

# OLAW Guidance on Annual Reports, Semiannual Inspections, and the AAALAC International Program Description

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National Institutes of Health  
Office of Laboratory Animal Welfare

# Objectives



- Reflect on 2020 Annual Reports to OLAW and Prepare for 2021
- Identify Flexibilities in Conduct of Semiannual Inspections of Animal Facilities
- Preview details on use of AAALAC Program Description in OLAW Domestic Assurance

Reflections:  
2020 Annual  
Report to  
OLAW

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# 2020 Annual Report Data

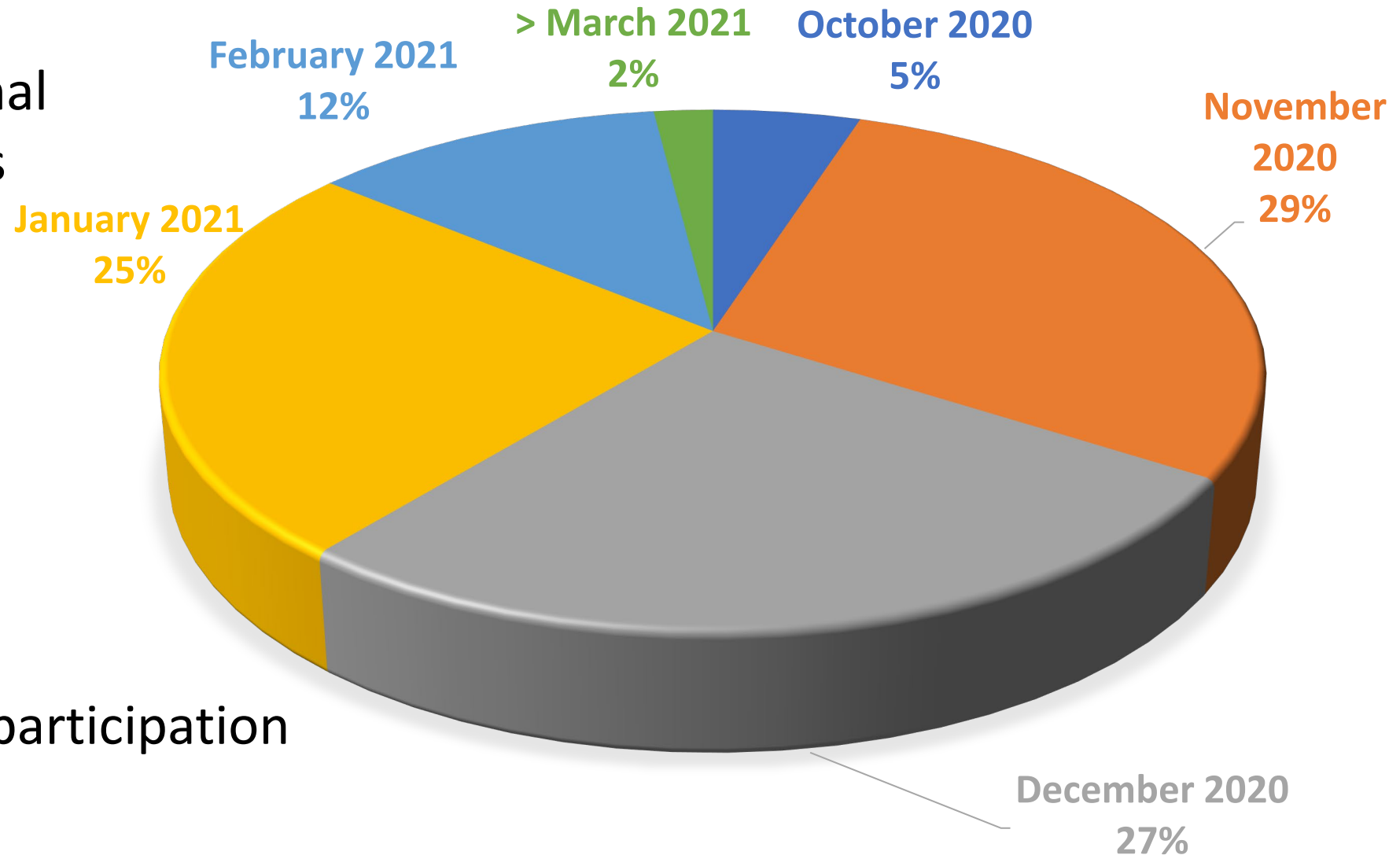
## Acknowledgement Letters Sent

886 Domestic Animal Welfare Assurances

72% Reviewed by Program Analysts

28% Reviewed by Assurance Officers

100% institutional participation





# Annual Report to OLAW Updated

Reporting period and due date harmonization with USDA

Year	Reporting Period	Due Date
2021+	October 1-September 30	December 1

OMB-approved Annual Report form, instructions and resources available at:

<https://olaw.nih.gov/resources/documents/annual-report.htm>



Did the harmonized dates reduce burden?





Planning for  
2021 Annual  
Report to  
OLAW

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# 2021 Annual Report

Institution:

Assurance Number:

Reporting Period: October 1, 2020 - September 30, 2021

This institution's Institutional Animal Care and Use Committee (IACUC) provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

## Program Changes [*Select A or B*]

- A. There have been **no changes** in this institution's program for animal care and use described in the Assurance. [*Skip to Item II.*]
- B. Change(s) in this institution's program for animal care and use have occurred during this reporting period.

Select all that apply:

- This institution's AAALAC accreditation status has changed:
  - [AAALAC Accredited](#) – Category 1
  - Non-Accredited – Category 2
- This institution's program for animal care and use has changed. [*Attach a full description of the changes.*]



# Program Review Dates

- Provide program review dates occurring in the reporting period October 1, 2020, through September 30, 2021
- Program reviews must be completed at least every 6 months with a 30-day grace period (provided no forward drift of dates year to year)
- No waivers were granted by OLAW for this IACUC function
- For information on Assured institution IACUC flexibilities during the pandemic, see Guide Notice NIH-OD-20-088 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html>

# Facility Inspection Dates

- Provide facility inspection dates occurring in the reporting period October 1, 2020, through September 30, 2021
- Facility inspections must be completed at least every 6 months with a 30-day grace period (provided no forward drift of dates year to year)
- OLAW waivers for facility inspections due to COVID-19
- For information on Assured institution IACUC flexibilities and OLAW waivers due to the COVID-19 pandemic, see Guide Notice NIH-OD-20-088 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html>

# OLAW Annual Report Resources

- Annual Report to OLAW website  
<https://olaw.nih.gov/resources/documents/annual-report.htm>
- Notice of Update to the Reporting Period of the Annual Report to OLAW NOT-OD-20-109  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-109.html>
- OLAW Special webinar: Update to the Reporting Period of the Annual Report to OLAW  
<https://olaw.nih.gov/education/educational-resources/webinar-2020-06-17.htm>
- Contact the OLAW Division of Assurances  
by phone 301-496-7163 or email [olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov)



# USDA Annual Report Resources

- Annual Report Webpage
- Resources
- Link to portal



[https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa\\_obtain\\_research\\_facility\\_annual\\_report](https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_obtain_research_facility_annual_report)







# Word Cloud

- Flexibilities for Semiannual inspections...

# New Guide Notice

## Flexibilities For Conducting Semiannual Inspections of Animal Facilities

- NOT-OD-21-164

<https://grants.nih.gov/grants/guide/notice-files/>



# Reducing Regulatory Burden



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



# OLAW Website

OER Home About Grants Funding Forms & Deadlines Grants Policy eRA News & Events About OER

NIH National Institutes of Health  
Office of Laboratory Animal Welfare

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Office of Laboratory Animal Welfare

- Policies and Law
- Guidance
- Education
- Resources

**21st Century Cures Act – Animal Care and Use in Research**  
Actions to reduce administrative burden on investigators conducting animal activities while maintaining research integrity and the protection of animals.

**COVID-19 Pandemic Contingency Planning**  
Resources for animal programs to prepare for and cope with the COVID-19 pandemic.

**Obtaining an Assurance**  
Criteria and process for getting an Animal Welfare Assurance.

**ICARE Project & Workshops**  
A federal interagency project to empower IACUCs and institutions to increase compliance while minimizing burden.

**Reporting Noncompliance**  
How to report situations of noncompliance and animal welfare concerns.

**Tutorial for the PHS Policy**  
Learn about the PHS Policy on Humane Care and Use of Laboratory Animals through this tutorial.

**OLAW News**

- Register Now for ICARE Dialogues: COVID-related Issues of IACUCs and ACUPs of Historically Black Colleges and Universities and Small Organizations – June 30, 2021
- OLAW webinar on IACUC Responsibilities Regarding Service Animals is now available
- Register Now for ICARE Dialogues: IACUC Responsibilities for Wildlife Research – June 23, 2021
- New OLAW website available for 21st Century Cures Act action items

View All News



## Office of Laboratory Animal Welfare

[Policies and Laws](#) ▾

[Guidance](#) ▾

[Education](#) ▾

[Resources](#) ▾

[Home](#) » [Policies and Laws](#) » [21st Century Cures Act – Animal Care and Use in Research](#)

## 21st Century Cures Act – Animal Care and Use in Research

The [21<sup>st</sup> Century Cures Act, Section 2034 \(d\)](#)<sup>1</sup>, directed the NIH, in collaboration with USDA and FDA, to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.



Zebrafish



Departures



AAALAC Program  
Description



21<sup>st</sup> Century Cures Act  
Working Group Process  
and Report



Annual Report to OLAW



60-day Comment Period



Semiannual Animal  
Facility Inspection



Photo: [https://fbresearch.org/wp-content/uploads/2018/03/FullSize\\_Poster\\_Mice.jpg](https://fbresearch.org/wp-content/uploads/2018/03/FullSize_Poster_Mice.jpg)

## Semiannual inspection of animal facilities

- IACUC responsibility
- Evaluate the humane care and use of animals
- Conduct at least once every six months
- Critical component of continuing review (post approval monitoring)

## PHS Policy III.B. Definition of an Animal Facility

- Includes any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities used for animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation





# PHS Policy III.B. Definition of Satellite Facility

- Any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.



# Animal Welfare Act Semiannual Inspection 9CFR 2.31 (c) (2)

- Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, ... provided however, animal areas containing free-living wild animals in their natural habitat need not be included in such inspection.
- Study area means any building, room, area, enclosure, or other containment outside of a core facility or centrally designed or managed area in which animals are housed for more than 12 hours.



# How Should the Semiannual Inspection be Conducted?

According to the PHS Policy Footnote 8

- The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite *ad hoc* consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report (Footnote 8, page 12).
- No member should be involuntarily excluded.
- The IACUC remains responsible for the evaluation and the report.



# Animal Welfare Act Requirements for Semiannual Inspection

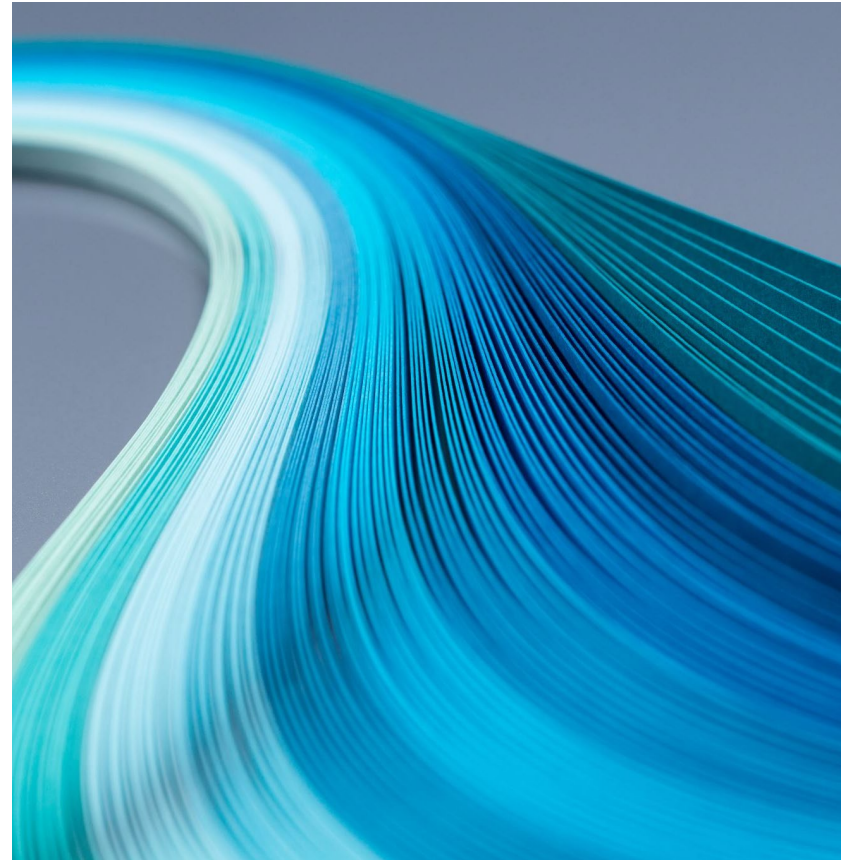
- For areas housing AWA-regulated species, the IACUC may use subcommittees composed of at least two committee members
- Ad hoc consultants may assist in conducting inspections
- IACUC members involved are not required to inspect together and may each inspect different parts of the facility



# Flexibilities

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- Timing – at least once every six months (+ 30 days)
- Use of subcommittees – minimize bias
- Staggered inspection schedule – schedule over a 6-month period







- Did you find any of these flexibilities helpful for your institution?
- What in particular worked?
- What did you find challenging?



# Flexibilities

- Announced
- Unannounced
- Inspecting areas of oversight other than animal facilities as defined by the PHS Policy (e.g., weighing, dosing, immunizations) but should have monitoring

# Flexibilities



- Methods of remote inspection
- Videos, photographs
- Use of OLAW's developed checklist (or other checklist)

- Did you find any of these flexibilities helpful for your institution?
- What in particular, worked?
- What did you find challenging?







## Flexibilities

- Using an AAALAC International Site Visit for the semiannual inspection





## Program Description

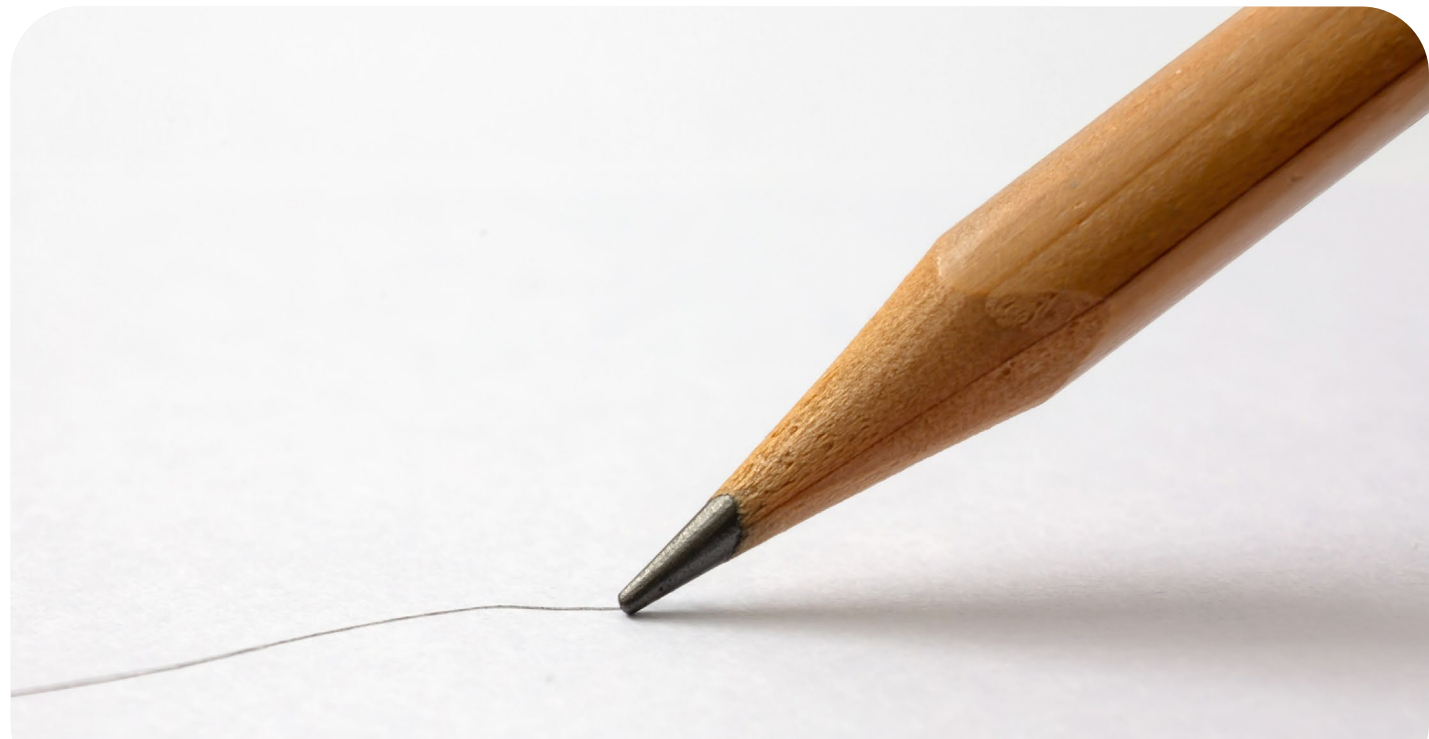
Sections in the OLAW Domestic Assurance





# Domestic Assurance Completion

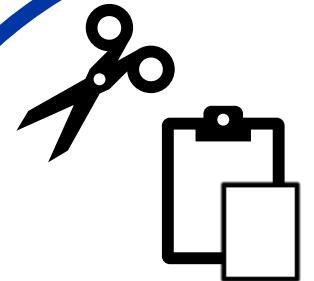
- Using Sections of the AAALAC International Program Description to Prepare the OLAW Domestic Assurance Guide Notice NIH-OD-21-130  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-130.html>
- NOT a Requirement
- Optional use of specific sections of the AAALAC Program Description



# AAALAC Program Description Sections

- Section 2.I.B.2. a and e Post-Approval Monitoring
  - Assurance Part III.D.9. How the IACUC monitors ongoing activities (post-approval monitoring).
- Section 2.I.A.2.b.\* Occupational Health and Safety of Personnel
  - Assurance Part III.E. Risk-based occupational health and safety program
- Section 2.I.A.2.a. i., ii.2), iii.1) a) and c) Training, Education, and Continuing Educational Opportunities & Section 2.I.B.1. a.iii. Role of the IACUC
  - Assurance Part III.G. Training or instruction available

21 Century Cures Act AAALAC Program Description site  
<https://olaw.nih.gov/policies-laws/21st-century-cures-act/AAALAC-Program-Description>



# TIPS

- Use only the specified sections
- Assurance documents are subject to FOIA  
OLAW FAQ C4

<https://olaw.nih.gov/faqs#/guidance/faqs?anchor=question3455>







The Freedom  
of Information Act (FOIA)

<https://olaw.nih.gov/education/educational-resources/webinar-2020-12-10.htm>

Developments in  
FOIA in the  
Context of  
Animal Research

# Upcoming OLAW webinar

Date	Title	Speaker
September 9, 2021	<a href="#">What Every IACUC Should Know About AAALAC International</a>	Jane Na, DVM, CPIA, Director, Division of Assurances, OLAW Helen E. Diggs, MEd, DVM, DACLAM, Senior Director AAALAC International

<https://olaw.nih.gov/education/educational-resources/webinar-2021-09-09.htm>



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# OLAW Contacts







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- ✓ Preview details on use of AAALAC Program Description in OLAW Domestic Assurance





**NIH** National Institutes of Health  
*Office of Laboratory Animal Welfare*

# Questions?