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Pandemic Contingency Planning and Its Impact on Animal Care

Speakers:

- Pat Brown, VMD, NIH, Office of Laboratory Animal Welfare
- Robert Gibbens, DVM, USDA, APHIS, Animal Care

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Slide 1: Pandemic Contingency Planning and Its Impact on Animal Care

Hello. Today is Thursday March 19, 2020. My name is Neera Gopee and I am the Director of the Division of Policy and Education at OLAW. Today it is my pleasure to welcome our speakers, Dr. Pat Brown, and Dr. Robert Gibbens (also known as Bob) to this highly anticipated and much needed special OLAW webinar to present "Pandemic Contingency Planning and Its Impact on Animal Care."

Dr. Pat Brown currently serves as the Director, Office of Laboratory Animal Welfare (OLAW). She received her undergraduate degree in Animal Science from the Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She completed her lab animal residency at Penn State Hershey Medical Center and is a diplomate of ACLAM. She served on active duty in the Air Force before joining the NIH in 1986, serving in several clinical and management positions in the Intramural Research Program before joining OLAW in 2006 as the Director.

Dr. Robert M. Gibbens (Bob) received his bachelor's degree in Zoology from Oklahoma State University in 1980. He received his Doctor of Veterinary Medicine degree from the Oklahoma State University College of Veterinary Medicine in 1984. He worked for six years in a small animal practice in Oklahoma before becoming a Veterinary Medical Officer with USDA in 1990. He became a field supervisor with USDA, APHIS, Animal Care in 1995, and Regional Director of the Western Region in 1997. In 2016, he became the National Director of Animal Welfare Operations. And is currently acting as Animal Care's Associate Deputy Administrator. Dr. Gibbens is located in the Animal and Plant Health and Inspection Service building in Ft. Collins, Colorado.

Without further ado, I'll hand the microphone over to Pat to get this discussion started.

Slide 2: Resources—Handouts

>> *Pat*: Before we start the discussion about contingency planning for pandemics, I'd like to call your attention to two of the handouts that are available for download and viewing during the webinar. [Note: Handouts are posted individually on the webinar archive webpage.] We will be referring to these throughout the presentation. The first of the two handouts includes:

- the recently released OLAW Guide Notice [NOT-OD-20-088](#) on flexibilities for IACUCs, • the OLAW Guide Notice [NOT-OD-06-052](#) on use of telecommunications, and
- OLAW's Frequently Asked Question [G.9](#). on pandemic preparation.

The second of the two handouts includes:

- the [NIH Intramural Program's 2008 Pandemic Flu Plan](#)
- the [NIH Division of Veterinary Resources current Continuity of Services Plans](#) and
- the [Johns Hopkins University Animal Research Coronavirus Phased Contingency Plan](#)

Slide 3: Coronavirus Disease 2019 (COVID-19)

What is coronavirus 2019, also known as COVID-19? It's a respiratory illness that can spread from person to person. It is caused by a novel coronavirus, first identified during an investigation into an outbreak in Wuhan, China. COVID-19, as you all know, is spreading from person to person globally.

Risk of infection from the virus that causes COVID-19 is higher for people who are close contacts of someone known to have COVID-19 such as healthcare workers, or household members. Other people at higher risk for infection are those who live in or have recently been in an area with ongoing spread of COVID-19. Most people are not severely affected but in the oldest individuals or those with compromised health it can cause serious disease and complications, and a high incidence of death.

Slide 4: Helpful Links

For one stop resources, [Medline Plus](#), a resource available to the public from the National Library of Medicine, has a landing page that links to both the CDC's and NIH's websites dedicated to COVID-19.

Slide 5: Helpful Links

This is the CDC's [landing page on COVID-19](#) and...

Slide 6: Helpful Links

...this is the NIH's [landing page](#). Each provides up to date details on the nature of the virus and the infection that it causes, ways to protect against exposure, and what is happening across the globe with the outbreak.

Slide 7: Helpful Links

In addition, the World Health Organization has a [landing page](#) with multiple resources about the outbreak.

Slide 8 [Not applicable for prerecorded webinar]

We are going to skip the poll questions that we had originally planned to ask, and we're going to go on to talk about OLAW's Guide Notice.

Slide 9: OLAW Guidance on Flexibilities for IACUCs—NOT-OD-20-088

On March 17, 2020, OLAW issued NIH Notice number NOT-OD-20-088 in the NIH Guide for Grants and Contracts to inform institutions of the flexibilities provided in the Public Health Service Policy on Humane Care and Use of Laboratory Animals [[PHS Policy](#)] that are applicable to implementing a pandemic plan for animal care and use programs. The PHS Policy also contains provisions that can be instituted as social distancing measures to prevent the spread of disease. The guidance addresses the following measures:

- conduct of semiannual facility inspections
- waivers of IACUC functions and
- conduct of IACUC meetings

This notice is included in the handout labeled OLAW guidance related to pandemic planning [Now under the Resources section of this webinar archive webpage].

Slide 10: Conduct of Semiannual Inspections

IACUCs may consider the following flexibilities already built into the PHS Policy in the conduct of semiannual facility inspections:

The timing of facility [inspections] may extend 30 days beyond the six-month interval from the last review as long as there is no forward drift of the date from year to year.

The IACUC has discretion to determine the best means of conducting facility inspections and program review. This includes using any qualified individuals as ad hoc consultants.

For areas housing non-USDA regulated species, the IACUC may use as few as one qualified individual to conduct the inspections. The IACUC of course still remains responsible for the evaluation and report of the inspections and the program review to the Institutional Official.

Slide 11: Waiver of IACUC Functions

OLAW may temporarily waive specific IACUC functions in accordance with PHS Policy Section V.D. Assured institutions that are unable to inspect, at least once [within] six months [plus 30 days], all of the institution's animal facilities (including satellite facilities) may request a waiver from OLAW. Authorized institutional representatives may request this waiver. Any of the following individuals may request the waiver as the authorized representative from the institution: the Institutional Official (IO), the IACUC Chair, the IACUC Coordinator, or the Attending Veterinarian.

Slide 12: Waiver of Functions, cont.

Other provisions of the PHS Policy that may be considered for waivers, include when the IACUC is unable to:

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

Note that this list represents the eight listed functions of the IACUC in Section IV.B. of the PHS Policy. OLAW expects Assured institutions to employ the flexibilities that we have described and only request waivers for justifiable reasons.

Slide 13: How to Request a Waiver

To request a waiver, the authorized representative should submit a request for the IACUC function or functions to be waived and include a justification for each of the requested functions. The request can be in email or in an attached letter sent from the authorized representative.

The waiver request should be sent to OLAW at olawdpe@mail.nih.gov. OLAW will review and approve the request in writing and respond by return email. Some of your institutions have already inquired about necessary delays to semiannual inspections because of the outbreak. We will be responding to those and any new requests that we receive as quickly as we are able.

Now I'm going to turn this over to Bob to talk about USDA and its guidance.

Slide 14: USDA

>> *Bob*: Thank you Pat. So, let's advance a couple of slides here.

Slide 15: COVID-19

I'm going to talk about:

- what we're doing with inspections, and how facility status relates to that
- regulatory requirements with deadlines, and flexibilities there, specifically with semiannual inspections, and then also
- how to contact us if you have questions

Slide 16: Facility Status and Inspections

APHIS is taking many steps to protect employees and to reduce the risk to their health and availability, and also to reprioritize work to ensure completion of our most essential and mission critical functions. For Animal Welfare Act inspections, APHIS is continuing to conduct regular inspections where local areas and individual premises conditions allow our inspectors to maintain social distancing norms. Our inspectors have been instructed to refrain from doing inspections in high risk areas identified by CDC, the State Department, and individual states. We've also given them these instructions.

So, if a 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, our VMO will not conduct the inspection, he or she will not write the inspection report, and there will be no negative repercussions to the facility.

There may be a situation where a facility does not believe it's safe for portions of the facility to be inspected due to COVID-19 concerns. In that situation our VMO will conduct the inspection on the portions the facility considers safe and will write a focused inspection report on what was inspected.

Also, if our VMO has concerns about his or her safety when inspecting a facility or portions of the facility, the VMO probably will not conduct the inspection, will not write an inspection report (or if it's a focused inspection, will do a focused inspection report), and again, there will be no negative repercussions for the facility.

For any facilities that are closed and cannot accommodate an inspection, feel free to let your VMO know, and he or she will not come to your facility to conduct an inspection. And just as a point of information, we are not tracking how many regulated facilities are closing.

Slide 17: Regulatory Requirements with Deadlines

So, with regard to semiannual inspections, facilities may delay those as long as necessary based on COVID-19 concerns. At this point, we're not placing a specific date on when semiannuals recommence in accordance with the regulations, because we don't know how long COVID-19 is going to impact facility operations. But we will allow sufficient time for this, and any facility that has a specific concern, we will work with on an individual basis.

Slide 18: Contacting AC [USDA, APHIS, Animal Care]

Many USDA office employees right now are teleworking, including those at the operations office in Ft. Collins, Colorado. That being said, all of our office employees are still working, and are reachable by telephone or email. You can contact anyone, but the best contacts are on this slide:

- top is AnimalCare@usda.gov, that just gets to Animal Care in general
- to contact the Ft. Collins office, contact 970-494-7478
- Riverdale is 301-851-3740. And of course, you can still call your Veterinary Medical Officer or the Supervisor

I've given my contact information there if you want to talk directly with me. Dr. Aaron Rhyner is currently the Acting National Director of Operations and his contact information is on this slide as well.

At this point, there are new developments involving COVID-19 much more frequently than daily, it seems to be happening almost hourly. So, if and when we need to change what we are doing or how we are doing it, we will do our best to let everyone know. And again, if you have questions, do not hesitate to contact us.

Slide 19: USDA COVID-19 Landing Page

This is the USDA's [landing page](#) on the internet. All updates concerning USDA operations and functions will be posted on this page. So again, when you have questions specific to the [Animal Welfare] Act, and you cannot find what you are looking for on the USDA website, please do not hesitate to contact us, and use the contact information on the previous slide to reach us.

I'm going to hand it back to Pat, I believe.

Slide 20: Guidance on Pandemic Planning

>> *Pat*: Now I am going to talk about our frequently asked question [[G.9.](#)] that provides guidance on pandemic planning. Beginning in 2008, OLAW provided guidance to a frequently asked question on how best to prepare for a pandemic. We recently updated this FAQ to address the current COVID-19 outbreak and it is available on the OLAW website. It is also included in the handout labeled OLAW guidance related to pandemic planning. Historically, the concern was with pandemic flu and that was why the original FAQ was drafted.

Slide 21: Key Issues

The primary emphasis of the guidance is the need for advance planning so as not to jeopardize the health and well-being of animals by preparing for when a limited number of personnel are

available to care for the animals and planning on how to conduct IACUC official business when social distancing is necessary.

Slide 22: Key Issues—Animal Facilities

In the event of a pandemic, animal facilities must be maintained at a level to ensure animal welfare. This is a mandatory requirement of the *Guide for the Care and Use of Laboratory Animals* [[Guide](#)] and agreed to in your institution's Animal Welfare Assurance agreement with OLAW. This contingency planning is similar to severe weather disasters where all staff may be unable to make it into a facility.

Plans should consider appropriate staffing levels, cross-training to cover critical operations, and adequate inventories of essential supplies such as feed, bedding, personal protective equipment, and cagewash supplies. OLAW recognizes that there are all sizes of animal care and use programs with different levels of complexity. Your plans should be tailored to your program and its unique needs. We will highlight some examples and present them later in the webinar.

Slide 23: Key Issues—IACUCs

The IACUC should be kept operational whenever possible and must continue to be properly constituted. If members are due to rotate off the committee, then extension of their appointments can be made due to the emergency circumstances. If the committee is meeting through social distancing, a quorum should be maintained to conduct official business. The IACUC must ensure that protocol approvals are not allowed to expire or if they do expire, that no further animal activities are conducted. Appointment and training of IACUC members (including nonscientific members and alternates) should be considered as a part of the plan.

Slide 24: Key Issues—IACUCs, cont.

The PHS Policy contains some provisions that can be instituted as social distancing measures to prevent the spread of disease.

These include:

- The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing as discussed in more detail in NIH Guide Notice [NOT-OD-06-052](#). This 2006 Notice is included in the handout labeled OLAW guidance related to pandemic planning [Now under the Resources section of this webinar archive webpage].
- The number of IACUC meetings may be reduced to as few as one every six months, the minimum allowed by the *Guide*.
- The IACUC may choose to expand their use of designated member review instead of full committee review.

Slide 25: Additional Guidance

If the situation is sufficiently severe and long-lasting that OLAW determines that the current guidance does not meet the needs of the research community and the funding components, additional guidance will be posted on the OLAW website and announced through our various communication mechanisms. This guidance may include additional types of waivers to PHS Policy. As mentioned previously, OLAW is the only entity authorized to make determinations regarding waivers to provisions of the PHS Policy.

Slide 26: Helpful Links

We're going to now switch gears and look at some examples of pandemic readiness planning for animal care and use programs. To start here are a few helpful links. The [American Association for Laboratory Animal Science](#) has a web site for IACUCs that includes links to institutional disaster plans. While not all of these include specific pandemic planning, several include staffing shortage discussions. Of particular note is the [Michigan State University's sample policy](#) on conducting IACUC business in the event of a pandemic. We didn't include this in the handouts today, but we will add it as a resource when we post the recording of the presentation. It has many good options to consider that address social distancing and how to keep the IACUC functioning.

Slide 27: Helpful Links

On a more general level, the [National Library of Medicine](#) has a website focused on pandemic influenza preparedness. Much of the information is applicable to the coronavirus outbreak. It includes relevant topics such as personal protective equipment and mental health guidelines.

Slide 28: Example Pandemic Readiness Planning for Animal Programs

Now I would like to focus on examples of pandemic readiness planning. You can find a handout labeled Examples of Pandemic Planning that includes three documents. [Note: Handouts are posted individually on the webinar archive webpage.] The first is the [NIH Intramural Research Program's 2008 Pandemic Influenza Plan](#). The second is [NIH's Division of Veterinary Resources](#) current Continuity of Service Plans. We very much appreciate the NIH Division of Veterinary Resources for their willingness to share their continuity of services plans. For those of you who want to fine tune your current plan, I think both of these examples will be helpful. Also included as a third example, and a very helpful document, is the [Johns Hopkins University's Animal Research Coronavirus Phased Contingency Plan](#) that was just recently released. We very much appreciate the Johns Hopkins University Research Animal Resources and Molecular and Comparative Pathobiology teams for their willingness to share this plan. It has many good operational considerations based on the level of impact from state and local restrictions caused by a pandemic.

So, let's move on and discuss the [NIH Intramural Research Program's] 2008 Pandemic Flu Plan and its three key topics areas for pandemic readiness planning. They are:

- personnel planning
- supply and logistics planning, and
- animal husbandry and health planning

Slide 29: Personnel Planning

There are four areas that are emphasized in personnel planning. The first of these is preparing for communication failures, as we all experienced earlier today. To best prepare you should:

- keep emergency contacts lists up to date
- be sure to share the list with all key staff, and
- a quarterly review and update is recommended

Slide 30: Personnel Planning

The second important aspect of personnel planning it to identify all essential positions in sufficient numbers to maintain animal facility operations. This includes positions involved with:

- cage wash

- autoclaves
- inventory of materials
- ordering of critical materials
- animal husbandry
- veterinary treatment
- surgical support, and
- record keeping

Slide 31: Personnel Planning

For each position, it is recommended that the names of three alternates to carry out the duties of that position be identified. Review of the responsibilities associated with the essential positions is recommended at least semiannually. Managers are also encouraged to designate the minimum number of essential personnel to keep all necessary functions operating.

Slide 32: Personnel Planning

The next part of Personnel Planning is to develop and conduct cross-training for animal care and administrative staff supporting the animal program. This of course is necessary to ensure all critical operations can continue. You may have to be creative and consider nontraditional arrangements for which people will do what jobs as alternates when the need arises. For example: Who will open and distribute the mail when the facility administrative staff are teleworking?

Slide 33: Personnel Planning

Lastly, consider a tiered continuity of services plan. As previously mentioned, the NIH Division of Veterinary Resources has created and recently updated a continuity of services plan. They have generously allowed OLAW to share their plans with the greater research community. The plans link a tiered reduction in staff levels that varies depending on the species housed in each facility. The Division manages a large collection of facilities in support of all of the Institutes and Centers of NIH that conduct research on the NIH campuses. For rodents, the plan identifies a 20-30% reduction of staff as having a minimal effect on operations, while 31 to 40% reduction has a moderate effect and 41% or greater has a potential severe effect on various key functions. The plans include how to mitigate the effects at each of the tiered levels.

The Johns Hopkins COVID plan similarly identifies mitigation methods and changes in research operations to accommodate the changing dynamics caused by a pandemic.

Slide 34: Supply and Logistics Planning

Three critical planning steps are proposed in the Supply & Logistics areas of the 2008 Pandemic Flu Plan. The first of those is identification of stockpile locations in the animal facilities for keeping critical items. A 1 to 2-month supply is recommended of feed, bedding, personal protective equipment, disinfectants and cage wash supplies, and other cleaning supplies, including hand sanitizers for personal hygiene.

Slide 35: Supply and Logistics Planning

The second part of the supply and logistics plan is to identify alternative sources for the critical supplies. Consider extended lead times for delivery that may occur as a result of distribution

slowdowns when planning how much to stockpile. Stay alert to information from state and federal authorities to determine when stockpiling may be indicated.

Slide 36: Supply and Logistics Planning

Because staff may be spread out with limited contact as part of social distancing and low staffing levels, it's important to consider alternative communication options. Within the facilities this may include the use of two-way radios, cell phones, and text messaging.

Slide 37: Animal Husbandry & Health Planning

It is also important in terms of animal husbandry and health planning to identify the key foot patterns to follow between clean and dirty areas of the facility or facilities. If you have fewer staff conducting additional functions and they need to travel beyond their normal locations, you need a traffic plan to avoid compromising animal health.

Slide 38: Animal Husbandry & Health Planning

It's also important to conduct training on prevention techniques. I've listed the website for the CDC that has a number of [videos specific for COVID-19](#) including:

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

Other examples from CDC on their [YouTube list](#) that may be useful for training are:

- What you need to know about hand washing, and
- How to prepare your home for an emergency

Slide 39: Prevention Training Resources

Additional prevention and training resources available from the CDC websites include factsheets and posters. I've listed the [web address](#), and the posters that I thought were of interest include:

- Stop the Spread of Germs poster
- Symptoms of Coronavirus Disease 2019, and
- several Wash Your Hands posters

Slide 40: Prevention Training Resources

This is one of my favorite CDC posters. Keep calm and wash your hands.

Slide 41: Prevention Training Resources

A more general resource on preparedness and emergency planning that is family oriented and that you might find of interest is the CDC's graphic novel titled Preparedness 101: Zombie Pandemic.

Slide 42: Prevention Training Resources

At the end of the story is a checklist for creating an emergency kit for your family. You may want to check it out.

Slide 43: Animal Husbandry & Health Planning

So, one of the questions to consider when we're talking about animal husbandry and health planning is what is going on with transmission between humans and animals. As of today [March 19, 2020], there has not been transmission of COVID-19 in a research setting from humans to

animals, but a number of species are being used in studies of the virus and have been infected experimentally. This includes ferrets, pigs, macaques, transgenic mice, and recently hamsters.

So, any of those animals would potentially—could be infected if an individual that was carrying the virus was in the animal facility and shedding at the time. And of course, if they were not taking appropriate protective care in terms of proper protective equipment.

There was one report internationally of a dog in Hong Kong that was placed under quarantine after its owner was hospitalized due to COVID-19 infection. While in the quarantine facility, the dog had nasal and other swabs taken. Nasal and oral samples did test positive for COVID-19, although the dog did not exhibit any clinical signs. Follow-up swabs over the next 10 days continued to test positive but subsequent samples tested negative. No clinical signs were ever detected during the quarantine period and the animal was returned to the owner after completion of quarantine. This 17-year-old dog unfortunately died after release and a necropsy was declined by the owner, so it is unclear whether the animal did have any consequences from being exposed.

Slide 44: Animal Husbandry & Health Planning

So, what should you do about your staff and their health? It's important that if staff have symptoms they don't come to work, and they seek care based on CDC's guidelines. It's important that they are aware of and follow state and federal requirements for testing, quarantine, and isolation.

Slide 45: Animal Husbandry & Health Planning

Another consideration for animal husbandry planning is the development of alternative standard operating procedures to allow fewer staff to manage the animals and their care, to include extended cage changing schedules, and caging and equipment sanitizing schedules. There are examples of some of these modifications in the Division of Veterinary Resources Continuity of Services Plan. If procedures are outside of *Guide for the Care and Use of Laboratory Animals* recommendations, the facility should obtain IACUC approval for these departures from the *Guide*, based on the emergency situation. And my guess is that an IACUC would readily approve any of these kinds of departures because of the nature of the circumstances.

Examples of conservation of resources include using more bedding in solid bottom cages for rodents to allow less frequent changing, and less frequent replacement of feed in rodent hoppers to extend feed supplies.

Slide 46: Animal Husbandry & Health Planning

The last consideration for animal husbandry and health planning is to develop plans for extended use of protective clothing or alternative types of protective clothing within the animal facility. As many of you know, the availability of masks, gloves, and disposable clothing is diminished, and for some supplies, non-existent.

Options to consider include not discarding masks, gloves, and coveralls as frequently and the use of durable personal protective equipment instead of disposable. You may also consider sanitization and reuse of some disposable items. The CDC has published recommendations on the reuse and extended use of N95 masks and I have listed the references here on the slide:

- <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

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

I would urge you to go to those links and take a look at the recommendations provided.

My final thoughts to you before we answer the questions that you submitted in advance, is that we in OLAW and USDA support all of your ongoing efforts to mitigate as much as possible the impacts of this unprecedented challenge on your animal care and use programs. We are here for you and will do our best to help you. Please do not hesitate to reach out to us for guidance. There are no wrong questions.

Thank you.

Slide 47 [Not applicable for prerecorded webinar]

Slide 48: Semiannual Inspections

>> *Neera*: Thank you, Pat and Bob. Not surprisingly, we've been inundated with questions from our constituents, and so we will spend the remaining time responding to questions.

Slide 49: Semiannual Inspections Question 1

The first question relates to semiannual inspections. And Pat: **Should Assured institutions add language in their Assurance regarding suspension of semiannual inspections in emergencies and performing them when the emergency ends?**

>> *Pat*: There is no necessity to include information in the Assurance on suspension of semiannual inspections in emergencies. However, it should be included in your emergency preparedness plan. OLAW will provide guidance in emergency situations, such as the recent Guide Notice [[NOT-OD-20-088](#)], and has done so in other emergency situations such as natural disasters. If conducting IACUC business by telecommunications is not included in your Assurance and your IACUC approves this new process during 2020, you should include that as a program change in your 2020 annual report [to OLAW]. It should then be updated in your next Assurance at the time of renewal.

Slide 50: Semiannual Inspections Question 2

>> *Neera*: To add on to that second question, the second part of that question: **If this is acceptable, does this change need to be approved by OLAW first or can OLAW be notified during the annual report?**

>> *Pat*: Documenting the delay and any waivers from OLAW in your IACUC records or minutes would be appropriate and then including it in your annual report would be also appropriate.

Slide 51: Semiannual Inspections Question 3

>> *Neera*: Question 3: **What is the best way to document delayed or canceled semiannual inspections to ensure that a timeline is noted for possible inspections?** Pat?

>> *Pat*: We would recommend that you keep track of what your regularly scheduled dates are, the amount of delay that occurred, when normal operations resumed, and when the inspections

are reinstated. And then plan your next inspection [no later than] six months [plus 30 days] after the reinstated ones. It's important to keep all this information in the IACUC's records.

>> *Neera*: Bob?

>> *Bob*: The USDA looks at this in the same way. Documenting what you are doing is very helpful to our VMOs. We're not specifying how it has to be documented, but the VMOs would want to look at the documentation, just as Pat mentioned.

>> *Neera*: Thank you, Pat and Bob.

Slide 52: Semiannual Inspections Question 4

Question 4: **For minor deficiencies identified on the semiannual inspection and review, how should we determine a date for [putting a] corrective action plan in place given the pandemic? Would a statement "x period of time after operations are resumed" meet OLAW's and USDA's expectations?** Bob?

>> *Bob*: We want the facilities to be able to provide all the resources they need to for the daily health and well-being of the animals. So, for minor deficiencies that don't impact animal welfare, whatever period of time is necessary after operations are resumed will meet the USDA's expectations.

>> *Pat*: We would agree. If the deficiency does not impact animal welfare, you should provide a reasonable and specific plan and schedule that incorporates the proposed "x period of time after operations are resumed."

Slide 53: Semiannual Inspections Question 5

>> *Neera*: Question 5 related to semiannual inspections: **May we use one person to give virtual tours to other IACUC members to conduct semiannual inspections?**

>> *Pat*: Yes, the PHS Policy allows the use of ad hoc consultants and in this particular case, that would be appropriate.

>> *Neera*: Bob?

>> *Bob*: For USDA it's the same. ~~We would say that virtual tour needs to be a live feed that involves live interactions and, as required by our regulations, at least two IACUC members need to be involved in viewing that live feed.~~

Slide 54: Semiannual Inspections Question 6

>> *Neera*: 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." according to the PHS Policy. Is using ad hoc consultants acceptable for facility inspections and program reviews, and what are the best practices when using ad hoc consultants?** Bob, would you like to take this one first?

>> *Bob*: Sure. ~~The USDA, we allow the use of ad hoc consultants. The regulatory requirement is that a minimum of two IACUC members be involved in the semiannual inspection, but neither the regulations nor [USDA, APHIS] Animal Care in general specify exactly how those two IACUC members have to be involved. That's left up to the IACUC. It's also a requirement that any member wishing to participate in the semiannual inspection be allowed to do so, but ad hoc consultants can be used as long as a minimum of two IACUC members are also involved.~~

>> *Pat*: Yes, we would agree. Appointing a qualified person to conduct a semiannual on behalf of the IACUC is certainly appropriate. The best practice would be to use similar techniques to what the committee typically employs. For example, potentially using a checklist and knowing what room order to go in. As I said, similar to what the entire IACUC does or however the IACUC currently does their inspections would be recommended.

Slide 55: Semiannual Inspections: Question 7

>> *Neera*: 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?**

>> *Pat*: We would say not necessarily. We would encourage the use of individuals who do not have direct oversight of a particular facility or facilities, but as long as there are other individuals involved that are also participating, we see no direct conflict of interest.

>> *Bob*: And the USDA views that the same way.

>> *Neera*: Thank you.

Slide 56: Semiannual Inspections Question 8

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?** Bob?

>> *Bob*: Right. And we have stated, and it is in our Inspection Guide, that the IACUC may adopt the AAALAC program assessment report as its semiannual program review or facility inspection. We do have some requirements that must be met. The report does have to comply with our section in the regs that describes the semiannual evaluations and report, that's 2.31-(c)(1), (c)(2), (c)(3). At least two members of the IACUC must assist in conducting the inspection. No IACUC member wishing to participate in the evaluation was excluded and the report has to be signed by a majority of the IACUC members and digital signatures are acceptable. And this guidance is in Chapter 7 of the Inspection Guide under section 7.1.2.

>> *Pat*: We would say that if the AAALAC site visit has recently been conducted and the IACUC accepts the recommendations from the site visit team, develops a corrective action plan for each recommendation, and incorporates both the recommendations and corrective action plans into their semiannual report, it would qualify as a substitution for the IACUC conducting the inspection. Additionally, the follow-on inspection should occur [no later than] six months [plus 30 days] after the AAALAC site visit had occurred. Suggest this with [similar to] a postponement: you would have the date of the next semiannual six months [plus 30 days] after the reinstated

inspection. When using an AAALAC site visit the next semiannual would be six months after that site visit.

Slide 57: Animal Study Protocols

>> *Neera*: Now we move on to questions regarding animal study protocols.

Slide 58: Animal Study Protocols Question 1

Question 1: **If investigators pause 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 issue a blanket statement allowing investigators to alter timelines, rather than requiring each PI to amend their study?** Pat?

>> *Pat*: Once work resumes, they should ensure the protocol has not expired, or if it is coming up on its expiration date, it should be reviewed and renewed so that approval is appropriately extended.

This review can be done by designated member review if the IACUC is not meeting formally. The IACUC can also put protocols on hold. But the expectation is that when facilities are back online, the IACUC will review the activity and confirm that the project can either go forward as described in the protocol or requires changes. Depending on the nature of such changes, they may require review via full committee review [FCR] or [designated member review] DMR, or in some cases [veterinary verification and consultation] VVC, or they may be minor administrative changes. As specific situations arise in the future, more detailed guidance based on such cases may be forthcoming.

>> *Neera*: Bob?

>> *Bob*: And the USDA has the same expectations in this area.

Slide 59: Animal Study Protocols Question 2

>> *Neera*: Thank you. Question 2: **What is expected of the institution for investigators finishing animal experiments up sooner than expected because of a shutdown or other issues?**

>> *Bob*: The USDA views that as being up to the institution, the PI, and the IACUC to determine what makes sense for the activity. So, from a regulatory perspective, the USDA has no expectations around this.

>> *Pat*: And neither does OLAW. Finishing earlier has never been a problem as far as OLAW is concerned. If for some reason the work could not be performed as expected under the grant, then the investigator should contact the Program Officer and inform them of the impact on the ongoing research.

Slide 60: Animal Study Protocols Question 3

>> *Neera*: 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?**

>> *Pat*: We understand that many institutions have been postponing research activities and are only providing basic animal care at this time. If the staff is present, able to work, and continuing to conduct their normal activities, the expectation is that veterinary resources would also continue and potentially protocol consultation could also continue.

>> *Bob*: So, under our regulations for veterinary care to the animals, it's a requirement and it's a critical piece of the Animal Welfare Act Regulations and certainly not something we're looking to waive. In that context, determining what research activities are postponed or will take place as planned is an institutional decision.

Slide 61: IACUC Business

>> *Neera*: Let me move on to the next category of questions, IACUC business.

Slide 62: 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—the institutional official.

>> *Pat*: No, it's best that the IACUC either meet virtually or conduct activities using designated member review. The IO is not allowed to overrule PHS Policy but can decide to halt or discontinue protocols.

>> *Bob*: We look at it the same way. Quorums are required in the regulations to conduct many official IACUC functions and that requirement remains in place. We do agree with Pat's comments about the use of designated member review and virtual IACUC meetings to be able to carry on the IACUC functions.

Slide 63: IACUC Business Question 2

>> *Neera*: Question 2: **Please explain what is meant by "access to technology" for IACUC business conducted using telecommunication.**

>> *Bob*: So, we have a section in our Inspection Guide that covers this, Section 7.1.8, Chapter 7, and I think one of the main things is methods of communication must allow for real-time back and forth communication and deliberation. You can mix and match methods of the real-time communication. For example, some members may use GoToMeetings, others may join by teleconference. Again, this is acceptable, as long as there is capability for real-time discussion from all the members. Similarly, access to technology from any workable location is permissible, again, as long as there is real-time communication for all IACUC members. On this slide is the link to the Inspection Guide and you can find this in 7.1.8.

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

>> *Pat*: And OLAW concurs. Our guidance can be found at [NOT-OD-06-052](#), which is included in the one handout on guidance from OLAW. [Note: Handouts are posted individually on the webinar archive webpage.] And, I'd also like to mention that the two specific requirements in the PHS Policy for what requires a quorum present to conduct IACUC business is either:

- suspension of a protocol or
- full committee review of protocols and significant changes

So, anything else that the IACUC is doing can be done through other mechanisms and does not require a quorum at a convened meeting. And again, a convened meeting can be virtual, with teleconferencing or video conferencing.

Slide 64: USDA

>> *Neera*: Thank you, Pat and Bob. So, this section is dedicated to USDA.

Slide 65: USDA Question 1

The first question: **Is the USDA offering any flexibilities in completing semiannual inspections and review due to COVID-19?**

>> *Bob*: I mentioned this on an earlier slide. Let's mention it again. For USDA-registered institutions, they can delay semiannual inspections as long as necessary due to COVID-19 concerns. At this time, we're not giving a specific date on when semiannual inspections need to be resumed in accordance with the regulations. If you have questions or concerns about this, we're very happy to work with facilities on an individual basis. Again, our primary concern, and I know yours is as well, is the care and welfare of the animals.

Slide 66: USDA Question 2

>> *Neera*: Question 2: **Will VMOs still be doing routine inspections during the COVID-19 pandemic?**

>> *Bob*: We talked a little bit about this earlier, but let's do it again. There are flexibilities in place. If the facility is closed or does not believe it's safe to be inspected due to COVID-19 concerns, or if the VMO has concerns about inspecting the facility, an inspection would not occur, there would be no negative impact on the institution, there would be no inspection report. Currently, again, just to reiterate, USDA institutions, our inspections are considered by both the USDA and the government's Office of Personnel Management to be mission critical functions and that will continue until our instructions change.

Slide 67: USDA Question 3

>> *Neera*: 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 so to ensure social distancing or [with] limited resources?**

>> *Bob*: Yes. We have. And we have flexibilities in place, and we've talked about some of those. Also, all of our inspectors have been instructed not to inspect in any facility or any part of a facility where they cannot maintain social distance. And this is within our research community, but also within our exhibition and breeder and dealer community. So, our VMOs have been given guidance. Again, if you have questions or you have some individual circumstances you want to bring up and discuss, please contact us. You can still contact your VMO or your supervisor. You can contact us in Fort Collins as well.

Slide 68: USDA Question 4

>> *Neera*: Question 4: **If facilities do not want two people in the facility simultaneously, can one person write the facility inspection report and the second person add to it as they do a separate inspection?** Bob?

>> *Bob*: I'm not exactly sure what the question is asking so I'll answer to cover both things that it could be asking. If this is about our inspections and we happen to send a team inspection or two VMOs to the facility, if the facility wishes them to inspect separately and combine their findings into one report, we can certainly accommodate that. ~~On the other hand, if this question is about is about semiannual inspections, we have no expectation that IACUC members and/or ad hoc consultants go hand in hand throughout the inspection. How those IACUC members are deployed is an institutional decision. There's no regulatory expectation—just let me say it again—that the two members go hand in hand throughout the facility inspection.~~

Slide 69: Other Topics

>> *Neera*: So, moving on to other topics.

Slide 70: Other Topics Question 1

The first question under this category is: **Can OLAW provide examples of disaster plans regarding COVID-19 pandemic and campus closures?**

>> *Pat*: Yes, as I've mentioned previously, we have examples of the [Johns] [Hopkins COVID plan](#), and we also have the [Continuity of Service Plan from the Division of Veterinary Resources of the NIH Intramural Research Program](#), and you may be able to find others on the AALAS website. We've uploaded those two examples as handouts on your GoToWebinar control panel, and they'll also be uploaded online with this webinar. [Note: Handouts are posted individually on the webinar archive webpage.] We recommend that [Michigan State University's Policy on IACUC Business in the Event of a Pandemic](#) also as a good resource for IACUC business. [Note: This handout is posted on the webinar archive webpage.]

Slide 71: Other Topics Question 2

>> *Neera*: 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?**

>> *Pat*: Your facility's and institution's disaster plan should indicate who is essential personnel, and it should always include consideration of care for the animals. This is a mandate from the *Guide*, a disaster plan must include identification of essential personnel who will be caring for the animals during any kind of a disaster, including a pandemic.

>> *Bob*: Under our regulations, the research facility itself is responsible for ensuring daily care and adequate veterinary care be provided to the facility's animals, so regulations do not prescribe who designates the essential personnel.

Slide 72: Other Topics Question 3

>> *Neera*: Question 3: **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?** Bob?

>> *Bob*: The regulations of the Animal Welfare Act do not have a specific requirement for how to conduct post approval monitoring [PAM], other than the not less than annual review of protocols. So, in regard to this question, we leave it up to the facility to decide the most effective way to address post approval monitoring.

>> *Pat*: Post approval monitoring does include various mechanisms. So, post approval monitoring can consist of just the observation of animals during daily routine facility activities would qualify. So that would be the minimal level of post approval monitoring necessary. There is no requirement that the formal PAM program continue, especially if there are reduced or limited research activities going on at the facility. If, as a result of the pandemic, changes are made to the PAM program due to the restrictions imposed by the circumstances and it becomes part of your ongoing plan, we would expect it to be described in your next annual report to OLAW as part of a program change.

Slide 73: Other Topics Question 4

>> *Neera*: **Do we need to update OLAW or NIH on our outcome during the recovery state or even USDA?**

>> *Pat*: We will issue guidance at a later date depending on the severity and nature of the ongoing situation.

>> *Bob*: And like OLAW, we will provide guidance at a later date as this situation develops further.

Slide 74: Other Topics Question 5

>> *Neera*: Question 5: **If personnel training expires during this pandemic, what are the consequences? Can they still work with the animals?**

>> *Pat*: If the personnel are trained in their duties, then there's no consequences. Personnel are not to conduct any animal procedures without prior training or experience, and they should be able to demonstrate proficiency, but if they've already gone through the training and they're considered proficient, there's no consequences. We would also encourage the cross-training that was mentioned earlier, that if you're anticipating that you may have limited personnel in certain positions to get those people cross-trained as soon as you can.

>> *Bob*: And the USDA views this the same way.

Slide 75: Other Topics Question 6

>> *Neera*: Question 6: **Should any deviation from standard practices related to COVID-19 be captured in the annual report to OLAW or even should it be reported to USDA?**

>> *Pat*: So, we will be providing guidance on that at a future date.

>> *Bob*: Likewise, once we get closer to annual report time, we'll also provide guidance on this.

Slide 76: Other Topics Question 7

>> *Neera*: Question 7: **What are OLAW and USDA's guidance on using electronic signatures versus "wet" signatures for official documents such as semiannual program reports to the IO?**

>> *Pat*: Electronic signatures have long been acceptable to OLAW, [but they need to be verifiable].

>> *Bob*: And that's the same for the USDA.

Slide 77: Other Topics Question 8

>> *Neera*: 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?**

>> *Bob*: For USDA, this decision needs to involve the attending veterinarian to help determine if it's appropriate to euthanize the animals. If that determination is made, the animals can be euthanized. The animals should be euthanized in a manner that meets the definition of "euthanasia" in the regulations of the Animal Welfare Act. As far as documentation for USDA, that would depend upon the species. If we're talking about dogs and cats, there is a requirement for disposition documentation for those species.

>> *Pat*: We would agree with USDA in terms of documentation that would be based on what the institution expects for animals that are assigned to a particular protocol. This is going to be part of the disaster plan, and institutionally driven in terms of the decision to euthanize. Again, the veterinarian would be the one involved in making the determination. Again, it's also based on your ability to maintain your program.

Slide 78: Other Topics Question 9

>> *Neera*: Question 9: **If animals already on study were scheduled for post-op analgesia, or other required treatments, but the university shuts down before the administration could occur, is this considered protocol noncompliance?**

>> *Bob*: For USDA, failure to provide post-operative analgesia or other necessary treatments as scheduled would be considered a failure to provide adequate veterinary care. So, if this becomes a viable scenario, it would be very good for the institution to look at stopping the research activity or see what other options are available to them.

>> *Pat*: If the analgesia cannot be given, this may constitute reportable noncompliance to OLAW. If appropriate animal care cannot be carried out, the activity should be stopped, and euthanizing instead is acceptable, again, with the veterinarian's involvement. If this is a different outcome than what is approved in the protocol, then it may be reportable. And again, this would be handled on a case-by-case basis where the [OLAW] compliance officer would want to have a discussion with the person reporting to understand the full nature of what went on.

Slide 79: Other Topics Question 10

>> *Neera*: Question 10: **Do we need to report institutional closures to USDA or OLAW?**

>> *Pat*: Our current plan is that as institutions request a waiver for semiannual inspections, we're documenting the request. We do not need to know about the closure itself, as long as the institution is maintaining care for the animals during the closure. If for some reason that's not the case and some animals are not getting the care they need, that would be something that we would want to hear about.

>> *Bob*: For USDA, you are not required to report closure to us, but if you choose to do so, our VMOs would not go to your facility to conduct an inspection. So, if you're closed and notify your VMO or supervisor in your area, then we will not even come to your facility while you are closed.

Slide 80: Other Topics Question 11

>> *Neera*: And our final question: **Will there be any flexibility for the three-year complete review?**

>> *Pat*: The answer is no. Protocols must be renewed prior to the three-year expiration date, however, there certainly are provisions where the IACUC could conduct designated member review for any protocols that are anticipated to be expiring in the near future. We would encourage institutions to have that practice in place as soon as possible because as this outbreak goes on, more protocols may be due to expire. Of course, if the IACUC wants to do full committee review, it can do it virtually.

Slide 81: [Not applicable during prerecorded webinar]

Slide 82: Animal Research and Public Support: A 2020 Vision for Strategic Communications and Micro-Messaging

>> *Neera*: So, we've come to the end of our discussion. OLAW and USDA's immediate concern is for the health and safety of people and animals in the programs we oversee. We recognize that as the novel coronavirus outbreak continues, it increasingly generates questions from our stakeholders. Please feel free to contact OLAW and USDA should you have any questions or concerns regarding the impact of COVID-19 on your institution's animal care and use program.

Many thanks to Pat and Bob. You have been incredibly generous with your time. We look forward to meeting with you again at our next OLAW Online Seminar on June 11th. Paul McKellips, who is currently affiliated with the US Army, will discuss the three new microtechniques that are now driving message marketing on a global scale in his talk titled "Animal Research and Public Support: A 2020 Vision for Strategic Communications and Micro-Messaging."

Please stay safe and healthy through these uncertain and trying times.

Good-bye.

Additional Submitted Questions Not Addressed During the Recording of the Webinar

Question A:

The NOT-OD-20-088 indicates that “The timing of facility inspections may extend 30 days beyond the six-month interval from the last review if there is no forward drift of the date from year to year.” Is this 30-day period strict to six months + 30-days from the exact date of the last inspection or if your OLAW Assurance indicates that inspections are performed every six months within the same two calendar months each year, can the 30 days extended through the next calendar month. This is of course ensuring that the next semiannual inspection falls on the appropriate month. Does the USDA and OLAW concur in their response?

>> *USDA*: If a facility has delayed its semiannual inspection, the facility should establish a new six-month deadline based on the first semiannual inspection post COVID-19. So, for example, if a facility delayed its semiannual three months from March 1 until June 1, the next semiannual would be due September 1.

>> *OLAW*: The timing for the semiannual program evaluation should be six months + 30 days from the previous semiannual program evaluation. If the institution’s schedule is greater than seven months, it is not consistent with the PHS Policy requirement of conducting the semiannual inspection at six-month intervals. As mentioned previously in this webinar and in [NOT-OD-20088](#), institutions that are unable to inspect in this time frame may request a waiver from OLAW. Any of the following individuals may request the waiver as the authorized representative from the institution: the Institutional Official (IO), the IACUC Chair, the IACUC Coordinator or the Attending Veterinarian.

Question B:

Can OLAW specify what facilities require semiannual inspections? OLAW [FAQ E.1](#) indicates that the only locations that require inspections every six months are satellite facilities (outside core/centrally managed area housed > 24 hours) and areas where surgical manipulation occur (all types). It reads as though all other locations (core/centrally managed area, laboratory areas with non-surgical procedures, animal support space, etc.) do not require inspections at six-month intervals, but on a schedule set by the institution. Please confirm.

>> *OLAW*: The PHS Policy states: “...inspect at least once every six months **all of the institution’s animal facilities** (including satellite facilities) using the *Guide* as a basis for evaluation”. FAQ E.1. clarifies that in addition to core animal facilities, OLAW considers satellite facilities and certain other areas required to be visited semiannually: “Satellite facilities (defined by PHS Policy as a containment outside a core or centrally managed area in which animals are housed for more than 24 hours) and areas where any form of surgical manipulations (minor, major, survival, non-survival) are performed must be inspected at least once every six months by the IACUC as part of the semiannual evaluation. Institutions have discretion with regard to how they oversee areas used for routine weighing, dosing, immunization, or imaging, but should monitor such areas on a random or fixed schedule to effectively oversee activities at the institution.”

Question C:

Can USDA specify what facilities require semiannual inspections? At the IACUC 101 series in June 2018, a USDA representative indicated that the only locations that

require inspections every six months by the USDA are animal housing facilities, study areas (outside core/centrally managed area housed > 12 hours) and centralized surgical suites. Further indicating that other areas do not require inspections by the IACUC (e.g., surgery in PI laboratories, laboratory areas with non-surgical procedures, animal support space, etc.). Please confirm.

>> *USDA*: The statement by the USDA representative at the 2018 IACUC 101 is correct. Those are the areas that are required to be included in the semiannual inspection. However, it is important to keep in mind that the institution is responsible for all research activities as well as the facilities that are used for those activities. And, USDA VMOs may inspect any of those areas during our inspections.

Question D:

If an investigator is not actively using a location in a non-centrally managed area (due to the COVID-19 response or another reason) and they officially remove the location for that animal activity (species and/or use), thus effectively eliminating the need to continue to perform semiannual inspections. Then, if/when animal work can resume, and they decide to use that location again, they regain IACUC approval at a later date (thus re-starting the requirement for semiannual inspections). Of course, they cannot use the location for an animal activity until they regain IACUC approval. Please confirm.

>> *USDA*: IACUC approval is required to begin using that location again. The area should be included on the next semiannual inspection.

>> *OLAW*: OLAW agrees with USDA.

Question E:

Once universities shut down and eliminate access to facilities, is there a limit to what activities the facility personnel can conduct on behalf of PI, and do the facility personnel need to be listed on the PI protocol(s) to do any specific activities including euthanasia? In other words:

- **Do facility personnel have to be listed as protocol personnel if they are going to euthanize animals on behalf of the PI (any/all species)?**
- **Do facility personnel have to be listed as protocol personnel if they are going to perform any activities or procedures other than euthanasia (any/all species)?**
- **Is there any specific documentation required if/when facility personnel perform any/all procedures/euthanasia on behalf of the PI?**

What are your thoughts on using DMR for all protocols, including those that may have unrelieved pain or distress?

>> *USDA*:

- The attending veterinarian or a veterinarian on staff needs to be involved in the decision to euthanize an animal. The euthanasia must be performed by a person trained and qualified to do so. And the method of euthanasia must meet the regulatory definition of euthanasia in the AWA regulations.
- Personnel should be trained in the activities or procedures they perform.

- If euthanasia is performed on dogs or cats, disposition records are required.

>> *OLAW*: If the individuals are part of the facility staff or a central core of technicians that are qualified to perform the procedures including euthanasia, then they may be added to all applicable protocols as an administrative change. It is not necessary to list each technician, just the identifying group. Clinical records should be kept as per facility recordkeeping requirements and list the procedures that were performed.

Question F:

If investigators having small numbers of non-USDA regulated, non-federally funded animals want to move those animals to their residence to ensure proper care during a COVID 19 quarantine/closure/semi-closure, can the IACUC approve this type of relocation? Would the IACUC need to inspect the housing of the animals at the private residences?

>> *USDA*: If the animals were regulated by USDA, we would not encourage this practice. And keep in mind that any animal housing facility must meet the requirements in the AWA Regulations and standards. Should an institution want to set up an employee's residence to house animals, it would become a site of the research facility and subject to inspection.

>> *OLAW*: For numerous reasons, OLAW does not approve of this practice: 1) the environmental conditions are unknown, 2) the animals' health could be compromised by exposure to unknown pathogens, and 3) biosecurity of the facility may be compromised if the animals return to the facility. Animals may be adopted out under specific institutional guidelines.

Question G:

Could you provide guidance that can be used for deciding whether to euthanize research animals for COVID-19-related reasons?

>> *USDA*: This is an institutional decision that should involve the attending veterinarian.

>> *OLAW*: Euthanasia of animals should be a last resort and the circumstances for when it is necessary should be described in the institution's disaster plan. It is an institutional decision involving the veterinarian and the institution's leadership. Careful planning and alternatives to consider include:

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

Question H:

Will there be any flexibilities from NIH funding agencies? For example: 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? I think some researchers will euthanize animal since

they cannot predict per diem charges for this (unknown duration) “shelter in place” period, which is truly unfortunate for the animals.

>> *OLAW*: Per diem charges during this time are allowable for animals placed on an IACUC approved holding protocol and maintained throughout the duration of the research stoppage. [Updated 07/22/2020: Grantees may contact the NIH awarding Institute/Center to request administrative supplements for these unanticipated costs. Please see [NOT-OD-20-086](#) (Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19) for guidance on rebudgeting authority. Recipients may rebudget funds to accommodate unanticipated costs without prior approval when rebudgeting does not constitute a change in scope and is not restricted by the terms and conditions of award (see NIH GPS 8.1).]

Question I:

If an organization must close to all personnel due to COVID-19 exposure, what precautions and guidelines should the animal holding facility within the same building take?

>> *OLAW*: Animal care staff are considered mission essential and should be identified in the disaster plan. The personnel in the animal facility should follow the facility’s disaster plan and the directions of institutional leadership.

Question J:

If a national lock down occurs, how should the animal facility of a private company conduct themselves if only rodents are housed there?

>> *USDA*: The primary concern is the routine care of the animals to ensure their health and wellbeing. USDA and *OLAW* have regulatory flexibilities in place with regard to semiannual inspections and other IACUC functions.

>> *OLAW*: Animal facilities must be maintained at a level to ensure animal welfare. This is a mandatory requirement of the *Guide for the Care and Use of Laboratory Animals* and agreed to in your institution’s Animal Welfare Assurance agreement with *OLAW*. Animal care staff are considered mission essential and should be identified in the institution’s disaster plan. If the situation is sufficiently severe and long-lasting that *OLAW* determines that the current guidance does not meet the needs of the research community, additional guidance will be posted on the *OLAW* website and announced through our various communication mechanisms.

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