

- Visit [https://thefdp.org/default/mailing-lists/](https://thefdp.org/default/mailing-lists/) to peruse all the FDP listservs that are available and sign-up.
- The listservs are a great way to stay up-to-date on current and new projects, volunteer opportunities, and share knowledge with our colleagues.
RCC Co-Chair Contact Information:
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Melissa_Korf@hms.harvard.edu

RCC website (under development):
https://thefdp.org/default/committees/research-compliance/