

Interagency Collaborative Animal Research Education

# **ICARE Dialogues**: Using Flexibility Provided in the PHS Policy and Animal Welfare Act and Regulations

Questions on this topic may also be forwarded to Susan Silk at <u>ICARE.SERO@gmail.com</u>

## Using Flexibility Provided in the PHS Policy and AWAR

Our Team

- 1. Bill Greer, University of Michigan
- 2. George Babcock, University of Cincinnati College of Medicine
- 3. Neera Gopee, Office of Laboratory Animal Welfare, NIH
- 4. Cody Yager, Animal Care, APHIS, USDA
- 5. Bill Stokes, Animal Research and Welfare Consultant (formerly NIH and Animal Care, APHIS, USDA)





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.	Period of the Annual Report to OLAW New OLAW Webinar now available: Animal Research and Public Support: A 2020 Vision for Strategic Communications and Micro-Messaging
		Commentary on Lab Animal Protocol Review Column: June Issue OLAW quarterly webinar on June 11, 2020, will be
Reporting Noncompliance	Tutorial for the PHS Policy Learn about the PHS Policy on Humane Care and Use of Laboratory Animals through this tutorial.	prerecorded.
How to report situations of noncompliance and animal welfare concerns.		View All News

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



**OLAW News** 

New OLAW Webinar available: Update to the Reporting

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#### Introduction

The IACUC is responsible for oversight of the animal care and use program and its components as described in the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) and the Guide for the Care and Use of The Guide (p. 35) states that facilities "must have a disaster plan" to cope with "unexpected conditions [including a pandemic] that result in the catastrophic failure of critical systems or significant personnel absenteeism, or other

unexpected events that severely compromise ongoing animal care and well-being." Here we provide resources and guidance to help IACUCs prepare for and cope with the COVID-19 pandemic. These options may be employed alone or in combination to meet the individual needs and circumstances of each

institution.

#### Frequently Asked Questions

These questions are also available on the NIH Grants & Funding COVID-19 Flexibilities for Applicants and Recipients webpage, along with other crucial information including changes to applications, reporting, costs, and delays in research progress.



### https://olaw.nih.gov/covid-19.htm

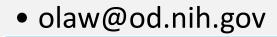
- OLAW-specific
- Guide Notices
- Webinars
- Articles
- Example Disas
- Useful Links, a
- Contacts

Also available at: NIH Grants & Fundi



National Institutes of Health Office of Laboratory Animal Welfare

### E-mail:



• 301-496-7163

• https://olaw.nih.gov

• @NIH\_OLAW

• subscribe through OLAW webpage for news and announcements.

### **OLAW Contacts**









### USDA Contacts

- E-mail: <u>Animalcare@usda.gov</u>
- Phone: (970) 494-7478
- Website: <u>https://www.aphis.usda.gov/a</u> <u>phis/ourfocus/animalwelfare</u>
- Stakeholder Announcements: Subscribe through the USDA Animal care webpage



# Flexibilities for the COVID-19 pandemic include:

- Delay as long as necessary due to the COVID-19 pandemic, but document the delay.
- Virtual meetings & virtual semiannual inspections are allowed.
  - (2) IACUC members must be involved, but can inspect separate areas.
  - Consultants may be used
  - Approval emails from IACUC members function as signatures





Flexibilities for the COVID-19 pandemic include:

- Annual reviews can be delayed but should be conducted when the regulated activity restarts
- USDA inspections will not occur if there is safety concerns during the COVID-19 pandemic
- Approval or waiver from USDA is <u>not</u> needed





**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.





### Zoom is great and it works, so do we need to ever go back to the "old" way?

- 1. Due to COVID some IACUCs are meeting less often. Could this lead to potential issues?
- 2. Does an IACUC ever need to meet in person or are teleconferencing or video conferencing acceptable alternatives?
- 3. What IACUC business cannot be conducted by virtual methods?

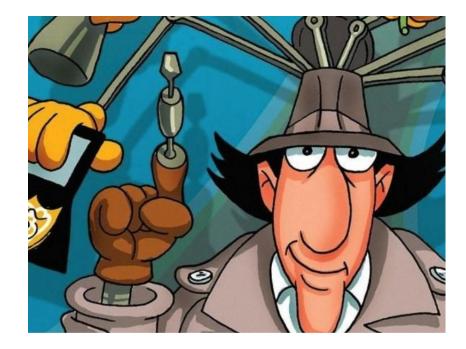
# Are there alternate ways to conduct the required semiannual facility program reviews?



- I have a waivers from OLAW to temporarily suspend my inspections. Is there anything I need to do when I restart the inspections?
- 2. How can I conduct the inspections while adhering to the pandemic restrictions?
- 3. Everyone at my institution wants to participate in the inspection but how do I do that given the restrictions?



# Are there flexible ways to conduct the required semiannual facility inspections?



- 1. Can I use Ad hoc consultants to conduct inspections?
- 2. How would we define a "qualified" person to complete the inspections if we move to a single inspector?



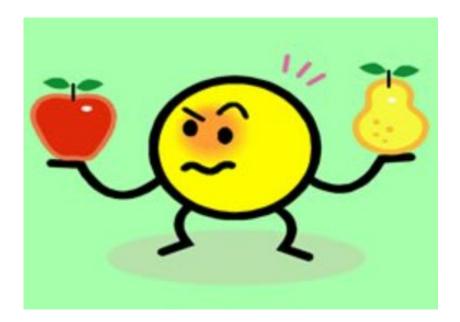
Our areas allow for appropriate housing and handling of animals, but rarely have a lot of space available for personnel. At some point I saw some discussion of the possibility of lab personnel using Zoom or other video conferencing to complete the inspections, is that an option, and if so, how would that work effectively?



Can a veterinarian make changes to the pain management plans (anesthetics and analgesics) that have been approved in a protocol?



### Are there any flexibilities that can be applied when performing protocol & grant congruency reviews?



### What do we do?

- 1. Due to the Pandemic restrictions, we are unable to conduct our facility inspections. What do I do to ensure my program remains compliant?
- 2. With the Pandemic, I haven't been able to inspect my animal facilities for the last 8 months. I'm beyond the 6 month exception period allotted through OLAW – what do I do, and what do I include on my OLAW annual report? What about my USDA facilities; it's been at least 8 months since they were inspected.
- 3. My IO report includes a summary of my program review and inspections reports. Due to COVID, I haven't been able to inspect my facilities or conduct a program review. Do I still need to provide a report to the IO, and what should it include?



Given any circumstances the IACUC has the option to decide how to conduct facility inspections. (PHS Policy, Footnote 8)

- 1. Could the IACUC conduct its inspection by using others to first tour the facilities and gather information? Who could gather this information?
  - a. The IACUC Administrator(s)
  - b. The QA/PAM staff
  - c. Husbandry Staff
  - d. Veterinary Staff
  - e. Pls
  - f. The Facility manager
- 2. Are there circumstances when the IACUC could establish different time periods for conducting the facility inspections (i.e., periods other than every six months)?
- 3. Can the IACUC conduct ongoing inspections if the animal room is under 24/7 video surveillance?
- 4. Can laboratory staff conduct self-assessments of their own animal use areas (e.g., surgery suites) and provide the assessment to the IACUC?

### Scenario #1 – The Great Eastern University (GEU) Deer Farm

GEU has a captive deer colony that's maintained 100 miles from campus.

#### Process:

- a. To conduct the inspection, the facility manager sends multiple photos of the food/drug storage areas, animal procedures area, clinical records, and video clips of the fencing as well as deer interacting with one and other.
- b. To finalize the inspection, a subcommittee of IACUC members review/analyzed the provided images and videos, and then submit a written report to the IACUC Administrator.
- c. The Administrator collates the information into the IO report, which is later reviewed by the IACUC and submitted the IO

### Questions:

- a. Are there any regulatory concerns associated with this process and if so what refinements would need to be made?
- b. Is this process acceptable given the Pandemic restrictions?
- c. Would this process be acceptable under normal circumstances?
- d. What if the species of interest were Salmon at remote GEU fish hatchery?

### Scenario 2 – Inspecting a vivarium dedicated to mice

Due to Pandemic restrictions and considering IACUC members, IACUC Administrators and PAMer's are working remotely (i.e., from home), the GEU IACUC approved the following process for inspecting its rodent vivarium:

#### Process

- 1. The IACUC developed an inspection checklist that includes various inspection tips/guidance and text boxes that will be used for gathering needed information;
- 2. Since staff that conduct the inspections are working remotely, the IACUC provided the checklist to husbandry staff, veterinarians, and vet techs and asked them to tour each facility and provided the information requested on the checklist:
- 3. To finalize the inspection, a subcommittee of IACUC members review/analyzed the provided the information, and submitted a report to the IACUC Administrator.

### **Questions:**

- a. Any regulatory concerns? If so what refinements need to be made?
- b. Acceptable given the Pandemic? How about under normal circumstances?
- c. What if the species of interest were rabbits (USDA)?

### Semi-Annual Program Review

True/False – Both OLAW and the USDA have provided institutions the option to delay their semi-annual program review.

- 1. Describe how you conduct the program review at your institution under normal circumstances (i.e., in the absence of pandemic restrictions).
- 2. What specific issues related to the pandemic restrictions have impeded your ability to follow your past practices?

