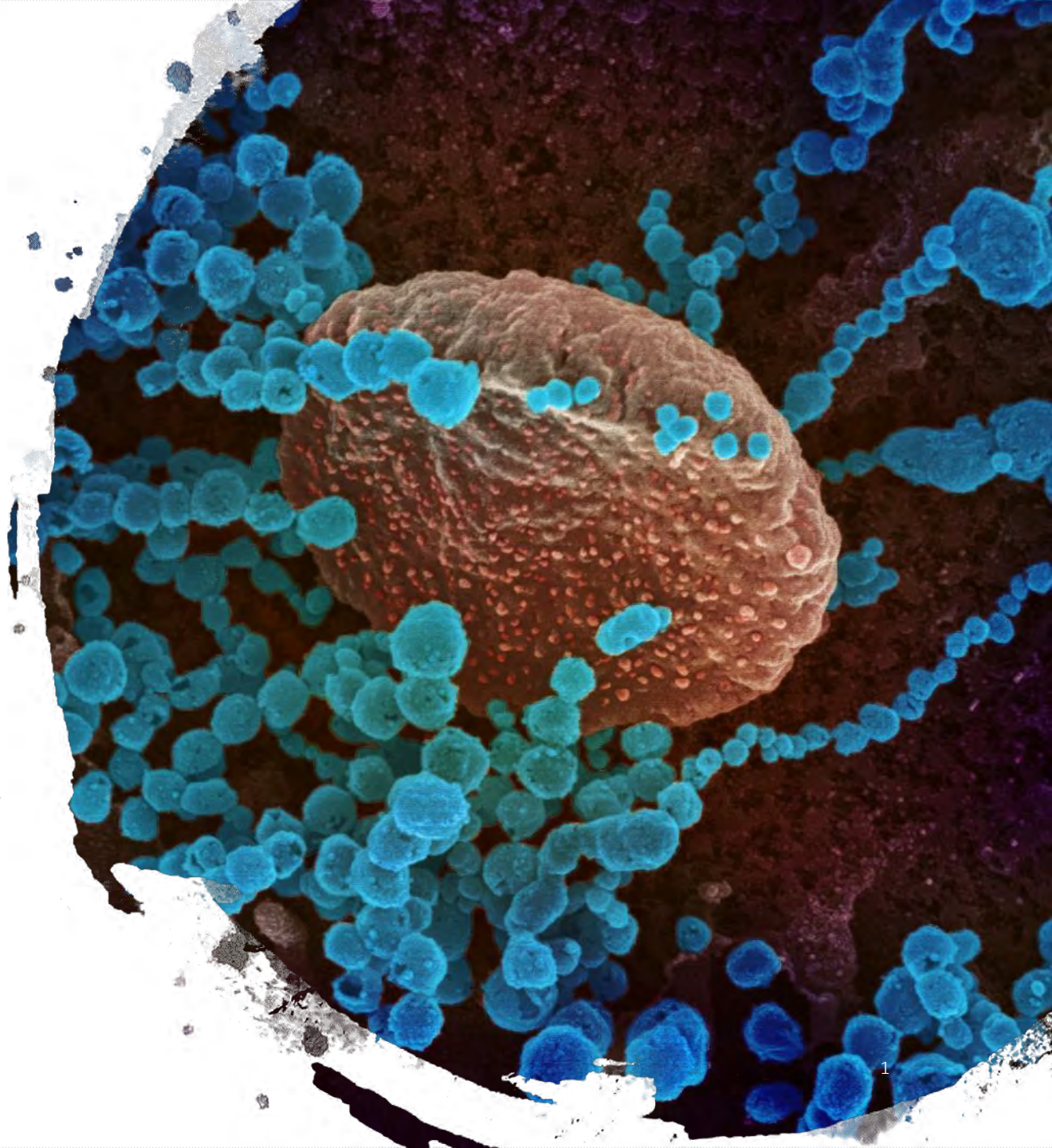


COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs

Patricia Brown
NIH, OLAW

Robert Gibbens
USDA, APHIS, Animal Care



**POLICY & COMPLIANCE****Policy Topics**[Natural Disasters](#)[Coronavirus Disease 2019 \(COVID-19\): Information for NIH Applicants and Recipients of NIH Funding](#)[Applicant/Recipient COVID-19 Update History](#)

Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding

The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects on the biomedical enterprise in the areas affected by the HHS declared [public health emergency for COVID-19](#). Due to the potential exceptional impact, we want to assure our recipient community that NIH will be doing our part to help you continue your research.

This is a rapidly evolving situation and we will provide updated guidance and information as it becomes available.

See [page update history](#).

Guidance

Proposal Submission & Award Management

- [UPDATE: NIH Late Application Policy Due to Public Health Emergency for United States for 2019 Novel Coronavirus \(COVID-19\) - NOT-OD-20-091](#)
- [General Frequently Asked Questions \(FAQs\) - Proposal Submission and Award Management Related to COVID-19 - NOT-OD-20-083](#)
- [Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 - NOT-OD-20-086](#)

Update on COVID-19 Flexibilities for the Research Community



Posted 3/26/2020 Duration 10:41

NIH Message to Research Community on Flexibilities Needed for COVID-19



Posted 3/17/2020 Duration 8:39

<https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>



Office of Laboratory Animal Welfare

[Policies and Laws](#)[Guidance](#)[Education](#)[Resources](#)

[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.

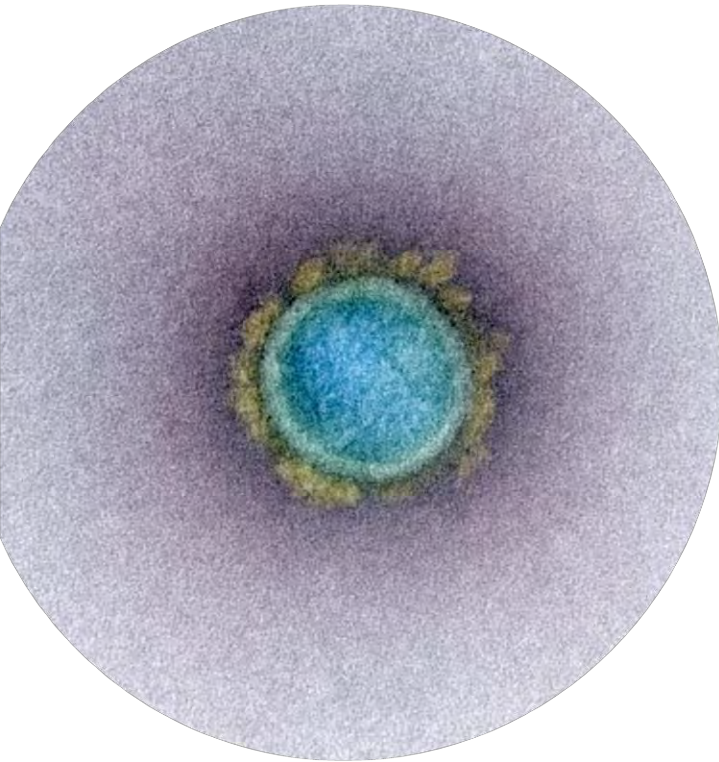
Introduction

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* (pp. 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.

Guide Notices

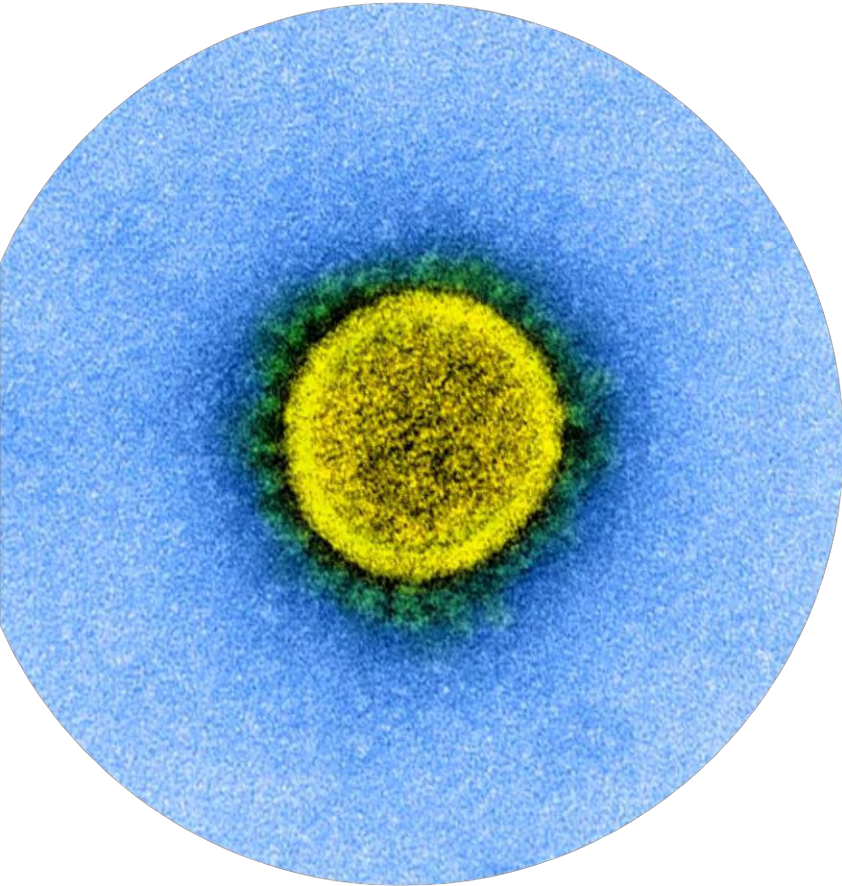


[NOT-OD-20-088](#) Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCs) Due to COVID-19

[NOT-OD-09-035](#) Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)

[NOT-OD-06-052](#) Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals

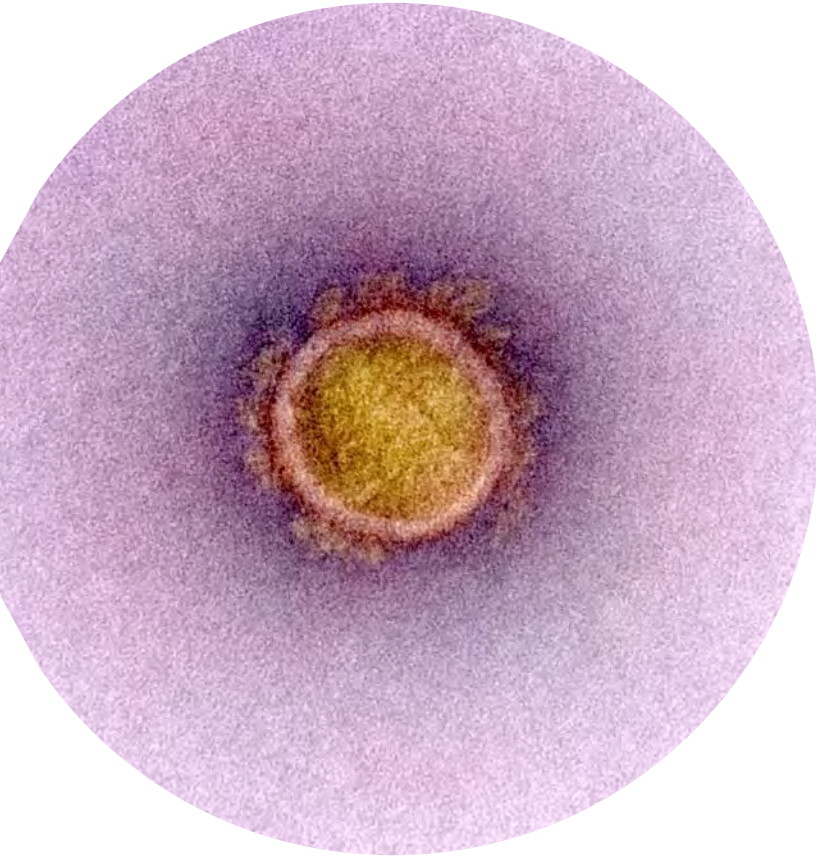
OLAW Webinars



[Pandemic Contingency Planning and Its Impact on Animal Care](#) (March 19, 2020)

[Building a Research Occupational Health Program](#)
(March 12, 2020)

Other Resources



Example Disaster Plans

Strategies to Optimize the Supply of
PPE and Equipment

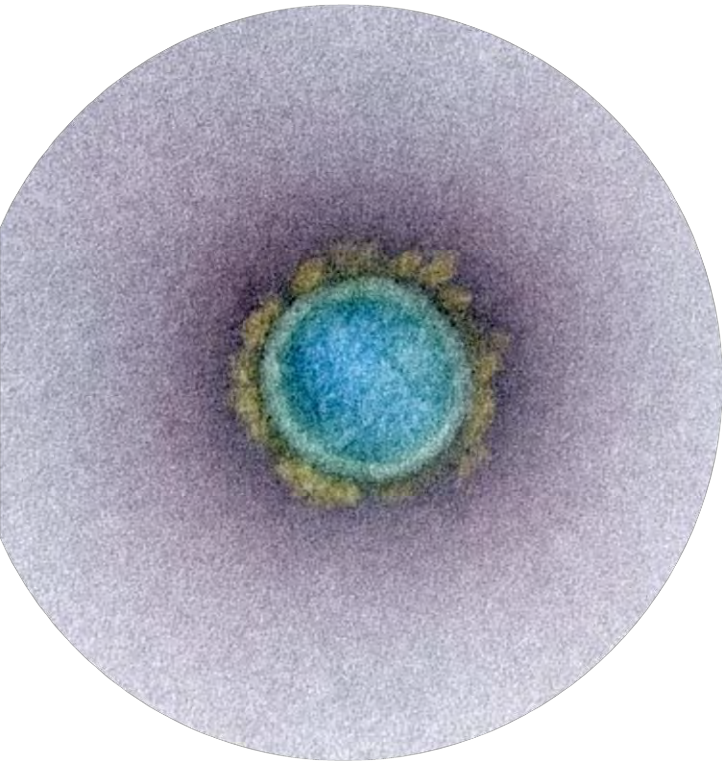
Useful Links

USDA



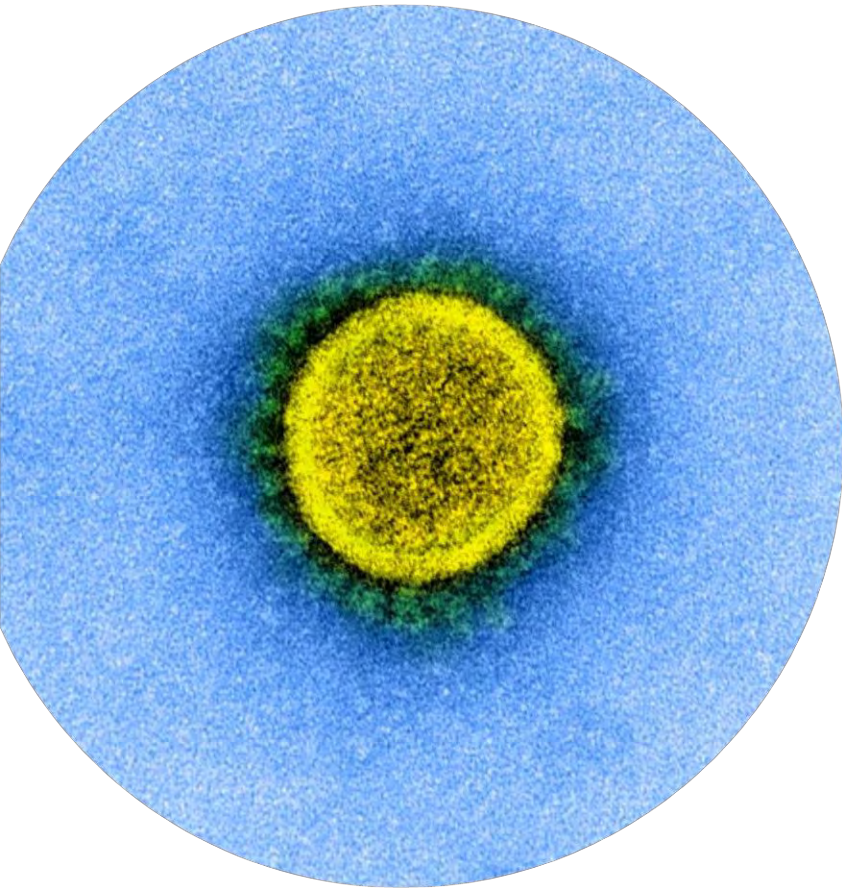
APHIS, Animal Care

Facility Status and Inspections



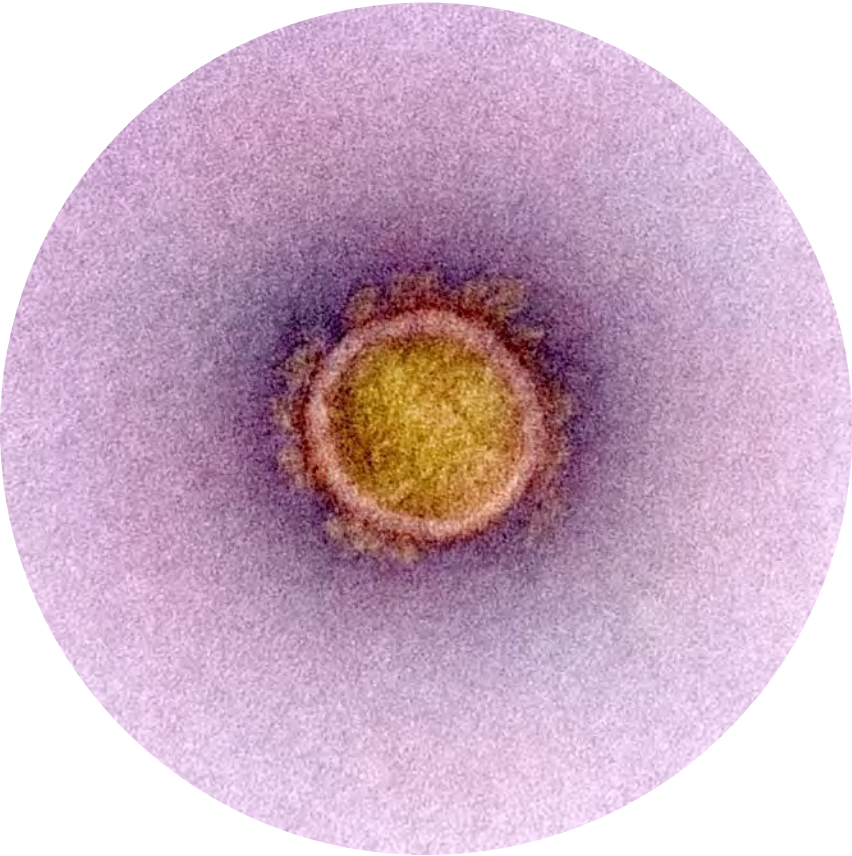
Update: Animal Care is only conducting inspections in response to the most serious animal welfare concerns, and only if social distance can be maintained during the inspection.

Semiannual Program Review and Facility Inspections



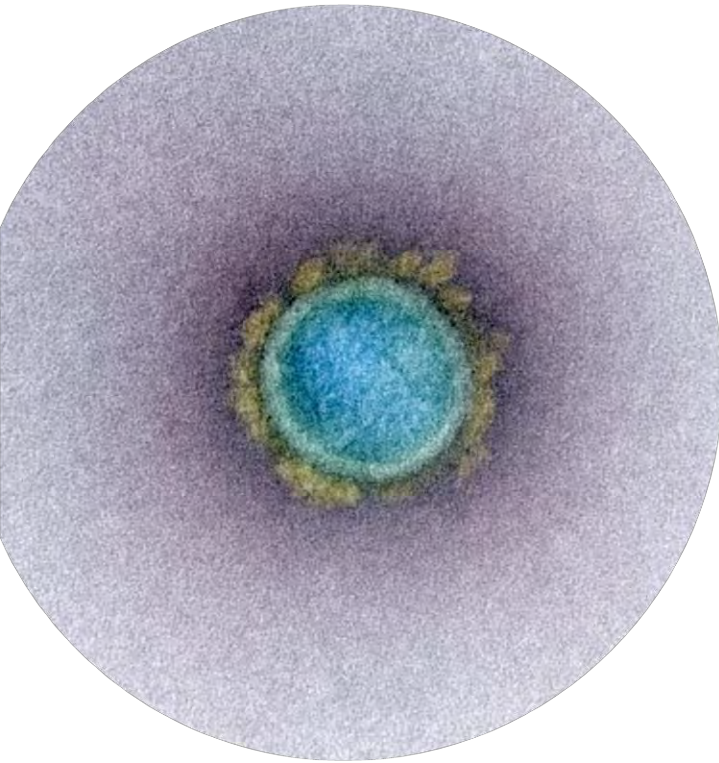
- Can delay as long as necessary based on the COVID-19 pandemic
- Permission or approval from the USDA is not needed
- Document the delay
- When semiannuals restart, the following semiannual would be due 6 months later

Facilities that also have Licenses



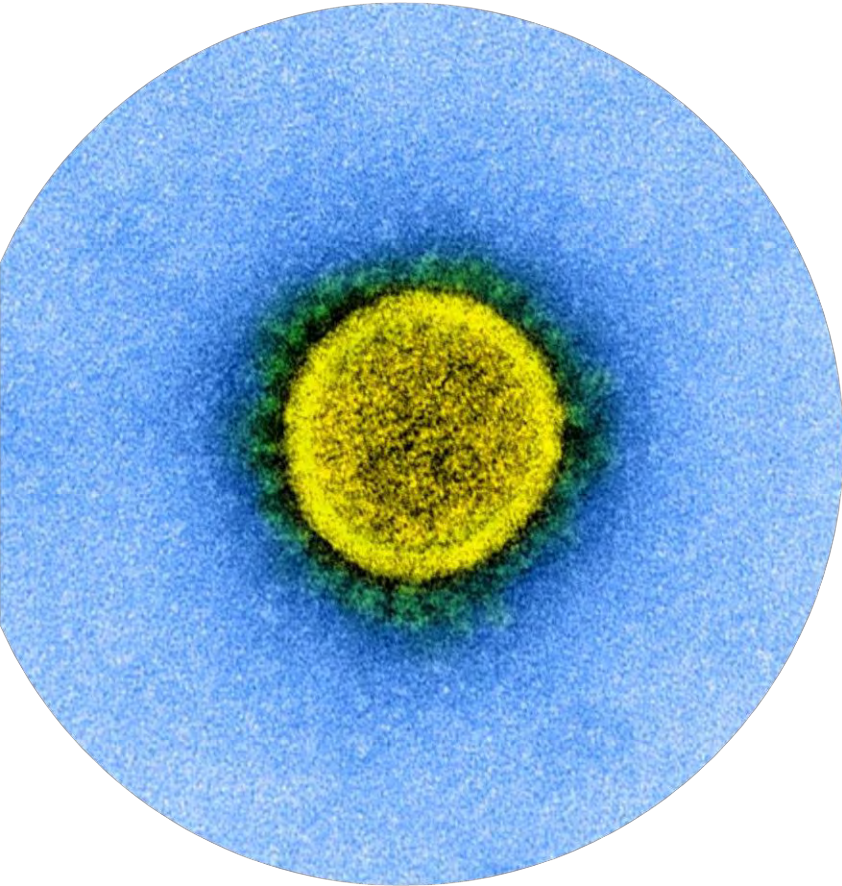
- Animal Care has limited access to mail at this time.
- To expedite the application and renewal process, we are now accepting applications and renewals online at animalcare@usda.gov or by phone at (970) 494-7478.

Essential Employees



“We know that facility employees are key to ensuring that appropriate care is provided to animals every day. State and local exceptions to travel and other restrictions are often focused on medical and emergency response personnel and may not include those employees who are so essential to the well-being of your animals. Animal Care cannot identify those essential personnel for each facility but we encourage you each to do so. And while Animal Care cannot overrule local restrictions on public citizens, we are available to explain the critical nature of the work of these essential employees to State or local officials if needed.”

<https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/28381a8>



Contacting AC

- AnimalCare@usda.gov
- Fort Collins: 970-494-7478
- Riverdale: 301-851-3751
- VMO or Supervisor
- Bob Gibbens: 970-494-7474
Robert.m.gibbens@usda.gov
- Aaron Rhyner: 970-494-7484
Aaron.a.rhyner@usda.gov



USDA COVID-19 Landing Page

<https://www.usda.gov/coronavirus>

USDA U.S. DEPARTMENT OF AGRICULTURE

GLOSSARY ASK USDA RECALLS CONTACT US

HOME **TOPICS** OUR AGENCY MEDIA

Coronavirus Disease (COVID-19)

USDA > TOPICS > DISASTER > CORONAVIRUS DISEASE (COVID-19)

Animals
Biotechnology
Broadband
Climate Solutions
Conservation
Data
Disaster
Farming
Food and Nutrition
Forestry

Latest news from the CDC on Coronavirus Disease 2019 (COVID-19)
[Learn more](#)

Frequently Asked Questions

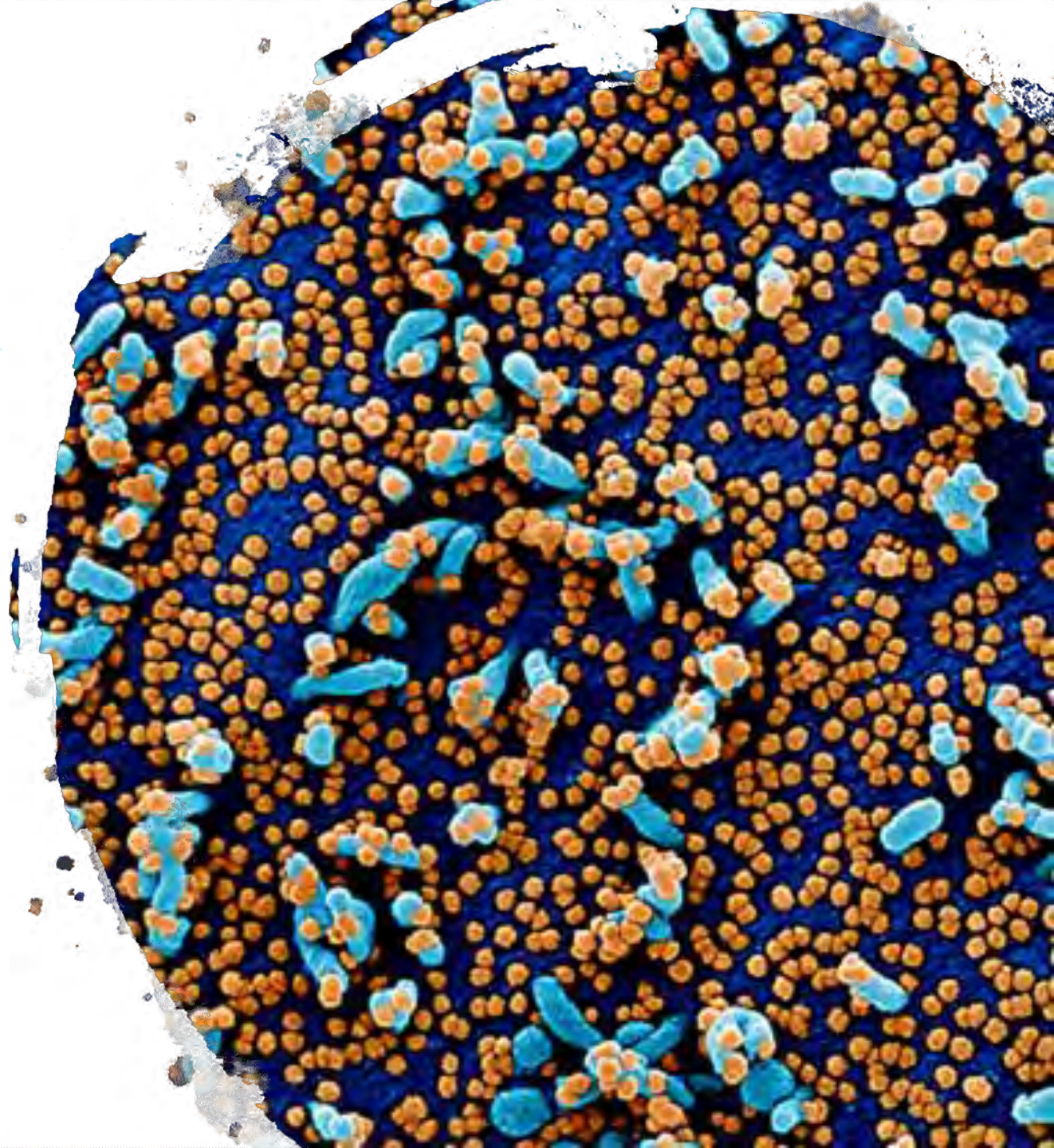
Food Safety +

Access to Food +

104%

Frequently Asked Questions:

Disaster Planning



Do awardee institutions need animal facility disaster plans?

OLAW FAQ G.3.

Yes



Required by the *Guide* (p. 35) and should define the actions necessary to prevent animal pain, distress, and deaths.

- Housing systems
- Transportation/relocation
- Essential supplies (feed, bedding, cagewash supplies)
- Policies and procedures
- Identification of emergency responders
- Personnel training
- Contingencies if power fails

How can institutions and their IACUCs best prepare for a pandemic [like COVID-19]?

COVID FAQ VI.1. and OLAW FAQ G.9.

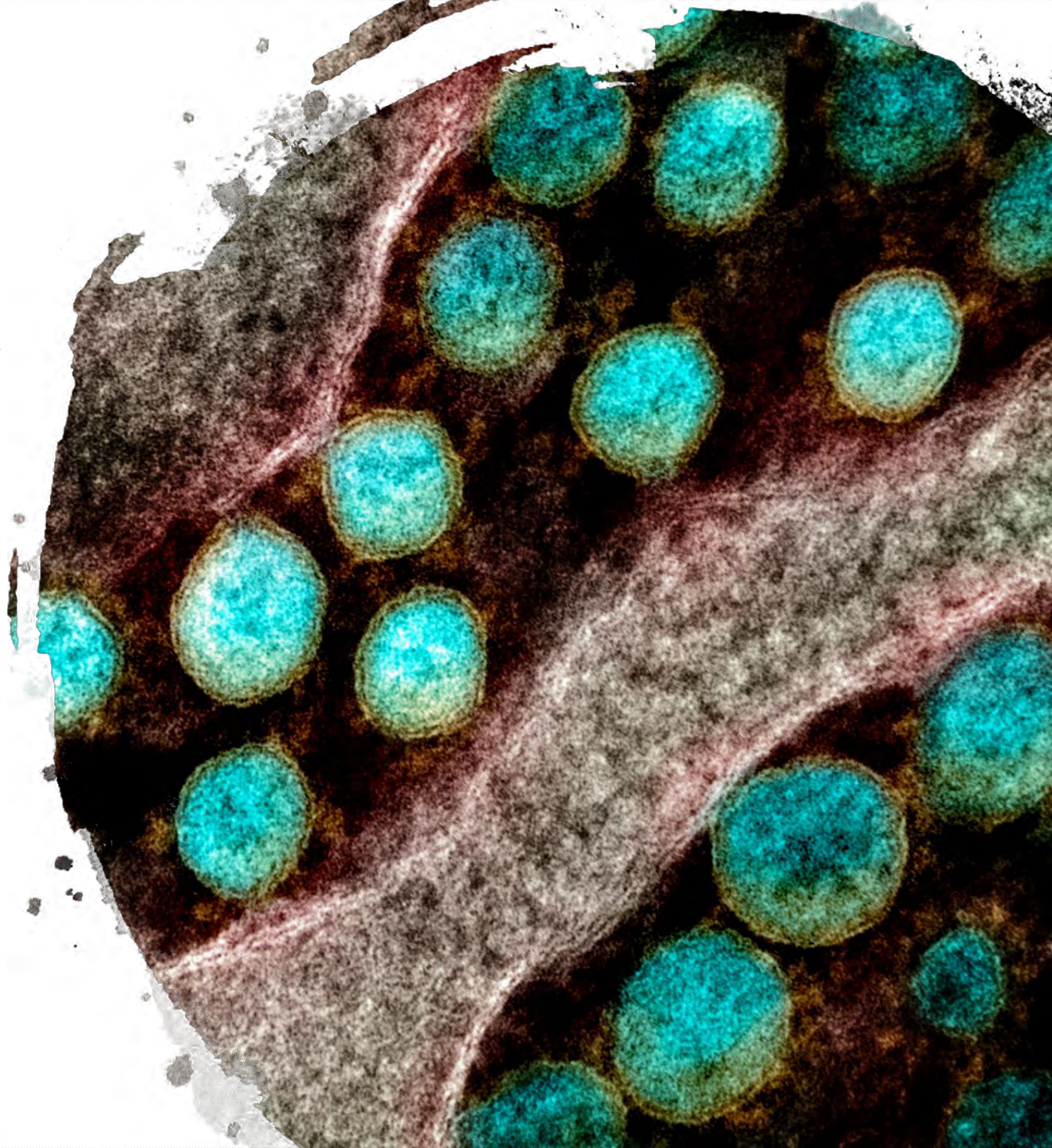
IACUCs

- Must be properly constituted
- Sometimes require quorums
- Expired protocols may not continue animal work
- IACUC training and appointment

IACUC Flexibilities

- Designated member review
- Teleconferencing
- Minimum of 1 meeting per 6 months

Frequently Asked Questions: Animal Care



If animals already on study were scheduled for post-op analgesia or other required treatment for clinical care, but the institution shuts down before the treatments are given, is this considered protocol noncompliance to OLAW and USDA?

COVID FAQ VI.3.

MAYBE

Discuss with OLAW's
Division of Compliance
Oversight before
reporting

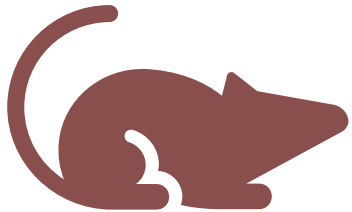


- “Procedures **must** be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours.”
(*Guide*, p. 114)
- Do not initiate new procedures requiring post-op analgesia.

If animals already on study need to be euthanized because the institution has shut down, what type of documentation or reporting is expected of the IACUC for USDA and OLAW?

COVID FAQ VI.4.

LAST RESORT!



Alternatives

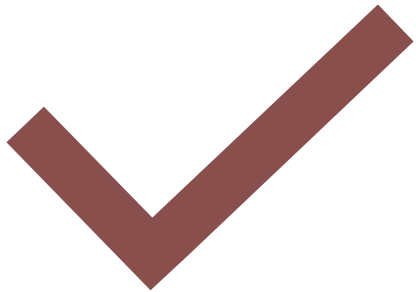
- Transferring animals to a holding protocol
- Postponing unnecessary procedures or manipulations
- Relocating animals to another facility
- Cryopreservation for certain species

If animals are currently in the vivarium but experiments have not started yet, can the animals be kept temporarily on a holding protocol (per diem charges still to the grant) until animals are used at the later postponed date?

COVID FAQ VI.5.

YES

(IACUC-approved
holding protocol)

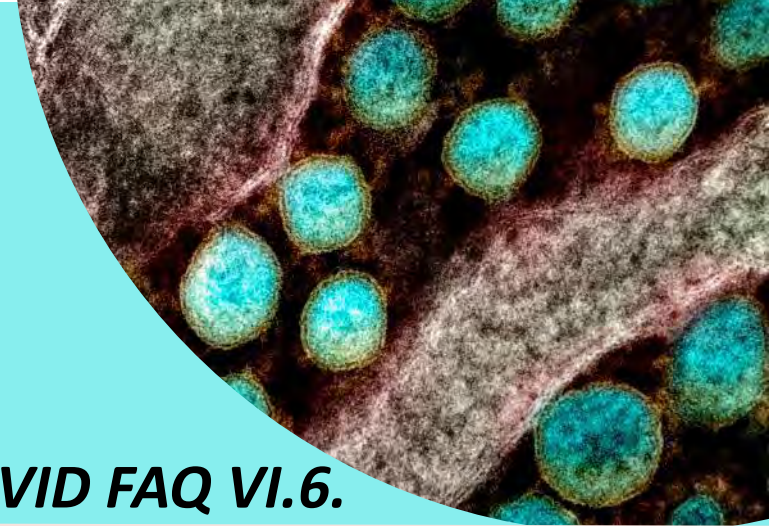


See [NOT-OD-20-086](#)

Flexibilities Available to Applicants and
Recipients of Federal Financial Assistance
Affected by COVID-19

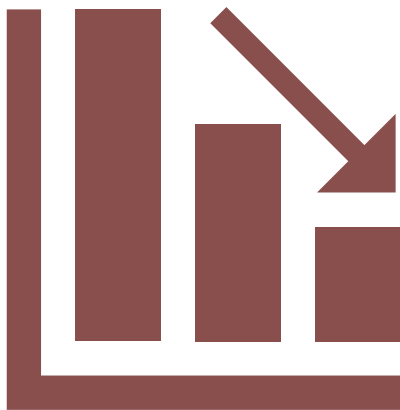
If investigators halt animal work due to the pandemic, preventing congruency with the approved protocol timeline, what is required of the investigator or the IACUC? Is it acceptable to USDA and OLAW to issue a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study?

COVID FAQ VI.6.



Ramp Down Non-Essential Research

Prioritize Daily Animal Care



Options

- Transfer affected protocols *en masse* to holding protocols
- Once fully operational, protocols may require modifications

Can OLAW and USDA discuss what options are available for institutions that are “shut down” and their animals must be relocated because their facility is being taken over for other functions related to COVID-19?

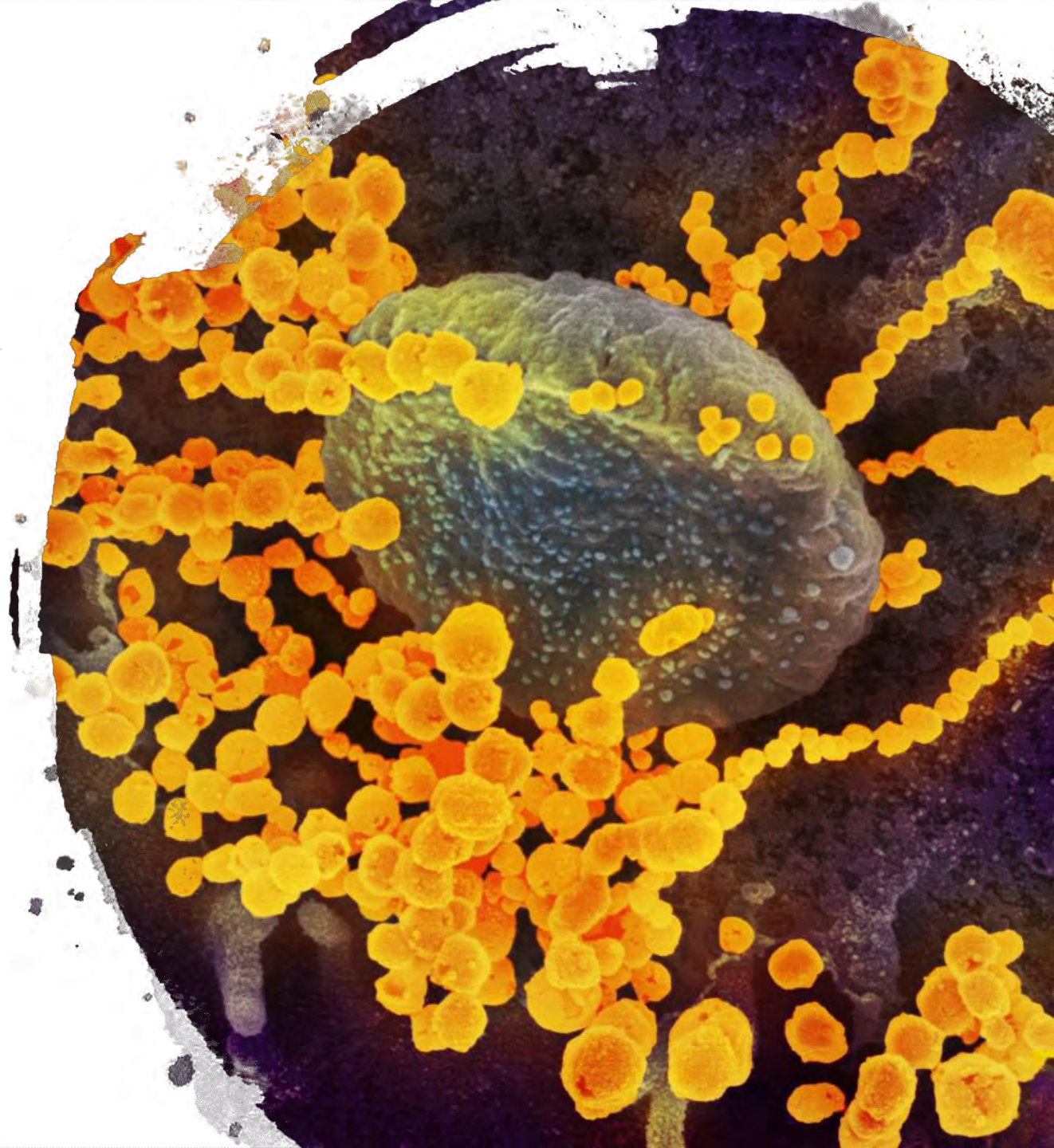
COVID FAQ VI.7.

Options:

- Partner with a neighboring institution to place animals there
- Move animals to another suitable building (not personnel residences)
- Cryopreservation—including through commercial institutions

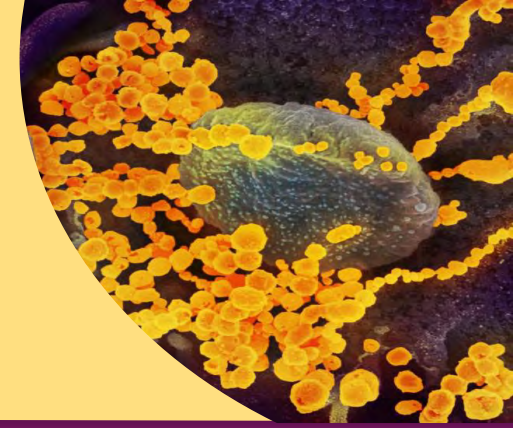
Euthanasia is a ***last resort***. Relevant conditions should be described in institutional disaster plan. The decision to euthanize needs to involve the institution’s leadership and veterinarian.

Frequently Asked Questions: IACUC Functions



What are these waivers we're hearing so much about?

They are waivers to elements of the PHS Policy.



3 Documents Govern Animal Care and Use Programs

- PHS Policy
- Animal Welfare Assurance with OLAW
- *Guide*

V. Implementation by the PHS

A. *Responsibilities of the Office of Laboratory Animal Welfare*

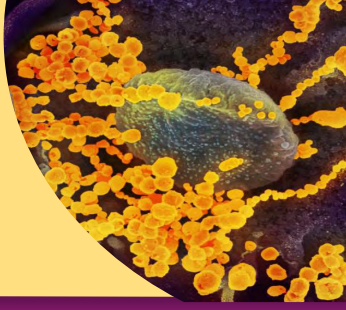
OLAW is responsible for the general administration and coordination of this Policy and will:

5. have the authority to review and approve or disapprove waivers to this Policy (see V.D. of the Policy); and

D. *Waiver*

Institutions may request a waiver of a provision or provisions of this Policy by submitting a request to OLAW. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OLAW.

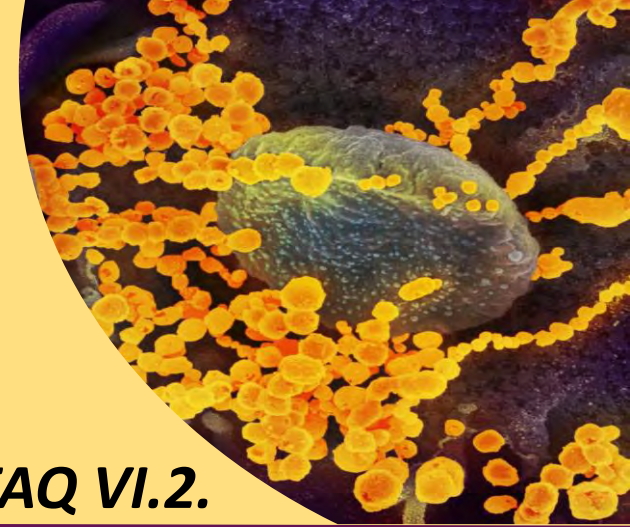
Functions of the IACUC



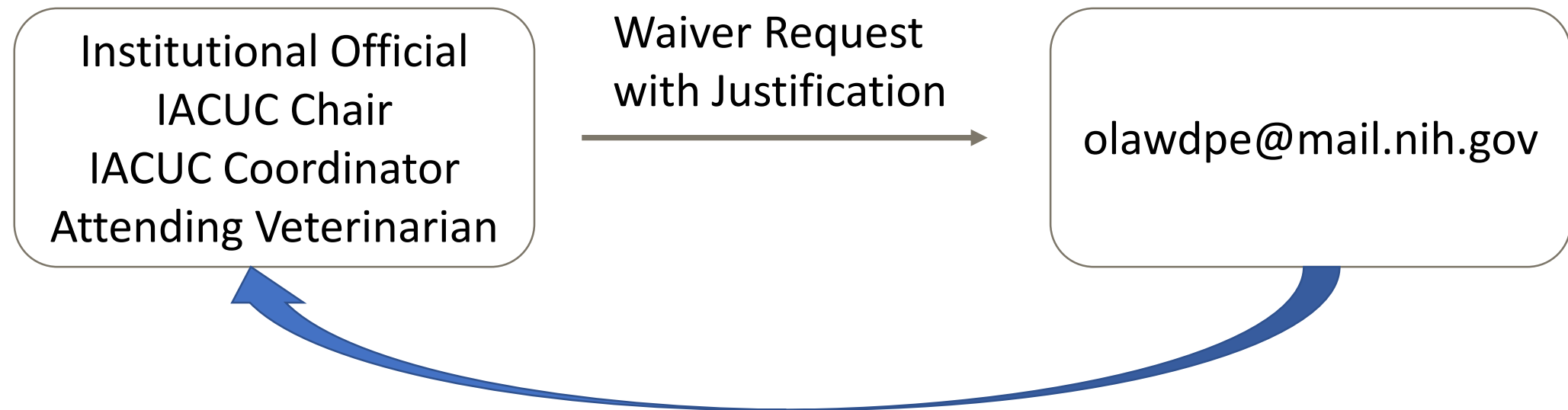
- Semiannual program review
- Semiannual facility inspections
- IACUC reports
- Protocol review
- Reporting requirements (including noncompliance and protocol suspensions)

What option is available if institutions cannot adhere to provisions of the PHS Policy due to the impact of COVID-19?

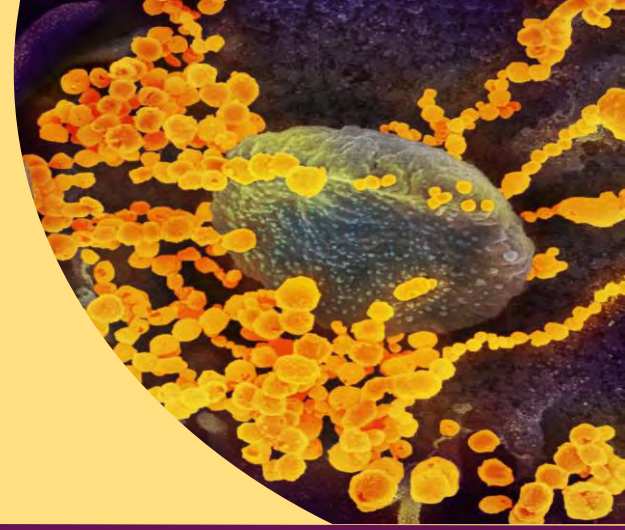
COVID FAQ VI.2.



Waivers

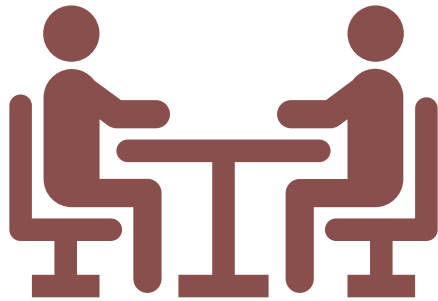


What option is available if institutions cannot adhere to provisions of their Assurance due to the impact of COVID-19?



Vague PHS Policy

Institutional Flexibility

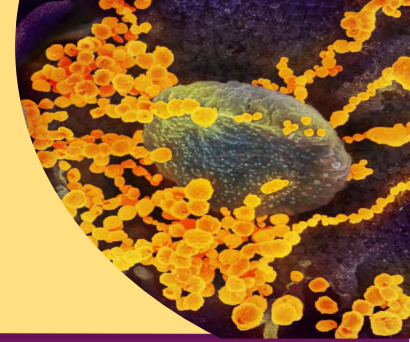


Changes due to COVID-19

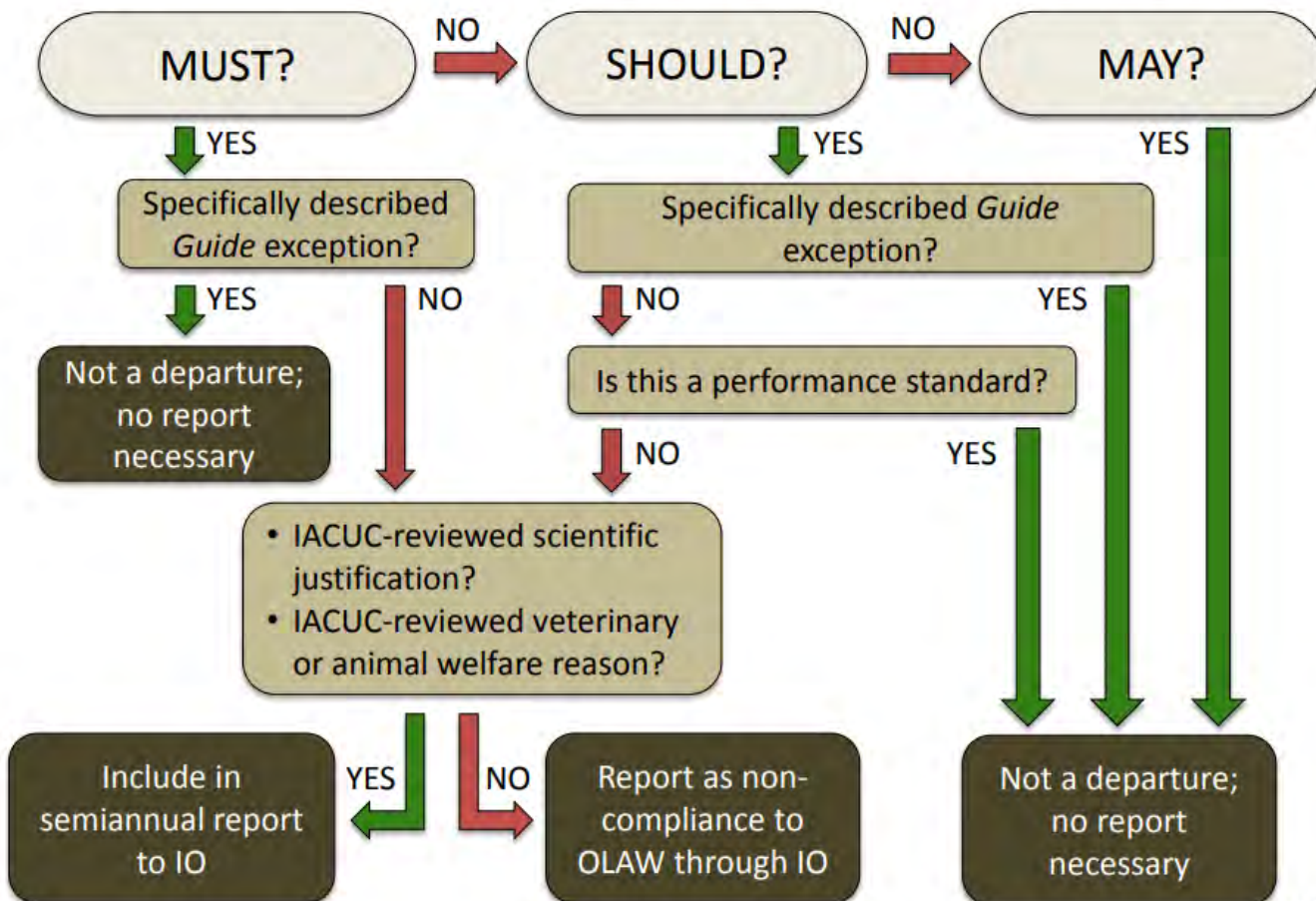
- *Temporary*: OK, as long as they meet PHS Policy requirements. No need to notify OLAW.
- *Permanent*: Update in your annual report and Assurance renewal, as necessary.

Example: Program review usually occurs at an extended IACUC meeting. Due to COVID-19, it will take place with a subcommittee and be conducted virtually.

What option is available if institutions cannot adhere to provisions of the *Guide* due to the impact of COVID-19?



Departure from *Guide*: Report Requirements



11/4/11

Example: The IACUC is asked to approve extended caging and equipment sanitizing schedules outside the *Guide* and the facility's normal performance standards.

Guide: "...enclosures and accessories **should** be sanitized at least every 2 weeks (p. 70).

Result: Include in the semiannual report to IO.

Are there flexibilities available to IACUCs regarding the conduct of IACUC meetings and semiannual inspections?

COVID FAQ VI.8.

YES!

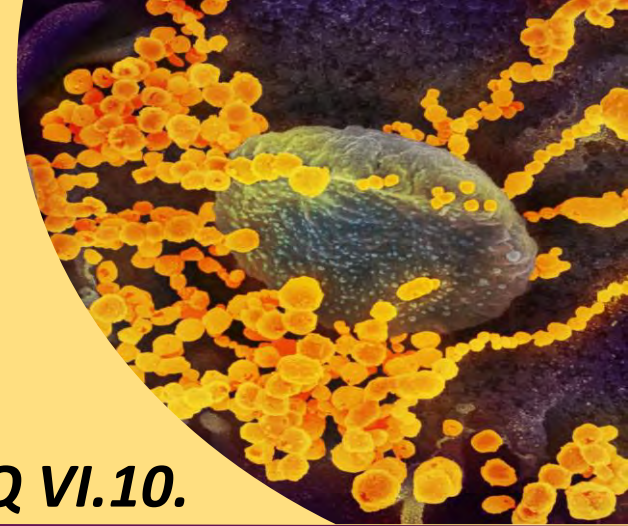
See [NOT-OD-20-088](#): Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCS) Due to COVID-19

Implementation:

- All IACUC members apprised prior to implementation
- Permanent changes recorded in 2020 annual report to OLAW
- Assurance is updated at renewal, as necessary

Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? Does USDA concur?

COVID FAQ VI.10.



Conduct of Semiannual Facility Inspections: No waiver needed

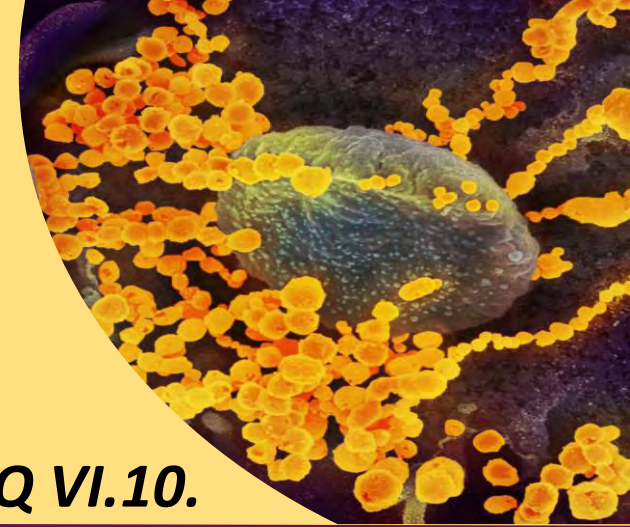
- Timing of facility inspection = Date of previous inspection + 6 months + 30 days (no drift year-to-year)
- Use of qualified ad hoc consultants
- Use of AAALAC site visit
- Non-USDA regulated species, just 1 person needs to inspect

Additional OLAW and USDA-approved flexibilities: No waiver needed

- ~~Use of ad hoc consultants to conduct virtual tours~~

Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business?

COVID FAQ VI.10.



Conduct of Semiannual Facility Inspections: No waiver needed

Timing of facility inspection =
Date of previous inspection
+ 6 months + 30 days
(no drift year-to-year)

Will you be able to safely conduct your semiannual facility inspections within:
Last inspection date + 6 months + 30 days ?

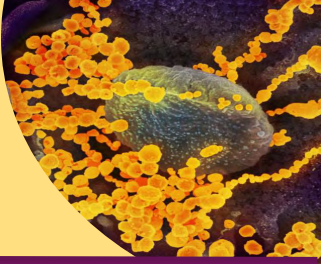
Yes

No

No waiver needed

Request a waiver

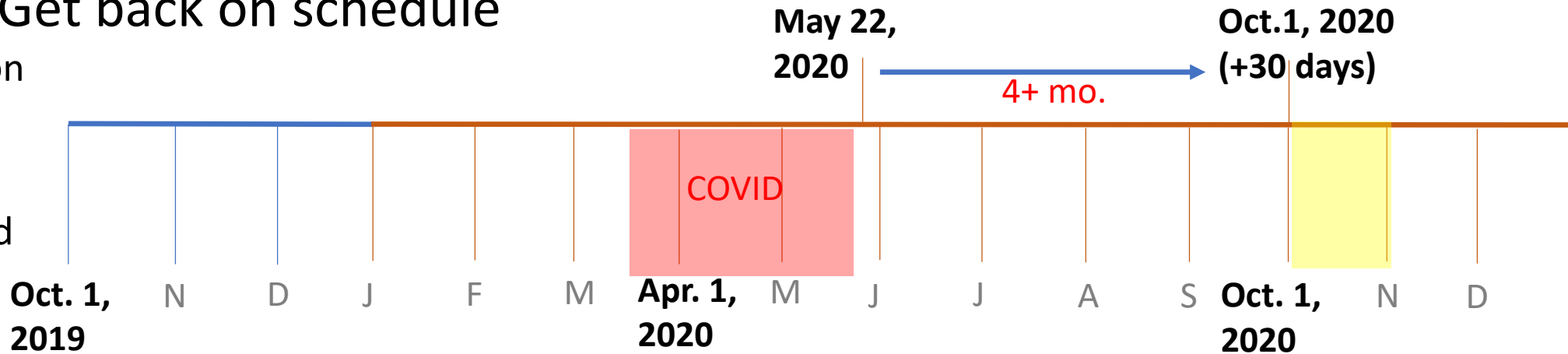
What happens if you do request (and are approved for) a waiver to semiannual facility inspections?



Option 1: Get back on schedule

New Inspection date

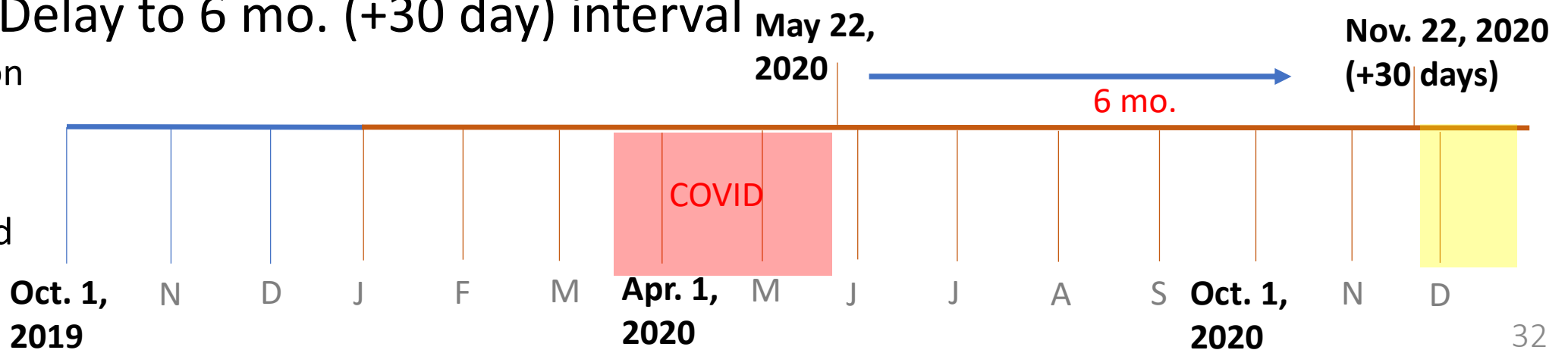
Reg. scheduled Inspection date



Option 2: Delay to 6 mo. (+30 day) interval

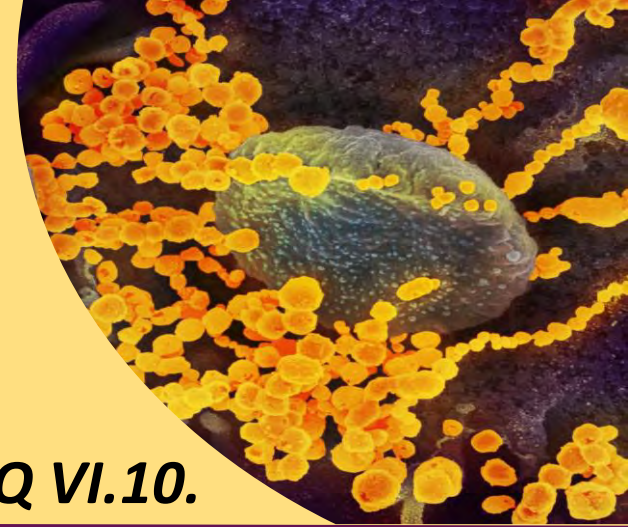
New Inspection date

Reg. scheduled Inspection date



Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business? Does USDA concur?

COVID FAQ VI.10.



Conduct of IACUC Meetings: No waiver needed

IACUCs may:

- Institute alternatives to face-to-face meetings such as teleconference or video conferencing (see NOT-OD-06-052)
- Reduced IACUC meetings to as few as one every six months
- Expand their use of designated member review in lieu of full committee review.

How may the IACUC extend a protocol that is due to expire and still meet the PHS Policy requirements?

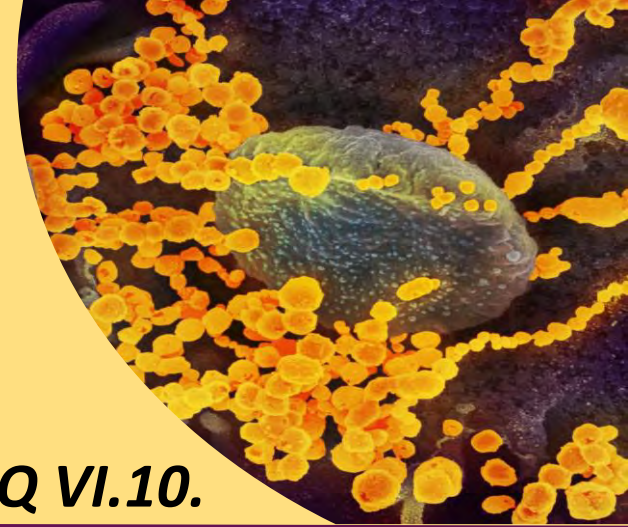
PHS Policy IV.C.2.



- Shorten response time for calling for FCR (e.g., 2 days)
- Develop policy for standard extension period (e.g., 6 months)
- Distribute list of protocols due to expire to all IACUC members
- If FCR is called for, it must occur
 - Otherwise, Chair assigns protocols to a qualified, designated member
- Once approved, protocols are extended based on the IACUC policy
- Only current procedures may be extended—otherwise new amendment is needed

Do institutions need a waiver to implement the flexibilities in OLAW's NOT-OD-20-088 regarding the conduct of semiannual facility inspections and IACUC business?

COVID FAQ VI.10.



Will you be able to safely conduct your semiannual facility inspections within:
Last inspection date + 6 months + 30 days ?

Yes

No

No waiver needed

Request a waiver

No waiver needed

Semiannual Inspections

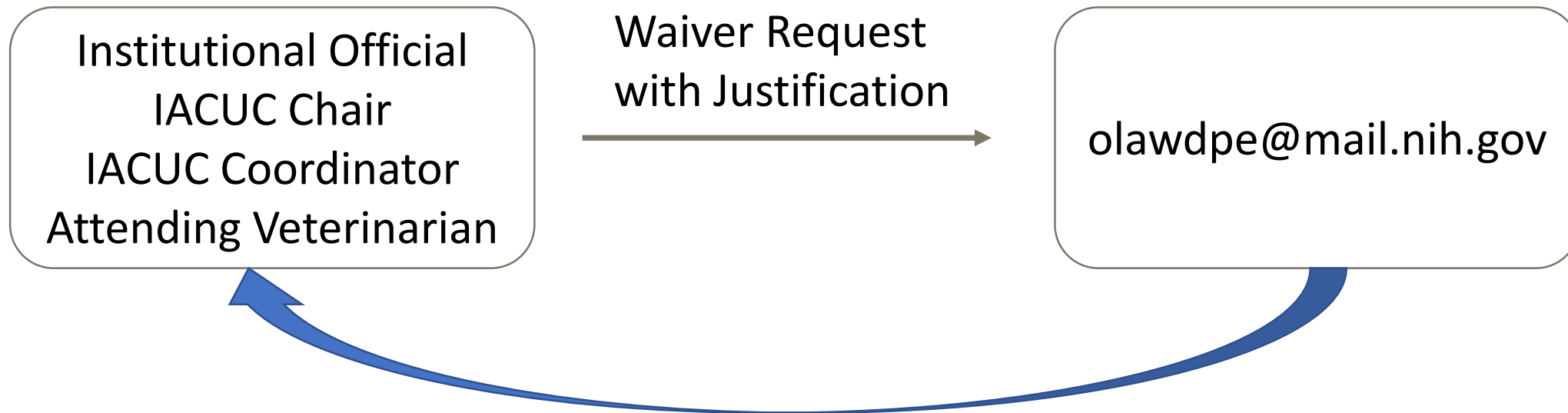
- Ad hoc consultants
- 1 IACUC Member

IACUC Meetings

- Virtual meetings
- Meeting 1x per 6 months
- DMR vs. FCR

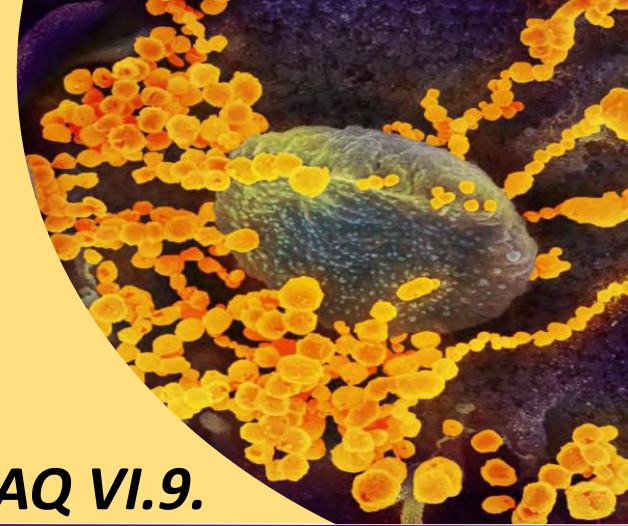
How can institutions request waivers if the IACUC cannot safely complete the semiannual facility inspections 30 days beyond the six-month interval from the last facility inspection?

COVID FAQ VI.11.

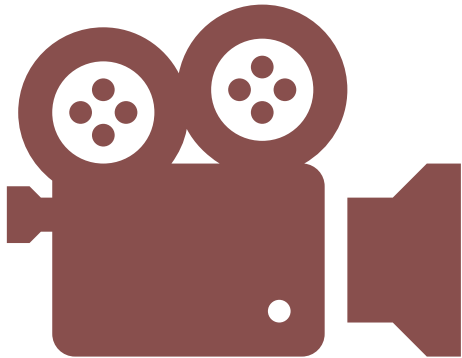


For USDA and OLAW, can one person broadcast virtual tours to other IACUC members as part of the semiannual facility inspections?

COVID FAQ VI.9.



~~YES!~~

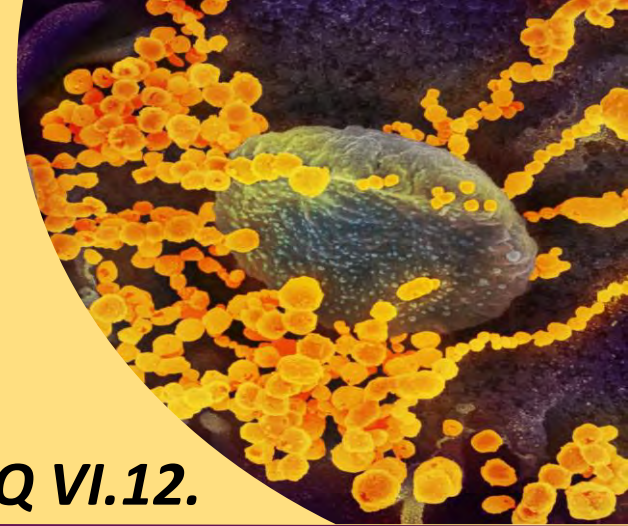


Flexibilities

- PHS Policy allows flexibility in how semiannual facility inspections are conducted
- ~~Ad hoc consultants~~
- ~~Real-time interaction~~

Will OLAW approve waivers for the semiannual program review?

COVID FAQ VI.12.



Important to Review Disaster Plans Now!



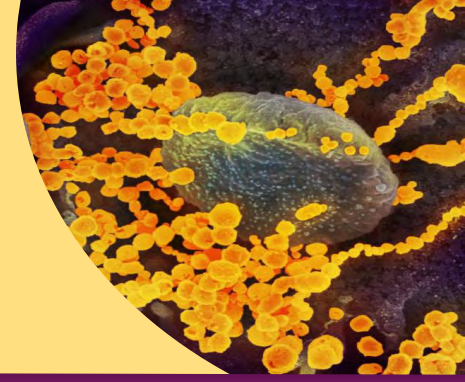
At this point, No. Explore flexibilities:

- 6 months + 30 days
- Ad hoc consultants
- Virtual meetings
- Electronic signatures
- Divide and conquer

Report must be submitted to the IO.

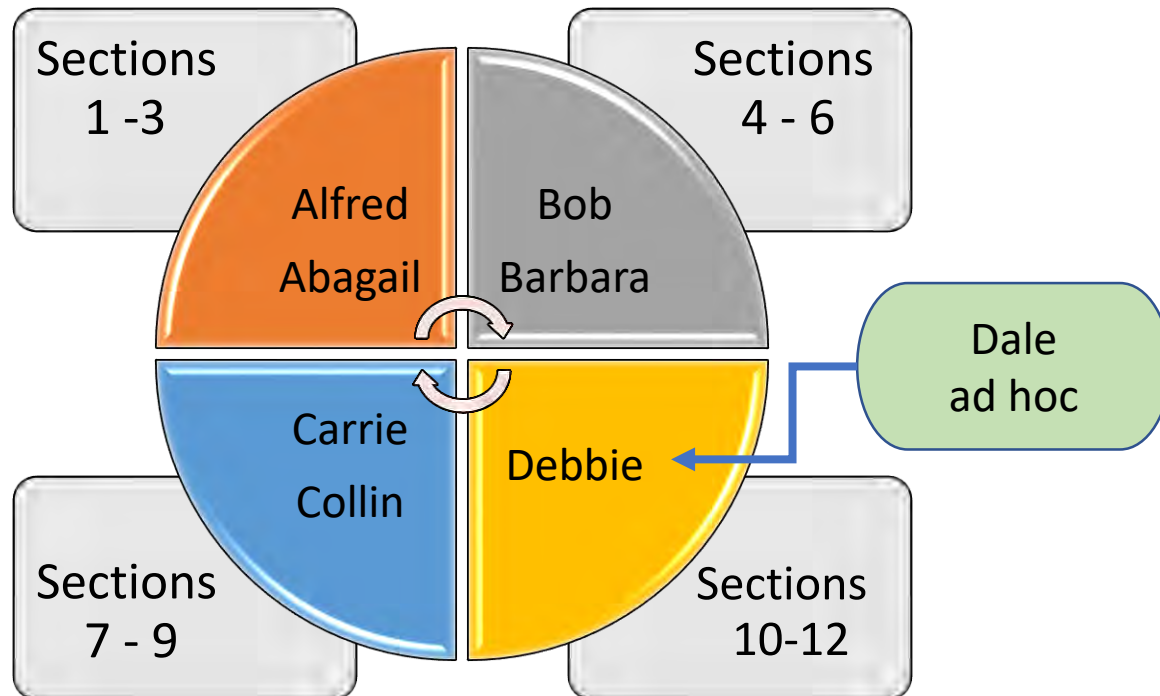
Ex: Semiannual Program Review under COVID-19

OLAW Semiannual Program Review Checklists



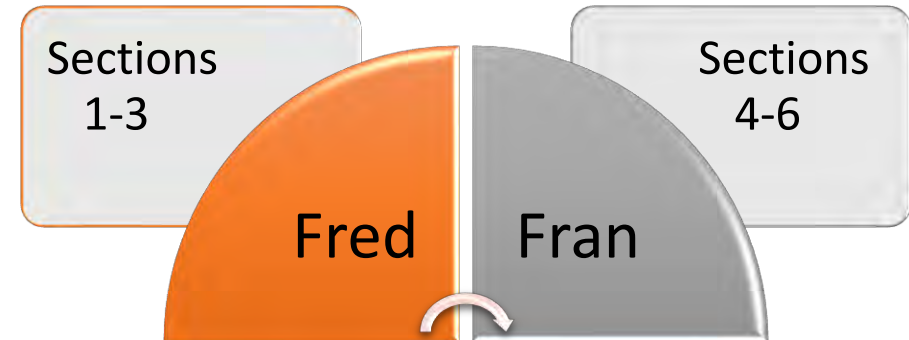
Institutional Policies and Responsibilities

(12 sections—OLAW checklist)



Veterinary Care

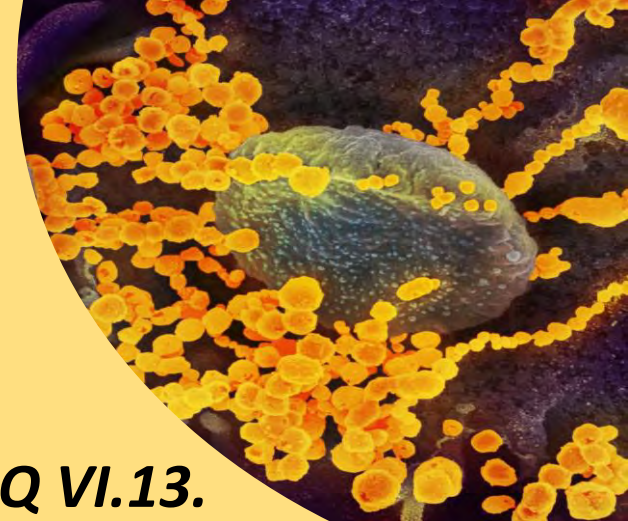
(6 sections—OLAW checklist)



- Ad hoc consultants
- Virtual meetings
- Electronic signatures
- Report to IO

Will OLAW and USDA waive quorum requirements in case the IACUC has to be convened to make decisions on short notice?

COVID FAQ VI.13.



No. PHS Policy mandates a quorum under two conditions:

- Suspension of a protocol
- Full committee review of protocols or significant changes



Flexibilities

- 1 meeting/6 months
- Virtual meetings
- Designated member review
- Veterinary verification and consultation

Will there be any flexibility for the three-year complete review?

COVID FAQ VI.14.

NO

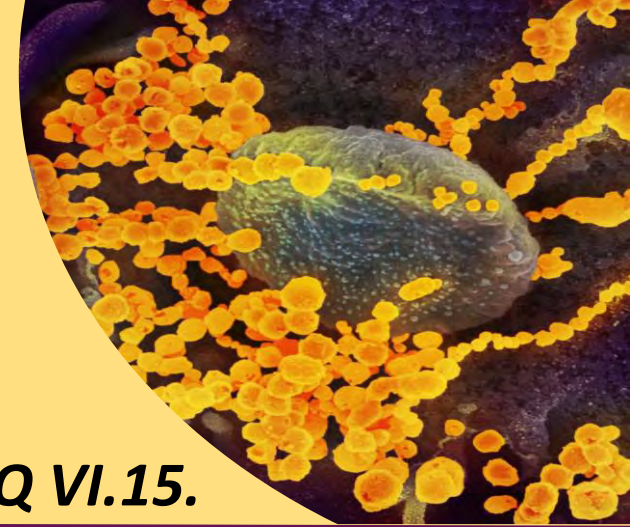


Flexibilities

- 1 meeting/6 months
- Virtual meetings
- Designated member review

USDA and OLAW, how can we continue to perform post approval monitoring activities when access to animals or animal housing areas are minimized or restricted due to COVID-19?

COVID FAQ VI.15.



PHS Policy requires IACUC oversight of animal activities, but is [intentionally] vague



Minimum Requirement

- Daily animal observations by trained personnel

Changes to your program?

- *Temporary*: Prioritize health and well-being of personnel and animals
- *Permanent*: Update in next annual report to OLAW

Do institutions need to notify OLAW or request a waiver from OLAW if implementing the flexibilities described in Guide Notice NOT-OD-20-088 that are not currently described in their Animal Welfare Assurance?

COVID FAQ VI.16.

NO



Just:

- Keep IACUC members apprised before implementation
- Record permanent changes in 2020 annual report to OLAW
- Update Assurance at renewal, if necessary

Do we need to report institutional closures to OLAW or USDA?

COVID FAQ VI.17.

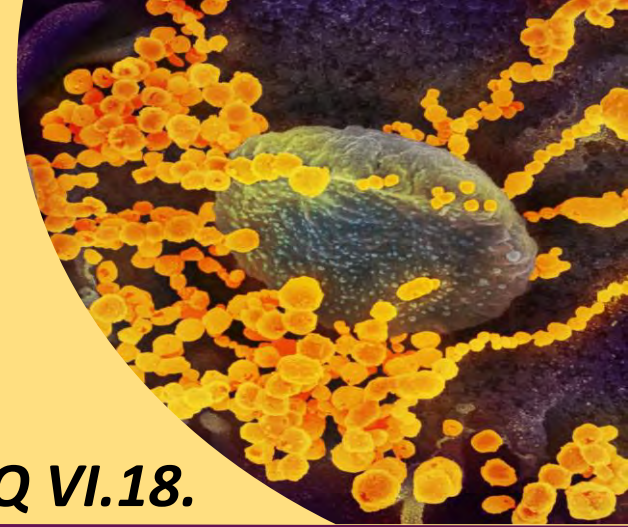
NO



Unless conditions develop that jeopardize the health or well-being of animals, which must be promptly reported to OLAW.

Can Assured institutions donate Personal Protective Equipment (PPE) and supplies acquired with NIH or USDA grant funds to local hospitals and health care facilities in support of COVID-19 efforts?

COVID FAQ VI.18.



YES!



Process

- Contact awarding IC to request administrative supplements to repurchase supplies.

See [NOT-OD-20-086](#) (Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19) for guidance on rebudgeting authority.

Summary:

46

	USDA	OLAW
Institutional disaster plan required?	No	Yes (as per the <i>Guide</i>)
Semiannual <u>inspection</u> delay allowed beyond 6 months + 30 days?	Yes <ul style="list-style-type: none">• No waiver is required for delay• Document delay• Conduct immediately once able to safely do so (do not wait for next scheduled semiannual inspection)	Yes <ul style="list-style-type: none">• Approved waiver from OLAW required for delay• No waiver required if using existing flexibilities (NOT-OD-20-088)• Conduct inspection when safe• Conduct subsequent inspection no later than 6 months + 30 days• Keep IACUC members apprised of flexibilities prior to implementation• Include permanent program changes in 2020 annual report to OLAW and Assurance at renewal

Summary, continued 1:

47

	USDA	OLAW
Semiannual program <u>review</u> delay allowed beyond 6 months + 30 days?	Yes <ul style="list-style-type: none">• No waiver is required for delay• Document delay	No <ul style="list-style-type: none">• No waiver is required if employing existing flexibilities (NOT-OD-20-088):<ul style="list-style-type: none">➤ dividing program review among members➤ use of ad hoc consultants➤ virtual meetings / telecommunications (see NOT-OD-06-052)➤ e-signatures• Keep IACUC members apprised of flexibilities prior to implementation• Include permanent program changes in 2020 annual report to OLAW and Assurance at renewal

Summary, continued 2:

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	USDA	OLAW
Is delay of 3-year complete review permitted?	Not applicable	No <ul style="list-style-type: none">• Consider existing flexibilities (NOT-OD-20-088):<ul style="list-style-type: none">➤ Expanded DMR use➤ Virtual meetings / telecommunications (NOT-OD-06-052)
May IACUC meeting and the quorum requirements for FCR and protocol suspensions be waived?	No <ul style="list-style-type: none">• Convened meetings are required to:<ul style="list-style-type: none">➤ Suspend protocols➤ Conduct Full Committee Review• Use existing flexibilities:<ul style="list-style-type: none">➤ Expanded DMR use➤ Permissible telecommunications➤ IACUC alternate members	No <ul style="list-style-type: none">• Convened meetings required no more than once every six months (<i>Guide</i>) to:<ul style="list-style-type: none">➤ Suspend protocols➤ Conduct Full Committee Review• Use existing flexibilities (NOT-OD-20-088):<ul style="list-style-type: none">➤ Expanded DMR use➤ Virtual meetings / telecommunications➤ IACUC alternate members

Summary, continued 3:

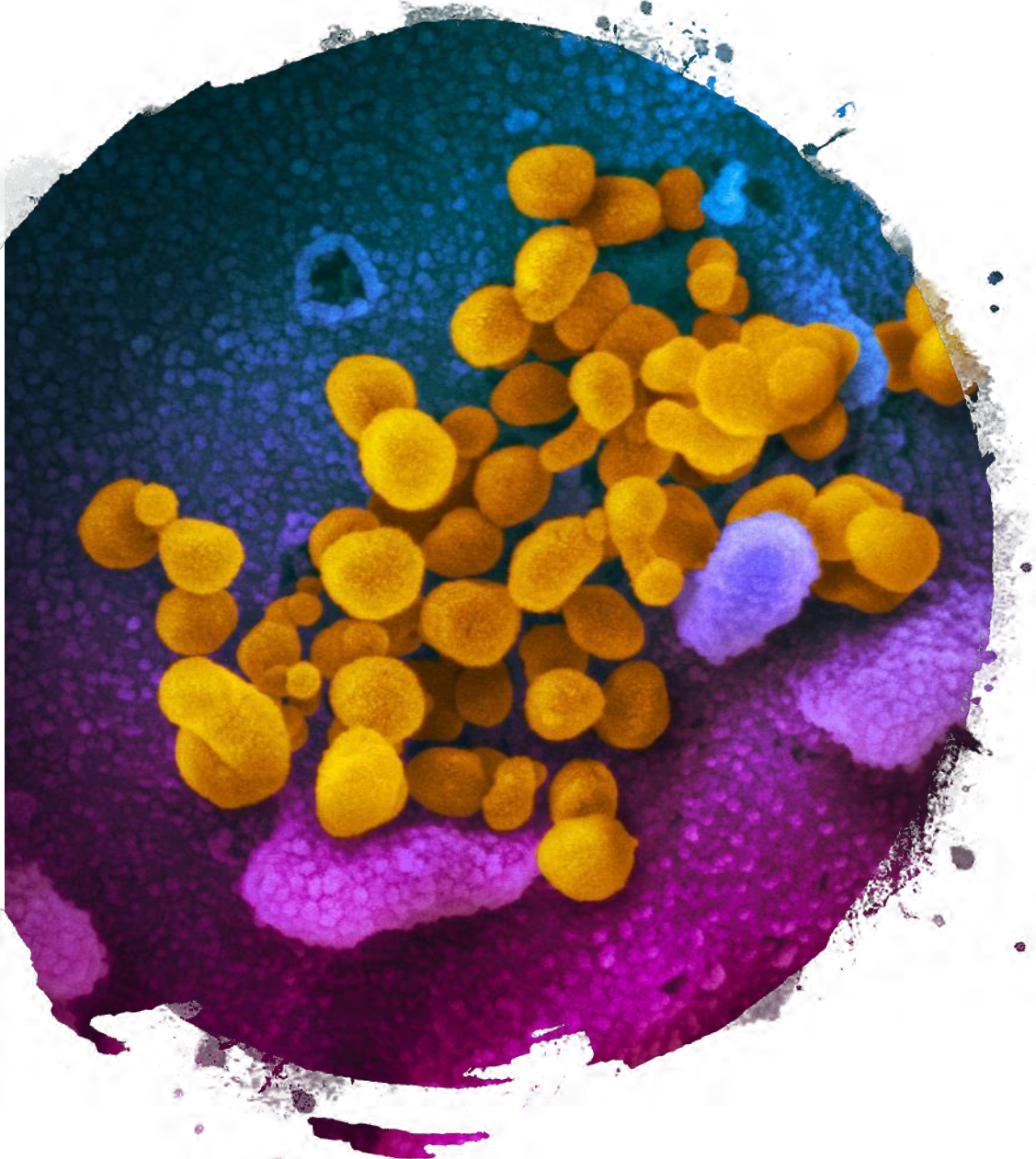
49

	USDA	OLAW
Euthanasia of animals because of pandemic?	Last resort <ul style="list-style-type: none">• Decision to involve AV and institutional leadership.	Last resort <ul style="list-style-type: none">• Decision to involve AV and institutional leadership, and be as specified in disaster plan• Alternatives to consider:<ul style="list-style-type: none">➤ Transfer animals to a holding protocol➤ Postpone unnecessary procedures➤ Relocate animals to another facility➤ Cryopreserve certain species
Blanket halting of protocols permitted?	Yes <ul style="list-style-type: none">• May halt research activities (protocols)	Yes <ul style="list-style-type: none">• May transfer <i>en masse</i> to holding protocols• IACUC must be informed of action• Document action as a program change• IACUC reevaluate protocols for modifications before resuming

Summary, continued 4:

	USDA	OLAW
Are institutional closures reportable?	No <ul style="list-style-type: none">• Need not report closures• Continue to adhere to regulatory reporting requirements	No <ul style="list-style-type: none">• Need not report closures• Continue to adhere to reporting requirements (PHS Policy IV.F.)• Include permanent program changes in 2020 annual report to OLAW and Assurance at renewal

Be Safe and Be Well



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National Institutes of Health
Office of Laboratory Animal Welfare

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