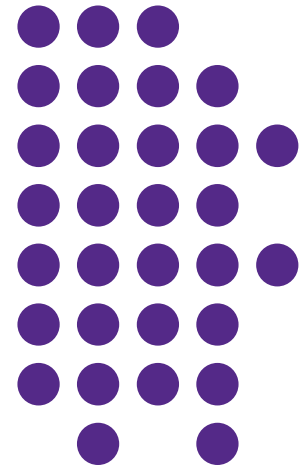

Pandemic Contingency Planning and Its Impact on Animal Care

Patricia Brown, NIH, OLAW

Robert Gibbens, USDA, APHIS, Animal Care



Resources – Handouts



- OLAW Guide Notice NOT-OD-20-088 on Flexibilities for IACUCs
- OLAW Guide Notice NOT-OD-06-052 on Use of Telecommunications
- OLAW FAQ G9 on Pandemic Preparation
- NIH Intramural Program 2008 Pandemic Flu Plan
- NIH Division of Veterinary Resources Continuity of Services Plans
- Johns Hopkins University Animal Research Coronavirus Phased Contingency Plan

Coronavirus Disease 2019 (COVID-19)



- A respiratory illness that can spread from person to person
- A novel coronavirus first identified during an investigation into an outbreak in Wuhan, China
- A global infectious disease with ongoing spread



Helpful Links

<https://medlineplus.gov/coronavirusinfections.html>

 U.S. National Library of Medicine



GO

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[Health Topics](#)

[Drugs & Supplements](#)

[Videos & Tools](#)

[Español](#)

[Home](#) → [Coronavirus Disease 2019 \(COVID-19\)](#)

Coronavirus Disease 2019 (COVID-19)



Stay up to date with the latest information from the **Centers for Disease Control and Prevention** and the **National Institutes of Health**.



Helpful Links

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

[All A-Z Topics](#)

Search

Coronavirus ▾



The President's Coronavirus Guidelines for America -- 15 Days to Slow the Spread of Coronavirus (COVID-19) [More at Whitehouse.gov.](#)

Coronavirus (COVID-19)

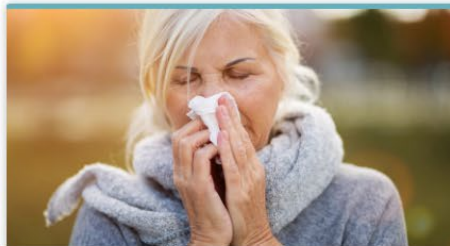
How to Protect Yourself ➤

If You Think You Are Sick ➤

What You Need to Know



Symptoms



Older Adults & Medical Conditions



Prepare Your Family



Helpful Links

<https://www.nih.gov/health-information/coronavirus>



Search NIH

[NIH Employee Intranet](#) | [Staff Directory](#) | [En Español](#)

Health Information

Grants & Funding

News & Events

Research & Training

Institutes at NIH

About NIH

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: <https://www.coronavirus.gov>

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>

Coronavirus (COVID-19)



Resources from NIH

- [Structural Biology Points Way to Coronavirus Vaccine](#) (NIH Director's Blog)
- [Information for NIH Applicants and Recipients](#) (Grants & Funding)
- [Coronaviruses](#) (National Institute of Allergy and Infectious Diseases)
- [Coronavirus resources](#) (National Library of Medicine)
- [Coronavirus news and resources for global health researchers](#) (Fogarty International Center)
- [In the News: Coronavirus and "Alternative" Treatments](#) (National Center for Complementary and Integrative Health)
- [NIH Guidance on Travel and Meetings](#)

News Releases from NIH

- [New coronavirus stable for hours on surfaces](#) (National Institute of Allergy and Infectious Diseases)
- [NIH clinical trial of investigational vaccine for COVID-19 begins](#) (National Institute of Allergy and Infectious Diseases)
- [NIH clinical trial of remdesivir to treat COVID-19 begins](#) (National Institute of Allergy and Infectious Diseases)



Helpful Links

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019>



Home / [Emergencies](#) / [Diseases](#) / [Coronavirus disease 2019](#)

Coronavirus disease (COVID-19) outbreak

[Protect yourself](#)

[Country & technical guidance](#)

COVID-19 Response Fund

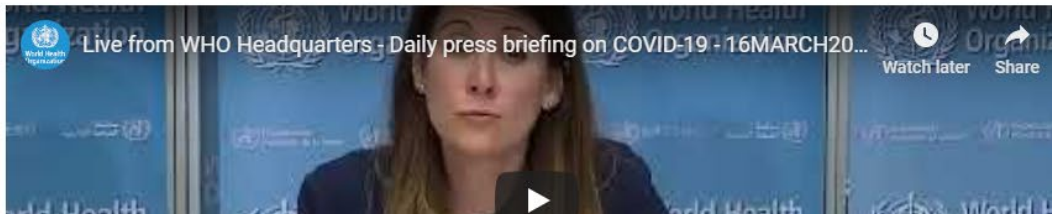
[Donate](#)

[Your questions answered](#)

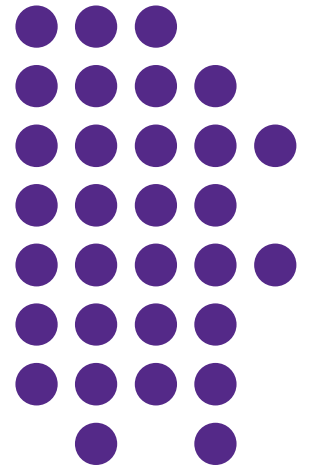
[Travel advice](#)

[Situation reports](#)

Latest updates



Poll Questions



OLAW Guidance on Flexibilities for IACUCs – NOT-OD-20-088



- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html>
- Conduct of semiannual facility inspections
- Waivers to IACUC functions
- Conduct of IACUC meetings

Conduct of Semiannual Inspections



- Timing of inspections may extend 30 days beyond the six-month interval from the last review as long as no forward drift from year to year
- ~~Any qualified individual can serve as an ad hoc consultant to conduct inspections~~
- For areas with non-USDA regulated species, the IACUC may use as few as one qualified individual to conduct the inspections



Waiver of IACUC Functions

- OLAW may waive specific IACUC functions in accordance with PHS Policy Section V.D.
- If unable to inspect all of the animal facilities (including satellite facilities) may request a waiver
- Authorized institutional representatives (IO, IACUC Chair, IACUC Coordinator or Veterinarian) may request a waiver



Waiver of Functions, cont.

If IACUC is unable to:

- conduct program review
- prepare reports to IO
- review concerns involving care and use of animals
- make recommendations to IO
- review animal activities or significant changes to ongoing activities
- suspend an activity



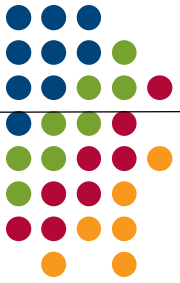
How to Request a Waiver

- Submit request for the IACUC function(s) to be waived
- Include a justification for each of the requested functions
- Request can be in email or attached letter sent from authorized representative
- Send to OLAW at olawdpe@mail.nih.gov

OLAW will review and approve the request in writing and respond by return email

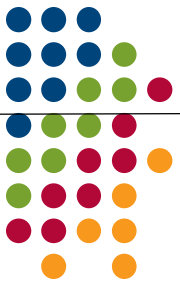


APHIS, Animal Care



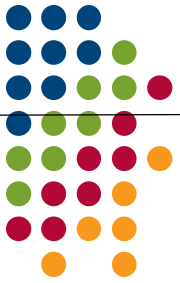
COVID-19

- Facility Status and Inspections
- Regulatory Requirements with Deadlines
- Contacting AC



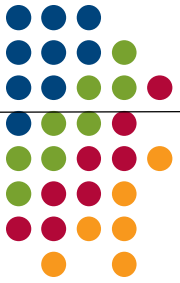
Facility Status and Inspections

- Facility is closed, or has a sick employee, or does not believe it is safe for an inspection to occur due to COVID-19 concerns
- Facility does not believe it is safe for portions of the facility to be inspected due to COVID-19 concerns
- VMO has concerns about safety of inspecting the facility or portions of the facility



Regulatory Requirements with Deadlines

- Semiannuals, annual protocol review, etc.
- VMOs will be giving latitude
 - How much?



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



United States Department of Agriculture



USDA COVID-19 Landing Page

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

An official website of the United States government [Here's how you know](#)



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Coronavirus Disease (COVID-19)

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[Climate Solutions](#)

[Conservation](#)

[Data](#)

[Disaster](#)

[Farming](#)

[Food and Nutrition](#)

[Forestry](#)

[USDA](#) > [TOPICS](#) > [DISASTER](#) > [CORONAVIRUS DISEASE \(COVID-19\)](#)



Latest news from the CDC on Coronavirus Disease 2019 (COVID-19)

[Learn more](#)

Frequently Asked Questions

Food Safety



Access to Food



Guidance on Pandemic Planning



- Frequently Asked Question G9
- How can institutions and their IACUCs best prepare for a pandemic?
- Updated March 2020
- <https://olaw.nih.gov/guidance/faqs#687>



Key Issues

- Advance planning
- Protect the health and wellbeing of animals
- Prepare for limited personnel to care for the animals
- Plan to conduct IACUC official business



Key Issues – Animal Facilities

- Appropriate staffing levels
- Cross-training to cover critical operations
- Adequate inventories of essential supplies
 - Feed
 - Bedding
 - Personal protective equipment
 - Cage wash supplies

Key Issues – IACUCs



Plan for conducting official business:

- The IACUC must continue to be properly constituted
- A quorum is required to conduct official business at a convened meeting
- The IACUC must ensure that protocol approvals are not allowed to expire or if they do expire, that no further animal activities (e.g., data collection) are conducted
- Appointment and training of IACUC members (including nonscientific members and alternates) should be considered as a part of the plan



Key Issues – IACUCs, cont.

Consider options provided in the PHS Policy:

- Social distancing to reduce contact
- Alternatives to face-to-face meetings:
 - Teleconference and videoconference
 - See NIH Guide Notice NOT-OD-06-052
- Number of IACUC meetings reduced to one every six months.
- Expand use of designated member review



Additional Guidance

If severe and long lasting situation develops

- Guidance posted on the OLAW website
- Assist with needs of research community
- Address the needs of funding components
- OLAW may consider additional waivers to PHS Policy

Helpful Links

https://www.aalas.org/iacuc/iacuc_resources/disaster-preparedness



[Membership](#) [Education](#) [Certification](#) [Publications](#) [National Meeting](#) [Public Outreach](#)

Laws, Policies, and Guidelines

[Associations and Councils](#)

[Universities](#)

[Corporations](#)

[International Government](#)

[US Government](#)

Agencies, Institutes, and Associations

[Agencies and Institutes](#)

[Associations, Centers, and Foundations](#)

Training Resources


[Animal Care and Use Staff](#)

[IACUC Members and Staff](#)

[Home](#) : [IACUC](#) : [IACUC Resources](#) : Disaster Preparedness

Institutional Plans

[Drake University](#) (PDF)

[Michigan State University](#), Sample policy on **Conducting IACUC Business in the Event of a Pandemic** 

[Mississippi State University](#), (PDF) Policy and Procedure Statement on Crisis Management Plan for (Biomedical) Animal Care and Use

[Oregon State University](#), (PDF) Animal Facility Disaster Planning Guidelines

[UCLA](#) (PDF)

[University of Georgia \(UGA\)](#) (PDF) Animal Care Program Disaster/Contingency Plan

[University of Michigan](#), Division of Public Safety and Security, Emergency Management

[University of Mississippi](#)

[University of Tennessee Health Science Center](#), (PDF) Disaster Planning for

Helpful Links

<https://disasterinfo.nlm.nih.gov/pandemic-influenza>



Disaster Information
MANAGEMENT RESEARCH CENTER

Improving Access to Disaster Health Information

NIH U.S. National Library of Medicine

Home

Disaster Literature

CBRNE/Hazmat

Disaster Information Specialist

Natural & Man-Made Disasters

Infectious Diseases

Special Topics

Home > Infectious Diseases : Pandemic Influenza

Ebola Outbreak 2018

Ebola 2014-2015 (Archive)

Zika Virus (Archive)

Pandemic Influenza

Emerging Infectious Diseases

Past Pandemics

Virus Variation Resource

Related Resources

Avian Influenza A(H7N9) Virus, 2013 (Archive)

Pandemic Influenza: Preparedness and Response

Overview

Surveillance and Monitoring

Information by Topic Area

Social Media

Apps and Widgets

Multilingual Resources

Resources for the General Public

Overview

- Pandemic Flu

Also available in [Spanish](#).

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Example Pandemic Readiness Planning for Animal Programs



- Personnel planning
- Supply and logistics planning
- Animal husbandry and health planning



Personnel Planning

Prepare for communication failures

- Keep emergency contacts list up to date
- Share the list with key staff
- Quarterly review and update recommended

Personnel Planning



Identify all essential positions in sufficient quantities to maintain animal facility operations:

- Cage wash
- Autoclaves
- Inventory of materials
- Ordering of critical materials
- Animal husbandry
- Veterinary treatment
- Surgical support
- Record keeping



Personnel Planning

Identify all essential positions in sufficient quantities to maintain animal facility operations:

- For each position, identify names of 3 alternates
- Review at least semiannually the responsibilities associated with each position
- Keep necessary functions operating!



Personnel Planning

Develop and conduct cross-training for animal care and administrative staff

- Ensure all critical operations can continue
- Be creative: nontraditional expectations for which people do what jobs
- For example: Who will open and distribute the mail?



Personnel Planning

Consider a continuity of services plan

- NIH intramural program, Division of Veterinary Resources model plans for rodent, ungulate, carnivore and nonhuman primate facilities (see handout)
- Plans link staff reductions in different tiers with the effects on various functions and how to mitigate the effects

Supply and Logistics Planning



Identify on-site stockpile locations for critical items

- Recommend 1-2 month supply with normal usage

Include:

- Animal feed and bedding
- Personal protective equipment
- Disinfectant and cage wash supplies
- Hand sanitizers for personal hygiene



Supply and Logistics Planning

Develop alternative sources for critical supplies

- Consider extended lead times for delivery when planning how much to stock pile
- Stay alert to state and federal authorities and when stockpiling may be indicated



Supply and Logistics Planning

Maintain at least one type of alternative communication capability within the facility

- Two-way radios
- Cell phones
- Text messaging

Animal Husbandry & Health Planning



Establish key foot patterns to follow between clean and dirty areas of the facility

- Fewer staff with multiple functions
- Don't compromise animal health

Animal Husbandry & Health Planning



<https://www.cdc.gov/coronavirus/2019-ncov/communication/videos.html>

Conduct training on prevention techniques – COVID-19 video examples:

- How to protect against novel coronavirus
- How does COVID-19 spread?

Other examples from CDC on YouTube:

- What you need to know about hand washing
- Prepare your home for an emergency

Prevention Training Resources

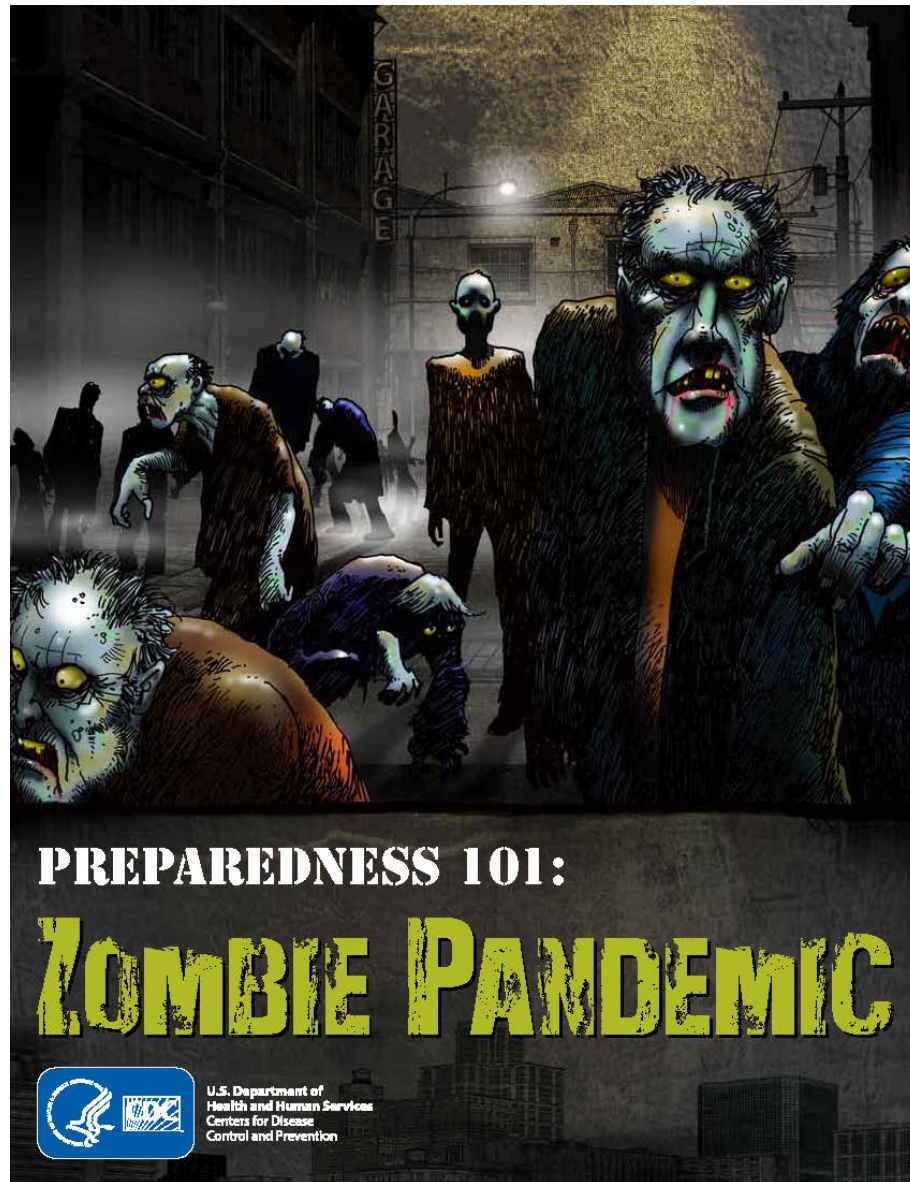


- <https://www.cdc.gov/coronavirus/2019-ncov/communication/videos.html>
- Stop the Spread of Germs poster
- Symptoms of Coronavirus Disease 2019 poster
- Wash Your Hands posters

Prevention Training Resources



Prevention Training Resources



Prevention Training Resources



ALL-HAZARDS EMERGENCY KIT

Assemble the following items to create a kit for your home, office, school, or vehicle:


- ☐ Water—one gallon per person, per day
- ☐ Food—nonperishable, easy-to-prepare items (minimum 3 day supply)
- ☐ Flashlight
- ☐ Battery-powered or hand-crank radio (NOAA Weather Radio, if possible)
- ☐ Extra batteries
- ☐ First aid kit (whistle, antibiotic ointment, bandages, face masks, gloves and reference book)
- ☐ Medications (7 day supply and medicinal dispensers if necessary)
- ☐ Multipurpose supplies (wrench, pliers, plastic sheet, duct tape, scissors, matches)
- ☐ Sanitation/personal hygiene items and bleach
- ☐ Copies of personal documents (medication list and pertinent medical information, proof of address, deed/lease to home, passports, birth certificates, insurance policies)
- ☐ Cell phone with charger
- ☐ Family Disaster Plan (family and emergency contact information)
- ☐ Extra cash
- ☐ Emergency blanket, extra clothes, sleeping bag (1 for each person)
- ☐ Map(s) of the area

Consider the needs of all family members and add supplies to your kit.

Suggested items to help meet additional needs are:

- ☐ Specific medical supplies (hearing aids/extra batteries, glasses, contact lenses, syringes, cane)
- ☐ Baby supplies (bottles, formula, baby food, diapers)
- ☐ Games and activities for children
- ☐ Pet supplies (collar, leash, ID, food, carrier, bowl)
- ☐ Two-way radios
- ☐ Extra set of car keys and house keys

For more information visit: www.cdc.gov/phpr



Animal Husbandry & Health Planning



- Transmission from humans to animals in a research setting has NOT been reported!
- BUT, experimental studies are ongoing in ferrets, pigs, macaques and transgenic mice.

Animal Husbandry & Health Planning



- Animal care staff who develop symptoms should not report to work.
- Follow state and federal requirements for testing, quarantine and isolation

Animal Husbandry & Health Planning



Develop alternative procedures to allow fewer staff to manage the husbandry

- Extended cage changing schedule
- Extended sanitizing schedule
- If outside the *Guide* – IACUC approval
- Add more bedding to rodent cages
- Less frequent replacement of feed in rodent hoppers

Animal Husbandry & Health Planning



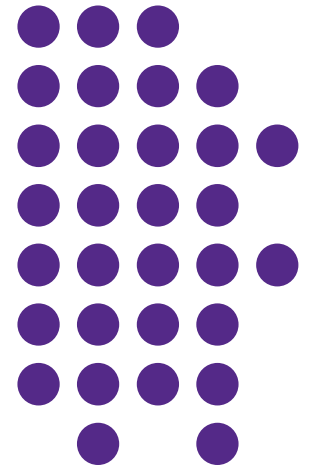
Develop plans for extended use of protective clothing or alternatives.

- Don't discard masks, gloves, coveralls as frequently
- Use of durable equipment instead of disposable

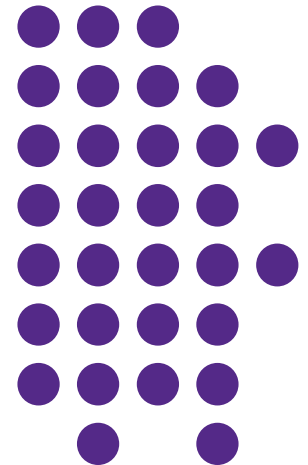
Consider sanitization and reuse

- <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>

**Submit to the chat box in the
GoToMeeting control panel**



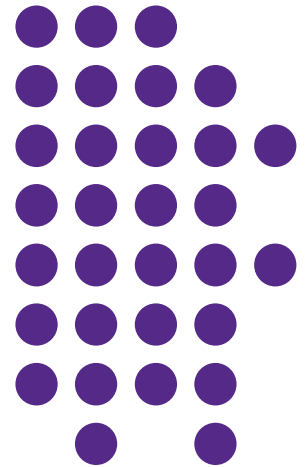
Semiannual Inspections



Semiannual Inspections

Question 1

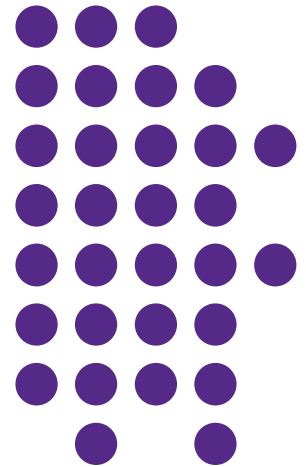
Should Assured institutions add language in their Assurance regarding suspension of semiannual inspections in emergencies and performing them when the emergency ends?



Semiannual Inspections

Question 2

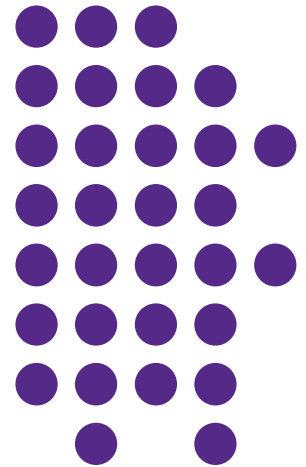
If this is acceptable, does this change need to be approved by OLAW first or can OLAW be notified during the annual report?



Semiannual Inspections

Question 3

What is the best way to document delayed/cancelled semiannual inspections to ensure that the timeline is noted for possible inspections?

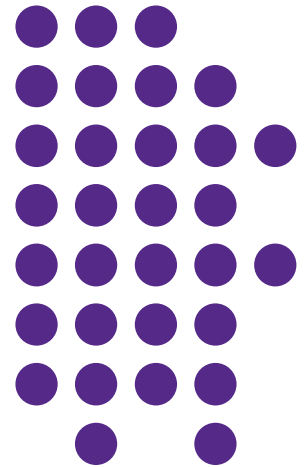


Semiannual Inspections

Question 4

For minor deficiencies identified on the semiannual inspection and review, how should we determine a date for corrective action plan in place given the pandemic?

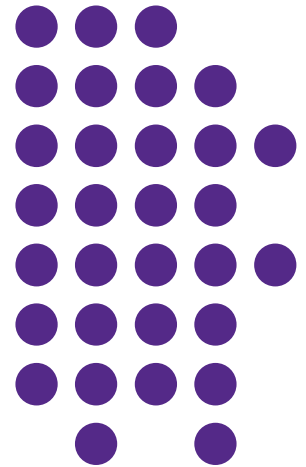
Would a statement “*x period of time after operations are resumed*” meet OLAW and USDA expectations?



Semiannual Inspections

Question 5

~~May we use one person to give virtual tours to other IACUC members to conduct semiannual inspections?~~



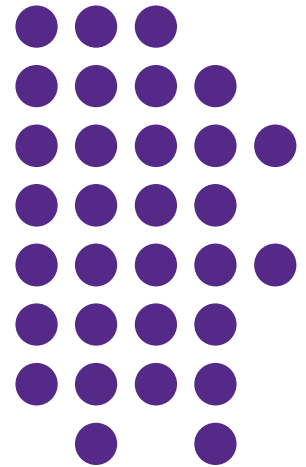
Semiannual Inspections

Question 6

~~*“The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.”*~~

~~Is using ad hoc consultants acceptable for facility inspections and program reviews?~~

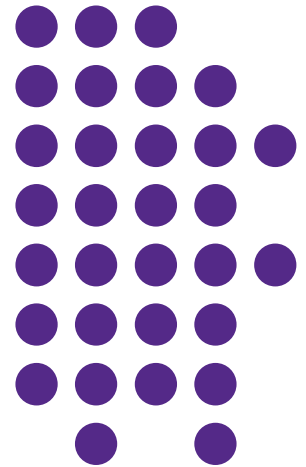
~~What are best practices when using ad hoc consultants?~~



Semiannual Inspections

Question 7

At many institutions, the essential personnel available to conduct the inspections may also have supervisory roles over parts of the facility. Is this considered a conflict of interest?

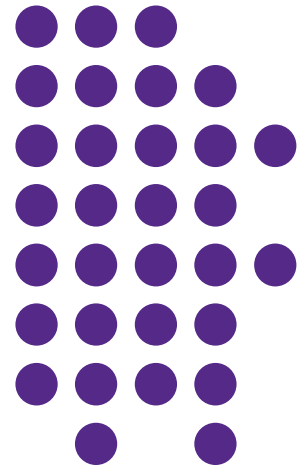


Semiannual Inspections

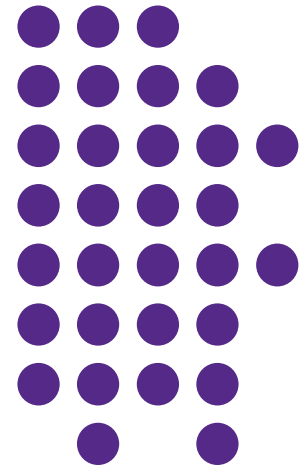
Question 8

How can institutions use a recently completed AAALAC site visit as a substitution for institutional-led site inspections during the pandemic?

Could you provide guidance as to timelines under which this would be suitable?



Animal Study Protocols

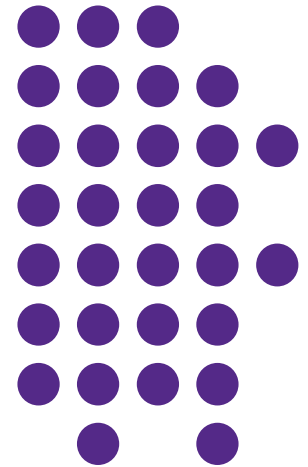


Animal Study Protocols

Question 1

If investigators “pause” animal work due to the pandemic, preventing congruency with the approved protocol timeline, what is required of the investigator/IACUC?

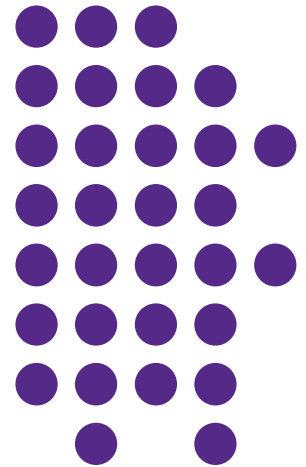
Is it acceptable to issue a blanket a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study?



Animal Study Protocols

Question 2

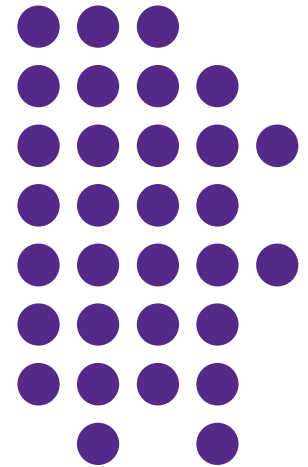
What is expected of the institution for investigators finishing animal experiments up sooner than expected because of a shut down or other issues?



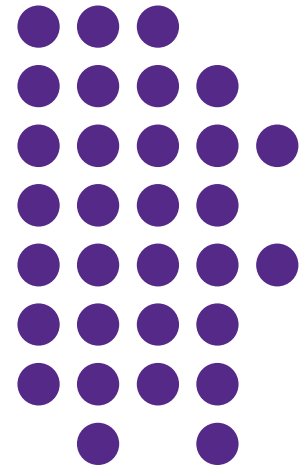
Animal Study Protocols

Question 3

When veterinary resources are focused on animal care and well-being during the pandemic, and they are unable to participate in protocol review and consultation, how can research institutions comply with the PHS Policy and the Animal Welfare Act Regulations?



IACUC Business

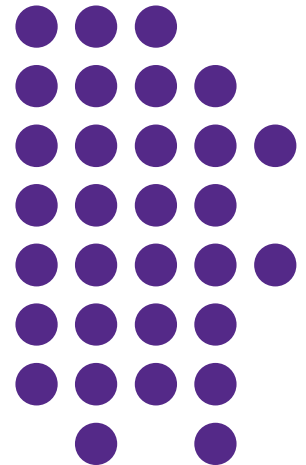


IACUC Business

Question 1

During pandemics, will quorum requirements be relaxed in case the IACUC has to be convened to make decisions at short notice?

What about under the direction of the IO only?



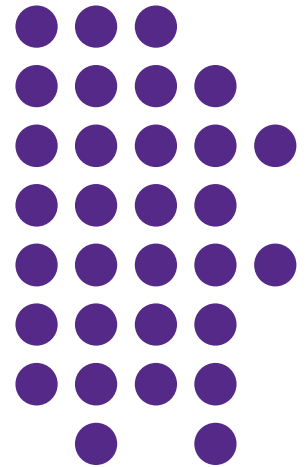
IACUC Business

Question 2

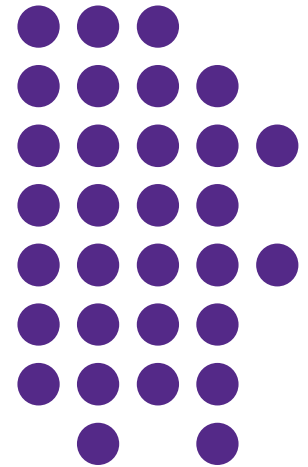
Please explain what is meant by “access to technology” for IACUC business conducted using telecommunication

Details about using electronic means to conduct IACUC meetings can be found in Section 7.1.8 of the Animal Welfare Inspection Guide.

https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf



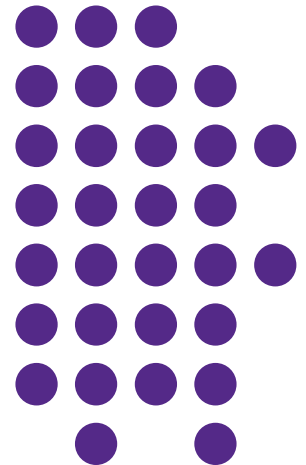
USDA



USDA

Question 1

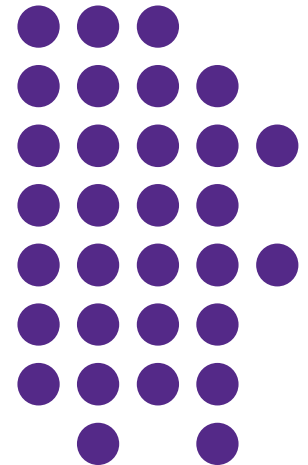
Is the USDA offering any flexibilities in completing semiannual inspections and review due to COVID-19?



USDA

Question 2

Will VMOs still be doing routine inspections during the COVID-19 pandemic?

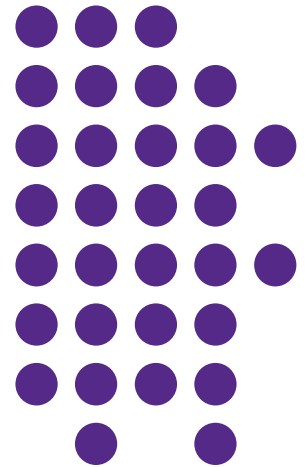


USDA

Question 3

For USDA inspections, we may have limited resources to provide documentation and tours to a USDA inspector.

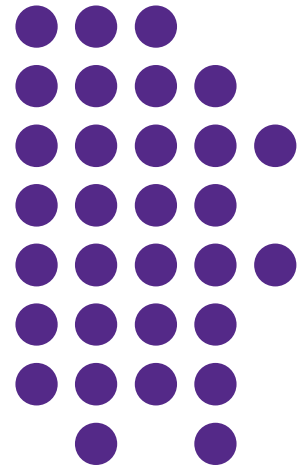
Have inspectors been given any guidance on how to proceed with site inspections to ensure social distancing or limited resources?



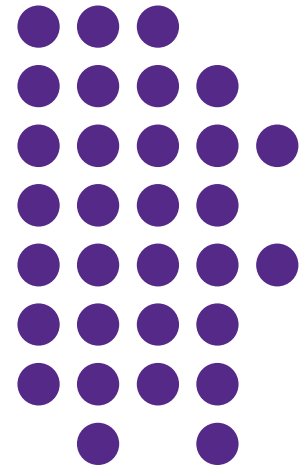
USDA

Question 4

~~If facilities do not want 2 people in the facility simultaneously, could one person write a facility inspection report and a second person add to it as they do a separate inspection?~~



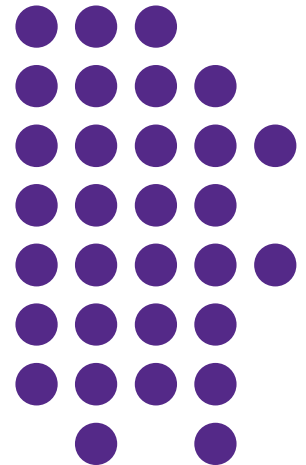
Other Topics



Other Topics

Question 1

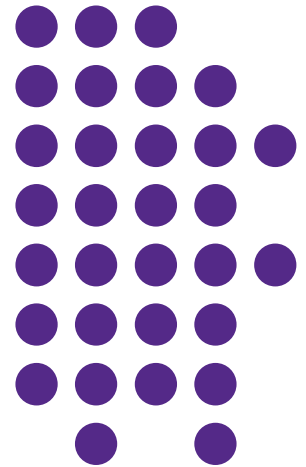
Can OLAW provide examples of disaster plans regarding COVID-19 pandemic and campus closures?



Other Topics

Question 2

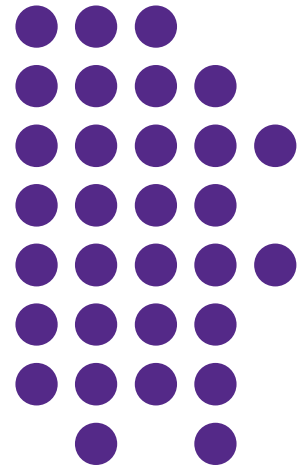
If our institution mandates that all personnel must work remotely for an extended period of time, whose responsibility is it for designating essential personnel needed to care for our research animals? The IACUC or the IO?



Other Topics

Question 3

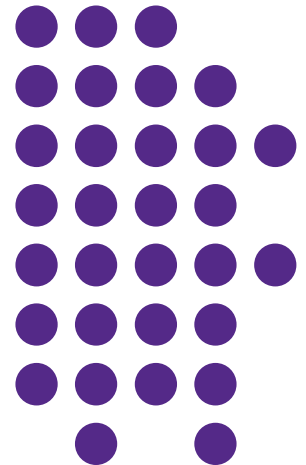
How can we continue to perform post approval monitoring (PAM) activities when access to animals or animal housing areas are minimized or restricted due to COVID-19?



Other Topics

Question 4

Do we need to update OLAW, NIH, or USDA on our outcome during the recovery stage?

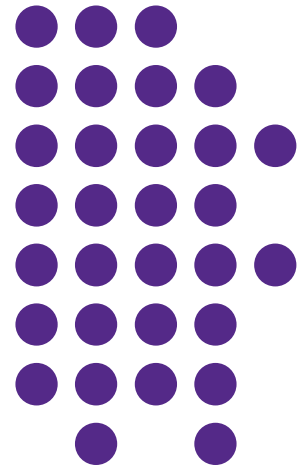


Other Topics

Question 5

If personnel training expires during this pandemic, what are the consequences?

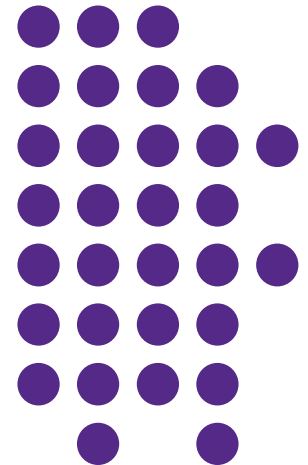
Can they still work with the animals?



Other Topics

Question 6

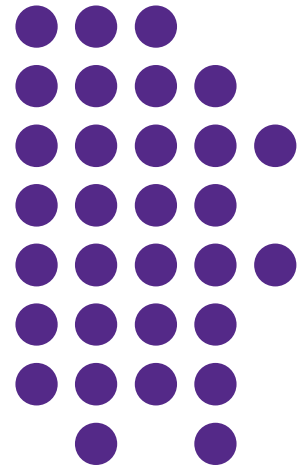
Should any deviations to standard practices related to COVID-19 be captured in the annual report to OLAW or USDA?



Other Topics

Question 7

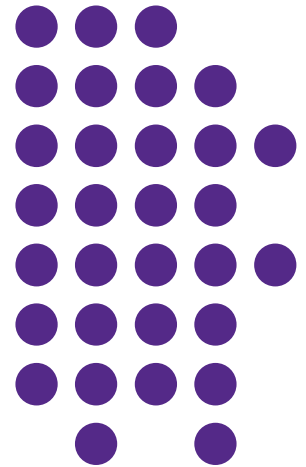
What are OLAW and USDA's guidance on using electronic signatures (vs. "wet" signatures) for official documents (e.g., semiannual programmatic report)?



Other Topics

Question 8

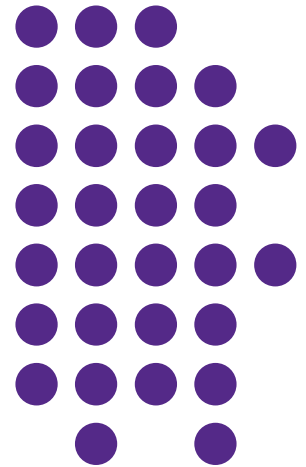
If animals already on study need to be euthanized because the university has shut down, what type of documentation and/or reporting is expected of each IACUC?



Other Topics

Question 9

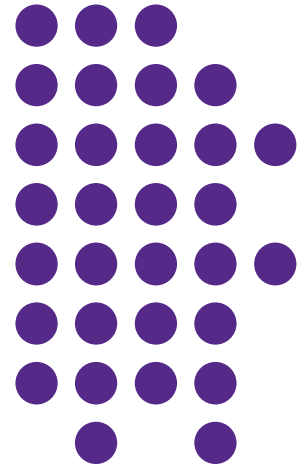
If animals already on study were scheduled for post-operative analgesia (or other required treatments) but the university shut down before the administration could occur, is this considered protocol noncompliance?



Other Topics

Question 10

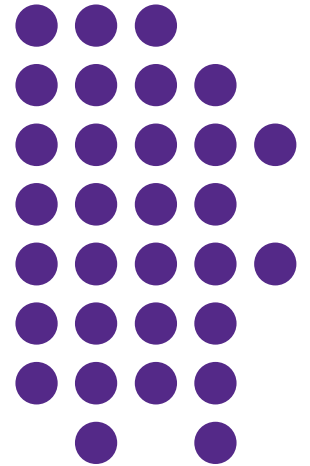
Do we need to report institutional closures to OLAW or USDA?



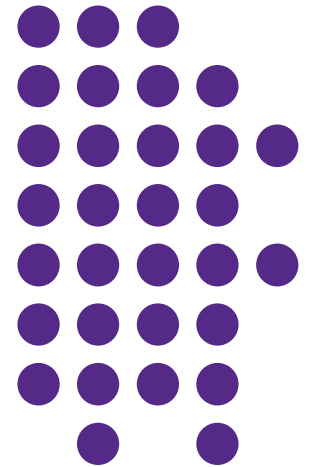
Other Topics

Question 11

Will there be any flexibilities with three year complete reviews?



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Paul McKellips
OLAW Online Seminar
June 11, 2020

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