

# 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. Wayne Barbee, Virginia Commonwealth University
4. Bob Gibbens, Animal Care, APHIS, USDA
5. Neera Gopee, Office of Laboratory Animal Welfare, NIH





National Institutes of Health  
Office of Laboratory Animal Welfare

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## Office of Laboratory Animal Welfare

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### 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

New OLAW Webinar available: Update to the Reporting 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 prerecorded.

[View All News](#)

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





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Policies and Laws ▾

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Home » COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs

## COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs

The following resources are provided to assist animal care and use programs of Assured institutions in preparing for and coping with the current COVID-19 pandemic while maintaining animal welfare.

Please also see our page on [Disaster Planning and Response Resources](#) for more resources related to preparing for and responding to natural and other disasters, including pandemics.

Rest assured that OLAW is monitoring the COVID-19 situation very closely. Our first priorities are human and animal health and well-being. This page will be updated as new guidance is developed.

[Subscribe](#) to our Listserv or [follow us](#) on Twitter to receive updates regarding newly developed resources, including Guide Notices, webinars, and FAQs relating to the COVID-19 pandemic.

### 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 Laboratory Animals* ([Guide](#)).

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.



National Institutes of Health  
Office of Laboratory Animal Welfare

<https://olaw.nih.gov/covid-19.htm>

# COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs

- OLAW-specific FAQs
- Guide Notices
- Webinars
- Articles
- Example Disaster Plans
- ~~Useful Links, and~~
- Contacts

Also available at:

[NIH Grants & Funding COVID-19 Flexibilities for Applicants and Recipients](#)

E-mail:

- [olaw@od.nih.gov](mailto:olaw@od.nih.gov)

- 301-496-7163

- <https://olaw.nih.gov>

- @NIH\_OLAW

- subscribe through OLAW webpage for news and announcements.

# OLAW Contacts





## Flexibilities for the COVID-19 pandemic include:

- Delay as long as necessary due to the COVID-19 pandemic, but document the delay
- Virtual meetings & semiannual inspections are allowed
  - (2) IACUC members are involved, but can be separate and consultants be used
  - Approval emails from IACUC members function as signatures
- Annual reviews can be delayed but should be conducted when the activity restarts
- USDA inspections will not occur if there is safety concerns during the COVID-19 pandemic
- Approval or waiver from USDA is **not** needed

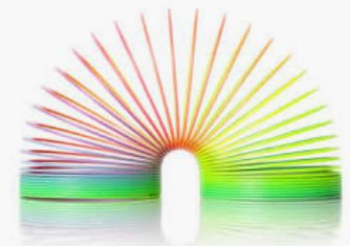
# Flexibility in the Regulations

## The IACUC's oversight of the Animal Care and Use Program

1. What flexibilities have always been in place?
2. “NEW” flexibilities due to COVID
3. Where can you find the flexibility
4. Engaging the IACUC
5. Semi-Annual Inspections during the pandemic (2X year?)
6. Semi-Annual Inspections (Ways it can be done)



**flexibleRules**



# 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.







# FAQ's (OLAW and the USDA)

## Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCs) Due to COVID-19

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**Notice Number:** NOT-OD-20-088

### Key Dates

**Release Date:** March 16, 2020

COVID FAQ VIII.10. Do institutions need to request a waiver if implementing the flexibilities described in OLAW's Guide Notice NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? +

If the IACUC can safely complete the semiannual facility inspections no later than 30 days beyond the six-month interval from the institution's last inspections, there is no need to notify OLAW or request a waiver since this timeframe is compliant with OLAW's guidance. However, Assured institutions that are unable to conduct facility inspections within this six month plus 30-day timeframe because of the COVID-19 pandemic, may request a waiver from OLAW (see [NOT-OD-20-088](#)).

COVID FAQ VIII.11. How can institutions request waivers if the IACUC cannot safely complete the semiannual facility inspections 30 days beyond the six-month interval from the last facility inspections? +

Assured institutions that are unable to conduct facility inspections at least once every six months plus 30 days because of COVID-19 restrictions may request a waiver (see [NOT-OD-20-088](#)). An authorized institutional representative (Institutional Official, IACUC Chair, IACUC Coordinator, or Attending Veterinarian) may request a waiver of the semiannual inspections or other provisions of the PHS Policy by submitting a request with justification related to the COVID-19 outbreak to [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov). OLAW expects institutions granted waivers to conduct the inspections that were postponed as soon as the IACUC can safely do so and then conduct another semiannual facility inspection, no more than six months and 30 days from that time.

COVID FAQ VIII.12. Will OLAW approve waivers for the semiannual program review? 4

A waiver request will only be required if deviating from a provision or provisions of the PHS Policy. At this point, OLAW expects Assured institutions to explore and implement available flexibilities when conducting the semiannual program (and protocol) review and only request waivers for justifiable reasons (see [NOT-OD-20-088](#)). Semiannual program review and in particular, review of the institution's [disaster plan](#), is even more critical and necessary to ensure the health and safety of personnel and animals during the pandemic.

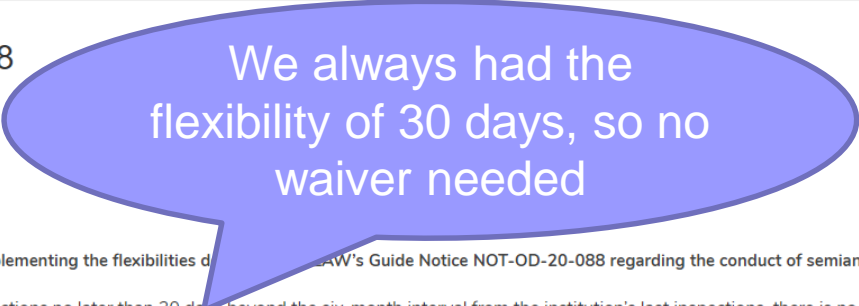
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We always had the flexibility of 30 days, so no waiver needed

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Can't do your inspections  
within 30 days of the due date  
– you need an exception for  
OLAW

and IACUC business?

OLAW or request a waiver since the COVID-19 pandemic, may

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Conduct your program review  
on time – use the available  
flexibilities!



# IACUC Meetings

## Remote Meetings

### Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals

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**Notice Number:** NOT-OD-06-052

**Key Dates**

Release Date: March 24, 2006

**Issued by**

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<https://grants.nih.gov/grants/olaw/olaw.htm>)

## Protocol Review Processes

- ☐ FCR
- ☐ DMR
- ☐ VVC

# IACUC Meetings

## Remote Meetings (Yes before and Yes after COVID)

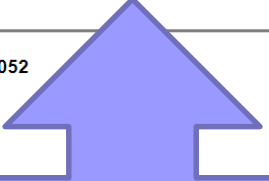
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**Notice Number:** NOT-OD-06-052

**Key Dates**

Release Date: March 24, 2006



All members receive notice of the meeting  
All members receive the related documents  
**All members can participate – technology...**  
Only members in attendance can vote  
Maintain meeting minutes

## Flexibilities for the Protocol Review Processes (Yes before and yes after!)

- ☐ FCR – **during remote meetings**
- ☐ DMR – “technically” a remote process anyway!!
- ☐ VVC –



## IACUC Meetings

Rem (after COVID)

Guida  
Lab

Policy on Humane Care and Use of

# Let's Talk!

All members receive notice of the meeting

All

All

Only

Maintain

Flexibilities for New Processes (Yes before and yes after!)

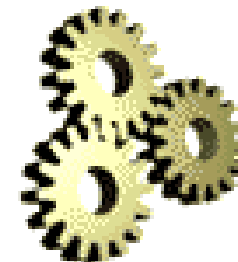
- ☐ FCR – during remote meetings
- ☐ DMR – “technically” a remote process anyway!!

☐ **VVC** –

# The VVC Policy

## Policy Statements:

- The VVC process can only be used to modify procedures that are already part of an approved protocol. It cannot be used to add new procedures.
- The VVC process may not be used to modify existing procedures if the modification increases the opportunity for the animals' welfare to be compromised.
- The VVC Policy must identify one or more veterinarians that have been authorized by the IACUC to perform VVC significant changes to previously approved protocols.
- **The policy must include specific changes the veterinarian is authorized to verify!**



# Facility Inspections – Footnote 8

1. Do them Virtually
2. Use Ad hoc consultants and specialists
3. Use on site staff
4. Use Post approval monitors and QA staff
5. Who/what else – your imagination is your limitation ??????????



# Program Reviews

1. Distribution of resources
2. Committee member interactions
3. Committee processes



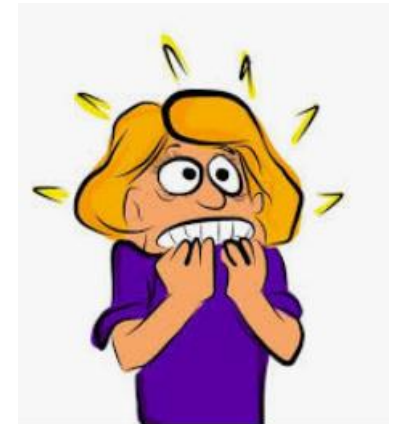
# What did we miss?

1. ACUP IACUC Oversight
2. Training animal users and handlers



# 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?

