Pandemic Contingency Planning and Its Impact on Animal Care Patricia Brown, NIH, OLAW Robert Gibbens, USDA, APHIS, Animal Care	
	1

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

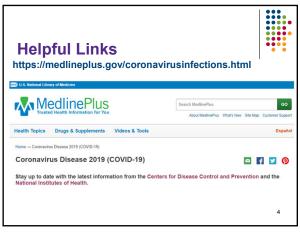
2

Coronavirus Disease 2019 (COVID-19)



2

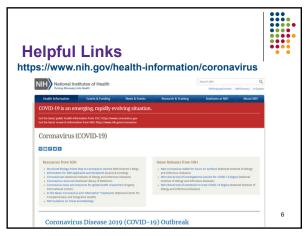
- A respiratory illness that can spread from person to person
- A novel coronavirus first identified during an investigation into an outbreak in Wuhan, China
- A global infectious disease with ongoing spread







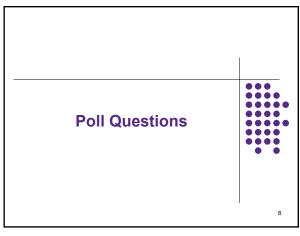












8

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

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

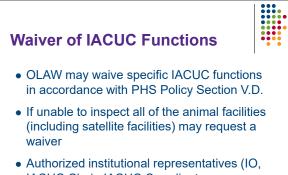
Conduct of Semiannual Inspections



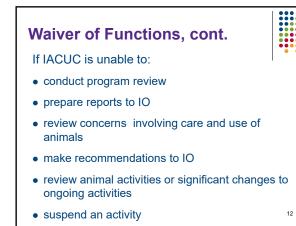
11

- 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

10



IACUC Chair, IACUC Coordinator or Veterinarian) may request a waiver





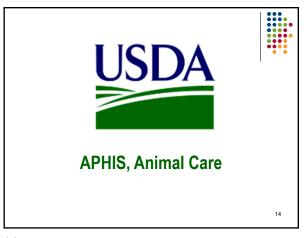


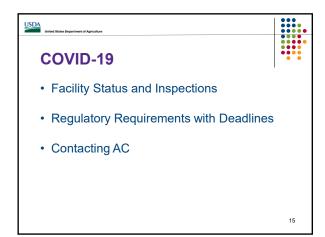
How to Request a Waiver

- 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

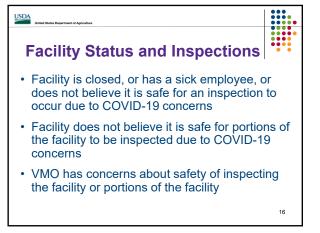
OLAW will review and approve the request in writing and respond by return email

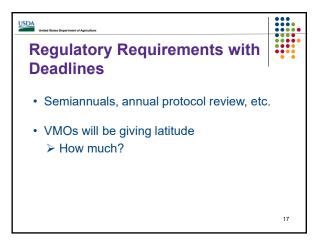
13



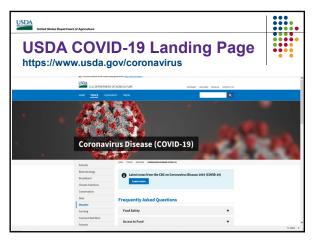


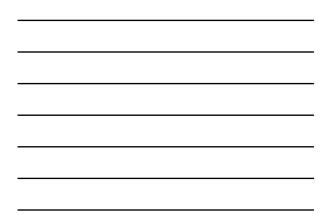
















20

- 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

20

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

22

Key Issues – IACUCs



22

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 23

23

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 24 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-052.html



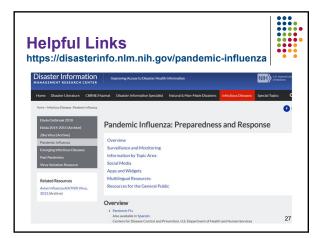
Additional Guidance

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

25







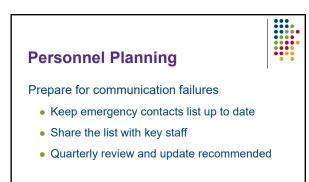
Example Pandemic Readiness Planning for Animal Programs



28

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

28



29

Personnel Planning



30

29

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

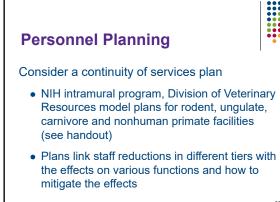
Identify all essential positions in sufficient quantities to maintain animal facility operations:

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

31



32





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

34



 Stay alert to state and federal authorities and when stockpiling may be indicated

35

Supply and Logistics Planning

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

- Two-way radios
- Cell phones
- Text messaging

35

Animal Husbandry & Health Planning



37

38

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

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

37

Animal Husbandry & Health Planning

https://www.cdc.gov/coronavirus/2019ncov/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

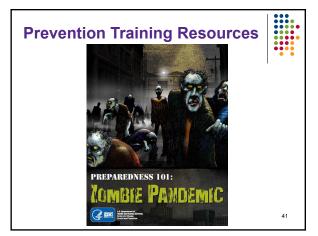
38

Prevention Training Resources

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













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.

43

Animal Husbandry & Health Planning



44

43

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

44

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



Develop plans for extended use of protective clothing or alternatives.

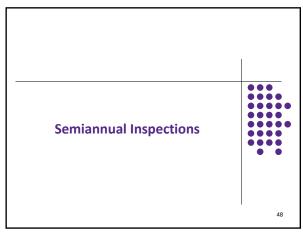
46

- 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/rec ommendedguidanceextuse.html
 - https://www.cdc.gov/coronavirus/2019ncov/hcp/respirators-strategy/index.html

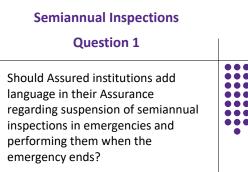
46



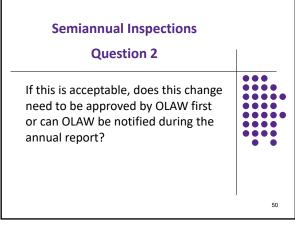
47



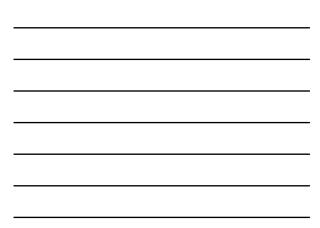








Semiannual Inspections Question 3	
What is the best way to document delayed/cancelled semiannual inspections to ensure that the timeline is noted for possible inspections?	
	51



Semiannual Inspections

Question 4

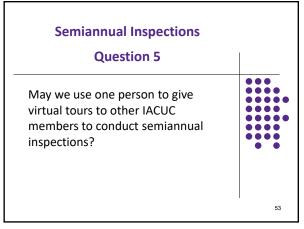
For minor deficiencies identified on the semiannual inspection and review, how should we determine a date for corrective action plan in place given the pandemic? Would a statement "*x period of time*

Ċ

52

after operations are resumed" meet OLAW and USDA expectations?

52



53

54

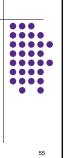
Semiannual Inspections Question 6	
"The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report."	
Is using <i>ad hoc</i> consultants acceptable for facility inspections and program reviews?	••
What are best practices when using <i>ad hoc</i> consultants?	54



Semiannual Inspections

Question 7

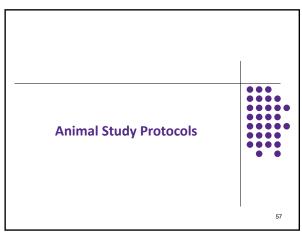
At many institutions, the essential personnel available to conduct the inspections may also have supervisory roles over parts of the facility. Is this considered a conflict of interest?



55

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?	56

56





Animal Study Protocols

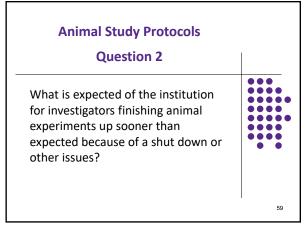
Question 1

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?

58

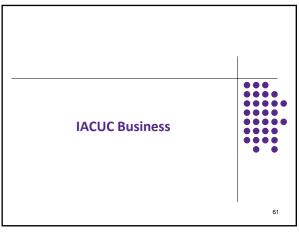
58



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?	60





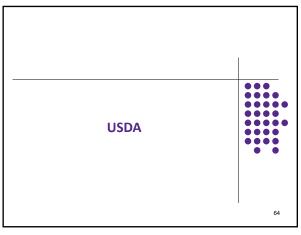




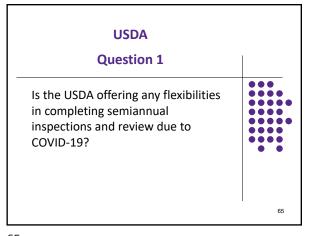
IACUC Business	
Question 1 During pandemics, will quorum requirements be relaxed in case the IACUC has to be convened to make decisions at short notice?	
What about under the direction of the IO only?	
	62

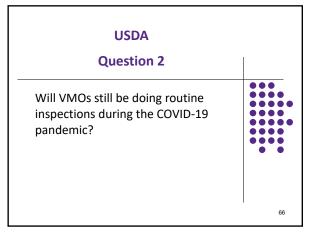
IACUC Business Question 2	
Please explain what is meant by "access to technology" for IACUC business conducted using telecommunication	
Details about using electronic means to conduct IACUC meetings can be found in Section 7.1.8 of the Animal Welfare Inspection Guide.	••••
<u>https://www.aphis.usda.gov/animal_welfare/</u> downloads/Animal-Care-Inspection-Guide.pdf	63





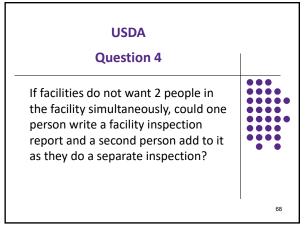


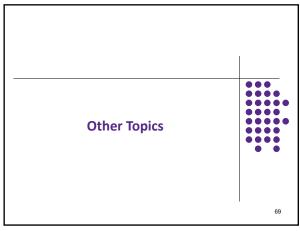


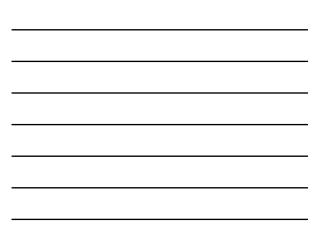


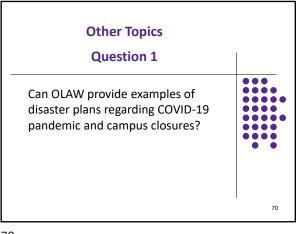


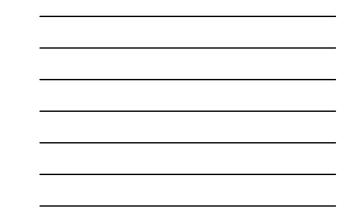
USDA	
Question 3	
For USDA inspections, we may have limited resources to provide documentation and tours to a USDA inspector.	
Have inspectors been given any guidance on how to proceed with site inspections to ensure social distancing or limited resources?	67





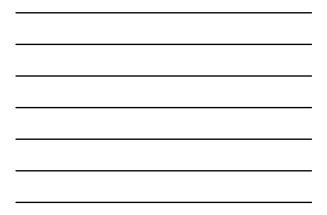


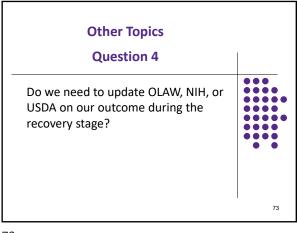




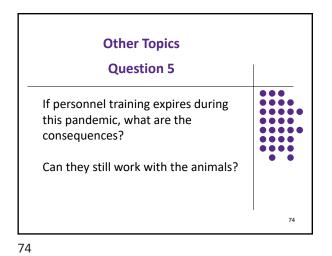
Other Topics	
Question 2	
If our institution mandates that all personnel must work remotely for an extended period of time, whose responsibility is it for designating essential personnel needed to care for our research animals? The IACUC or the IO?	
	71

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?	
	72



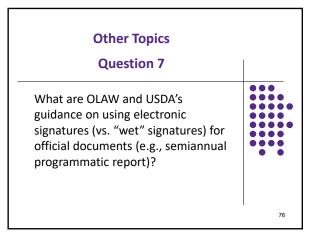


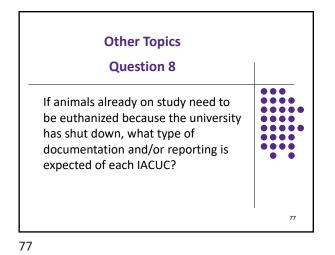


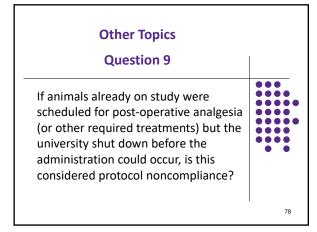


Other Topics Question 6	
Should any deviations to standard practices related to COVID-19 be captured in the annual report to OLAW or USDA?	
	75





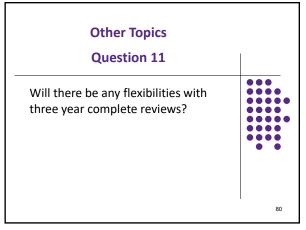


















Paul McKellips OLAW Online Seminar June 11, 2020

82