



ICARE Dialogue: Optimizing Animal Welfare during the Pandemic

Resources and References: OLAW, USDA, National Park Service, VA

OLAW:

The OLAW website for COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs includes links to Guide Notices, Webinars, Frequently Asked Questions, Disaster Planning, and other information, which are provided below for your convenience. The website can be found at: <https://olaw.nih.gov/covid-19.htm>

Guide Notices

- [Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19](#) (NOT-OD-20-088, March 16, 2020). This Notice highlights flexibilities for the conduct of semiannual facility inspections and conduct of IACUC meetings under the current pandemic situation.
- [Guidance to IACUCs Regarding Use of Designated Member Review \(DMR\) for Animal Study Proposal Review Subsequent to Full Committee Review \(FCR\)](#) (NOT-OD-09-035, January 8, 2009). This Notice highlights flexibilities in using DMR, which may ease logistical constraints under the current pandemic situation.
- [Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals](#) (NOT-OD-06-052, March 24, 2006). This Notice highlights flexibilities in IACUCs using telecommunications for business requiring a quorum.

Webinars

- [COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs](#): NIH OLAW and USDA, APHIS, Animal Care discuss the most recent updates and guidance for animal care and use programs during the COVID-19 pandemic.
- [Pandemic Contingency Planning and Its Impact on Animal Care](#) - March 19, 2020: NIH OLAW and USDA, APHIS, Animal Care discuss how your institution can prepare for a pandemic that may impact your animal care and use program.

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- [Building a Research Occupational Health Program](#) - March 12, 2020: OLAW responds to some questions relating to the COVID-19 pandemic.

Example Disaster Plans

- [NIH Division of Veterinary Resources Continuity of Services Plan](#) (PDF)
- [Johns Hopkins University Animal Research Coronavirus Phased Contingency Plan](#) (PDF)
- [NIH 2008 Pandemic Flu Readiness Plan for Research Animals](#) (PDF)

Strategies to Optimize the Supply of PPE and Equipment

- CDC: [Strategies to Optimize the Supply of PPE and Equipment](#)
- CDC: [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#)
- CDC: [Coronavirus Disease 2019 \(COVID-19\) N95 Respirators](#)

Articles

- [Laboratory Animal Science Professional 2020; 8\(4\)](#). Maintaining Compliance in Unprecedented Times: Flexibilities for Compliance with the PHS Policy During the COVID-19 Pandemic. *This article appeared in the AALAS membership magazine, Laboratory Animal Science Professional, July - August 2020, and is reprinted by permission.*
- [Lab Animal 2020: 49\(5\)](#). A Word from OLAW: COVID-19 guidance.

USDA: APHIS AC links for “Optimizing Animal Welfare During the Pandemic Crisis”

7/22/20 Message to AWA Licensees and Registrants: Resumption of Animal Care Inspections During COVID-19 Pandemic

<https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/296d93e>

5/4/20 Message to AWA Licensees and Registrants: Status of Animal Care Inspections During COVID-19 Pandemic

<https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/289c9b5>

4/8/20 USDA/OLAW COVID-19 Pandemic Response Resources and FAQs for Animal Care and Use Programs <https://olaw.nih.gov/education/educational-resources/webinar-2020-04-08.htm>

3/27/20 Message to AWA Licensees and Registrants: Animal Care Inspections During COVID-19 Pandemic

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

3/19/20 USDA/OLAW Pandemic Contingency Planning and Its Impact on Animal Care <https://olaw.nih.gov/education/educational-resources/webinar-2020-03-19.htm>

Link to overview of the Animal Welfare Act, AWA Blue Book, Inspection Guide and other resources https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa

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National Park Service:

Examples of COVID-19 Guidance For Wildlife Research and Domestic Animal Care
Developed by the National Park Service (NPS) Wildlife Health Branch Veterinarians and the
Senior Research Scientist

Scientific Research and Collecting Permits, Permit Holders and Permit Applicants

Scientific Research and Collecting Permits

Changes in park operations mean some parks have reduced or ceased processing of applications for Scientific Research and Collecting Permits during the coronavirus response period. Scientists submitting permit applications should not expect a rapid response and may be requested to submit additional information. Additionally, park conditions may change, permittee access to parks may be adjusted, so possession of a signed Scientific Research and Collecting Permit does not in itself guarantee access to all areas authorized under the permit. Please check with individual park research coordinators to inquire about fieldwork status and guidance. Park contact information is available from the RPRS Search menu: see the "Parks" search option.

Field Work Involving Bats [\(updated June 4, 2020\)](#)

What's the issue?

There is potential risk for bats to be infected with SARS-CoV-2 (the virus that causes COVID-19 in humans) via handling or being in close proximity to an infected human. If this were to occur, the consequences for health of bats and subsequent risks for human health if a persistent reservoir of the virus was established in bat populations is unknown. A rapid risk assessment lead by the USGS and FWS in collaboration with multiple experts, agencies and institutions nationally and internationally indicated that there is a non-negligible risk of bats becoming infected with SARS-CoV-2 from research or management personnel who handle or are in close proximity (within 6 ft) of bats and that proper use of PPE can substantially reduce that risk. However, a great deal of uncertainty still exists as to as to the susceptibility of North American bat species to SARS-CoV-2 and the potential consequences if bats are infected. Experimental infection trials in North American bat species are underway to directly assess susceptibility to infection, development of disease and potential for bat-bat transmission. Outcomes of these infection trials will provide the empirical data needed to better assess the true risk and possible consequences. Until more information is available, it is important that we consider these potential risks associated with activities requiring direct handling or close proximity to bats and continue taking precautions to minimize those risks as much as possible.

Current Recommendation

Avoid handling or being in close proximity (within 6 ft) of bats unless necessary for protection of human health and safety or for high priority purposes. Determining priority purposes depends on careful consideration of the risks and benefits associated with any

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activities that require close contact with bats and the ability to implement appropriate mitigation measures to reduce risks as much as possible. This discussion should include all parties involved and should be done in consultation with an NPS Wildlife Veterinarian.

References

Runge, M.C., Grant, E.H.C., Coleman, J.T.H., Reichard, J.D., Gibbs, S.E.J., Cryan, P.M., Olival, K.J., Walsh, D.P., Belhert, D.S., Hopkins, M.C., and Sleeman, J.M., 2020, **Assessing the risks posed by SARS-CoV-2 in and via North American bats—Decision framing and rapid risk assessment**: U.S. Geological Survey Open-File Report 2020–1060,43p., <https://doi.org/10.3133/ofr20201060>

<https://www.nps.gov/subjects/bats/bats-and-covid-19.htm>

Wildlife Health (updated June 30, 2020)

Wildlife health surveillance and disease monitoring is an essential function necessary for parks to preserve natural resources within NPS lands. However, COVID-19 may change if and when certain activities can be accomplished and requires additional planning to conduct wildlife health work. The NPS Biological Resources Division hosts a Wildlife Health Branch and Veterinary Diagnostic Service that provides veterinary consultation and disease investigation and diagnostic services to support parks. The Wildlife Health Branch is closely monitoring information on SARS-CoV-2 and implications it may have for wildlife and domestic animals.

Recent reports have indicated that several species of the families Mustelidae, Felidae, and Canidae are susceptible to infection by SARS-CoV-2, the causative agent of COVID-19. Research suggests dogs are not as easily infected with the virus as cats and ferrets. More studies are needed to understand if and how different animals could be affected by SARS-CoV-2 and what risks infected animals may pose to humans or other animals. The CDC has the most current information about [SARS-CoV-2 in animals](#).

The potential for transmission of the SARS-CoV-2 virus to free-ranging wildlife is unknown at this time. If you have urgent field work that involves close contact with live free-ranging wildlife in NPS units we suggest taking basic precautions including:

- Monitor yourself for symptoms (i.e., fever, cough, shortness of breath), follow public health guidance on [quarantine](#) following any possible exposures to COVID-19, and stay at home if you are sick.
- If you have a fever or respiratory symptoms, refrain from handling wildlife until you can discontinue home isolation according to [current CDC guidance](#).
- Practice good hand hygiene.
- Wear gloves and dedicated clothing when handling wildlife.
- Wear a cloth face covering or other barrier that covers your nose and mouth to prevent respiratory droplets being transferred to people or animals nearby. Face coverings should be laundered daily or after each use.
- Clean and [disinfect](#) high touch surfaces often.

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- Work outdoors or in a well-ventilated area if possible.

This guidance is based on preliminary and incomplete information available to date and may change as our knowledge evolves. These recommendations are to be applied in concert with all CDC and local public health recommendations and restrictions for social distancing between humans. Please remain flexible in your wildlife handling plans this season and watch for updated guidance and recommendations as more information becomes available.

Routine testing for the virus in free-living or captive North American wildlife species is not currently recommended, but there may be situations in which testing should be considered. Refer to [CDC guidelines for testing wildlife](#) and contact a member of the NPS Wildlife Health Branch if you believe a wildlife species in your park meets these criteria.

If you have research, disease surveillance or management activities planned involving **felid or mustelid species**, please reach out to a member of the NPS Wildlife Health Branch.

Useful Links:

- [Centers for Disease Control FAQs on Animals and COVID-19](#)
- [European Association of Zoo Veterinaries FAQs on SARS-COV-2 in wild and zoo animals](#)
- [World Organization for Animal Health FAQs on COVID-19](#)
- [OIE Considerations for sampling, testing, and reporting of SARS-CoV-2 in animals](#)
- [Curated literature hub for tracking up-to-date scientific information on COVID-19](#)

Domestic and Captive Animals (updated June 30, 2020)

To date, there have been no reported infections of SARS-CoV-2 in livestock in the US. However, given isolated cases of SARS-CoV-2 infections in [pets](#) and scientific studies suggesting that some domestic animal species, including cats, dogs, and ferrets, may be susceptible to infection, basic precautions are recommended when handling captive animals. The [US Department of Agriculture](#)(USDA) and [American Veterinary Medical Association](#)(AVMA) have compiled current information and recommendations for caring for and handling animals during the pandemic. Routine testing for [SARS-CoV-2 in animals](#) is not recommended.

For any personnel caring for captive animals used in cultural displays, education and interpretive programs, or working and service animals (hereafter known as “animals”) in NPS units we recommend basic precautions including:

- Monitor yourself for symptoms (i.e., fever, cough, shortness of breath), follow public health guidance on [quarantine](#) following any possible exposures to COVID-19, and stay at home if you are sick.
- If you have a fever or respiratory symptoms, refrain from handling or caring for animals until you can discontinue home isolation according to [current CDC guidance](#).

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- Practice good hand hygiene.
- Wear gloves and dedicated clothing when handling or caring for captive animals.
- Wear a cloth face covering or other barrier that covers your nose and mouth to prevent respiratory droplets being transferred to people or animals nearby. Face coverings should be laundered daily or after each use.
- Clean and **disinfect** high touch surfaces such as sinks and counters often.
- Work outdoors or in a well-ventilated area if possible.
- If an animal you care for is sick, contact your local attending veterinarian and they can advise on appropriate testing and treatment.

This guidance is based on preliminary and incomplete information available to date and may change as our knowledge evolves. These recommendations are to be applied in concert with all CDC and local public health recommendations and restrictions for social distancing between humans. Please remain flexible in your animal care and handling plans this season and watch for updated guidance and recommendations as more information becomes available. If you have questions pertaining to your specific animal care or handling situation, please reach out to a member of the NPS Wildlife Health Branch.

Veterans Administration

April 13, 2020 FAQs Covid-19 and VA Animal Care and Use Programs

April 13, 2020
Frequently Asked Questions (FAQs)
COVID-19 and VA Animal Care and Use Programs

Point of Contact: Dr. Michael Fallon, CVMO
michael.fallon@va.gov, 404-732-5471

Revision History:

- The original 14 items were released on March 19, 2020.
- March 23 revision: Item 15 on VA animal research policy waivers was added, and Item 13 was revised to note that AAALAC site visits can substitute for IACUC semi-annual self-assessments.
- March 30 revision: Consistent with OLAW guidance, item 13 was revised to allow a “qualified individual” to perform program or facility semi-annual reviews. The qualified individual does not have to be an IACUC member. Items 16-19 were added to address questions that have been raised about Item 15. Small changes were also made to other items for clarity.
- April 13 revision: Item 20 added on containment needed for COVID-19 studies in animals.

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1. Does the COVID-19 administrative hold announced by the Chief Research and Development Officer apply to animal research?

No, the COVID-19 administrative hold applies to research interactions with human subjects.

2. How can we help protect critical animal care staff to ensure continuity of animal care?

In general, if conditions warrant it locally, stations may institute measures as needed to help prevent COVID-19 infections in the animal care staff by limiting access to the animal facility to as few people as possible. The situation is changing across the country on a daily basis, and if the perceived risk to the animal care staff increases locally due to any number of possible factors, Research Services are authorized to limit entry to the animal facility to just designated essential research technicians and staff to minimize the chance of COVID-19 transmission between people.

Also, to reduce the opportunity for all caretaker staff to be exposed at the same time and to become ill at the same time, it is wise to consider varying the tours of duty so that all care staff are not present at the same time. Keep in mind that it is best to always have two animal care staff members present at all times, although this will not necessarily be possible in small facilities.

3. Our program is experiencing challenges with maintaining our animal facility or supporting ongoing animal research activities due to COVID-19 restrictions. What should be our priorities and what do we do?

If these FAQ items on animal research do not resolve problems, or you have an emergency issue, call Mike Fallon, CVMO, at 404-732-5471. If there are less pressing concerns regarding the management of animals during this period, email Michael Fallon (michael.fallon@va.gov), Alice Huang (alice.huang@va.gov), and Joan Richerson (joan.richerson@va.gov).

The first priority is to ensure that proper care continues to be administered to all VA research animals during the agency response to COVID-19 infections in people. Just as care of hospital and clinic patients must continue, care for the animals must continue.

As containment procedures continue to evolve, all programs must remain in good communication with hospital response teams to ensure that any required employee PPE use or other practices are adopted as needed to ensure continued care for the animals. Please continue to read and monitor agency emails concerning ongoing containment practices.

4. How do we deal with possible animal care staff shortages caused by COVID-19 infections, quarantine procedures, or other restrictive policies intended to prevent transmission between people?

A very good approach is to immediately train some research technicians with animal research experience in the basic skills needed to care for the animals as backups, in case of disruptions

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in animal care staffing. The greatest threat to the animals is the loss of onsite personnel who know how to change cages, provide water and food, and provide treatments without compromising quarantine or special barrier procedures that could put many animals and studies at risk. In addition to the animal care staff and veterinarian, research technicians have a great deal of knowledge about research animals, and in unusual circumstances, can be invaluable backups in maintaining animal care.

If local circumstances allow, neighboring institutions might also be able to provide additional caretaker support.

5. How can we mitigate the impact of COVID-19 containment procedures on VA funded animal studies?

Please reach out to investigators conducting animal research and find out if there are any longitudinal studies underway with multiple time point interventions, or any studies that are heavily dependent on the current age or weight of animals. Find out what is needed and coordinate with the Attending Veterinarian, VMU Supervisor, and animal care staff to make any needed arrangements so that those studies can continue to receive support and not end up with lost animals due to incomplete data collection.

For those studies that do not have time-sensitive studies, it would be very wise to postpone them until the COVID-19 situation stabilizes, and the possibility of staffing disruptions decreases.

Likewise, it is best to postpone new animal research studies that are heavily resource dependent or would be compromised with the loss of just one or a few key staff members.

6. What if delays or unfortunate disruptions prevent an investigator from completing key animal studies, thus raising concerns about progress on a VA-funded project?

Please see the ORD plan for general research disruptions due to COVID-19, which will be considered on a case-by-case basis.

7. What about impacts on animal facility budgets?

Because the current VA cc105 subsidy is only about 30% of operating costs, any disruption in collection of per diems and other chargeable services could result in funding shortfalls. It is possible that a cc105 approach could be taken (across the board increase), but a major component of cc105 is the number of funded VA projects involving animals, so a case-by-case approach like that in item 6 might be better targeted to fairly address any problems. Some locales will certainly be impacted more severely than others. Please let Mike Fallon know of any problems you are experiencing as soon as possible (404-732-5471).

8. What about animal to human or human to animal transmission of COVID-19?

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There were some initial reports that dogs might possibly carry the virus, but those reports appear to be false. The American Veterinary Medical Association has released the following guidance (<https://www.avma.org/resources-tools/animal-health-and-welfare/covid-19>):

“Out of an abundance of caution, it is recommended that those ill with COVID-19 limit contact with animals until more information is known about the virus. Have another member of your household take care of walking, feeding, and playing with your pet. If you have a service animal or you must care for your pet, then wear a facemask; don’t share food, kiss, or hug them; and wash your hands before and after any contact with them.”

Note: As is true of almost all pathogens, animals such as nude mice and SCID mice that have severely compromised immune systems could be at increased risk of becoming infected with COVID-19 (or any other virus). It is standard practice in the laboratory animal community to house these rodent strains under special conditions to carefully protect them from environmental infectious agents, which include the use of PPE such as masks and gloves for people who are handling them. Such practices should of course continue.

9. What about the use of Personal Protective Equipment in the animal facility?

Keep in mind that the very best safety practices are to wash hands frequently and to not touch the eyes, mouth, or face with unwashed hands. No changes in PPE practice in the animal facility are needed unless additional PPE is required per hospital policy or suggested by best practices to prevent the spread of COVID-19 between staff members.

AAALAC Issues

10. Our station is scheduled to have an AAALAC site visit in the summer or fall of 2020; given the COV-19 restrictions, should we ask for the site visit to be postponed?

Each station, in consultation with their affiliate university as is appropriate, should decide if postponement of the site visit is needed. If the decision is to request postponement of the upcoming site visit, the designated AAALAC institutional representative should contact the AAALAC Executive Office (accredit@aaalac.org) by email and request that the site visit to be postponed. Your six-digit AAALAC unit number should be included in the request.

11. What options do we have about re-scheduling our site visit, or possibly postponing submission of our Program Description?

Because there are so many options, the designated AAALAC institutional representative should contact Dr. Gary Borkowski, gborkowski@aaalac.org, Global Director, to discuss site visit scheduling and Program Description submission options.

12. Will we lose our AAALAC accreditation if the site visit isn’t conducted within three years of the last site date?

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No. According to AAALAC senior staff, accreditation status will be unchanged even if the site visit is conducted later.

Conduct of Semi-Annual IACUC Self-reviews and IACUC Meetings

13. The time to conduct our semiannual facility inspections is approaching but due to COV-19 restrictions, we do not want to gather groups of people together. What options do we have?

VA adheres to PHS Policy, which is administered by the Office of Laboratory Animal Welfare (OLAW). OLAW has offered the flexibilities to IACUCs in a new guidance document (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html>) when planning for semiannual program and facility assessments:

- Assessments may occur up to 30 days past the semi-annual date of the last assessment as long as the date has not drifted forward from year to year. If you anticipate the need for more than a 30 day delay, a waiver may be requested from OLAW for additional flexibility in scheduling assessments by submitting a written justification to OLAW at olawdpe@mail.nih.gov.
- VHA Handbook 1200.07, par. 8.f(1)(d)5 requires “At least three IACUC members (including the veterinarian) need to conduct the program and facilities review, unless exceptional circumstances prevent attendance.” VA considers the current circumstances to be “exceptional”, and it is acceptable to limit the number of participants in the semiannual evaluation to the minimum allowed by USDA and OLAW.
- If USDA species are not involved, which requires a minimum of two IACUC members to participate, the IACUC may use a single “qualified individual” to conduct program or facility reviews. The “qualified individual” be an IACUC member or an ad hoc research or animal caretaker staff member.
- Keep in mind that the findings of the individuals who conduct the program and facility reviews must still be evaluated by the IACUC, to determine whether deficiencies are “minor” or “significant”, to analyze their root causes, and to decide on appropriate corrective measures and timelines for completion. The report is not considered final until it has been signed (electronically is fine) by a majority of the total voting membership of the IACUC.

Note: if you had a recent AAALAC site visit, that visit can be used as your semi-annual IACUC self-assessment, but the VA semi-annual form will need to be completed, based upon the site visit findings. The out-briefing provided by the AAALAC site visitors to medical center managers at the end of the visit (to summarize the preliminary findings) satisfies the requirement for a meeting with the IACUC to discuss the semi-annual self-review (see also FAQ item 15.e below).

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14. How can we have IACUC meetings and still practice social distancing measures to help prevent of COVID-19 transmission?

OLAW recommends the following measures

((<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html>) when planning for semiannual program and facility assessments:

- The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing (see [NOT-OD-06-052](#)).
- The number of IACUC meetings may be reduced to as few as one every six months.
- The IACUC may choose to expand their use of designated member review in lieu of full committee review.

Waivers to VA Animal Research Policy

15. What waivers of VA animal research policy are available to reduce IACUC burden and reduce the need for face to face meetings while concerns about COVID-19 require social distancing?

Effective immediately, the following requirements in VHA Handbook 1200.07 (https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2464) are waived or changed as indicated below, to support social distancing efforts and reduce IACUC burden. Electronic signatures continue to be acceptable on all VA animal research documents. You will need to notify OLAW of any changes needed in your Assurance to match any practices adopted below (see FAQ 18 for details).

- a. Paragraph 7.c., Standard Operating Procedures (SOPs) [Page 15]. The requirement for annual review of animal facility SOPs is waived, and replaced with a requirement for review at least every three years.
- b. Paragraph 8.a., Membership, Composition, and Terms of Service [Page 18]: Letters of appointment by the Medical Facility Director no longer must stipulate the length of IACUC member appointments, may be in the form of an email, and may remain in force until rescinded by the Medical facility Director. The term requirements in paragraph 8.a.(7) [Page 20] for IACUC members are rescinded.
- c. Paragraph 8.f.(1)(b), IACUC review of Records [Page 23]: The requirement for IACUC random review of IACUC records is rescinded.
- d. Paragraphs 8.g. (Annual Review of Proposals) and 8.g.(1) (First and Second Annual Review of Protocols)[Page 28]: The requirement for annual reviews of protocols involving non-USDA species is rescinded; such protocols must be reviewed at least every three years, consistent with PHS Policy.

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e. Appendix E, item 7.e. [Page E-10]: The requirement for a face to face meeting with the Medical Facility Director to discuss the results of the IACUC semi-annual self-review is clarified to include meetings conducted by teleconference or videoconference, as described in Guidance Document AR2016-001 on https://www.research.va.gov/programs/animal_research/guidance.cfm.

f. Appendix E, item 7.f [Page E-10]: A signed copy of the completed IACUC semi-annual self-assessment must now be sent through the ACOS for R&D and the Medical Facility Director to the CVMO within 120 days of the date on which the report is finalized, as indicated by the signatures of a majority of the total voting membership of the IACUC, instead of within 60 days.

16. Are the changes described in FAQ 15 permanent changes in VA policy, or only interim measures for addressing the current situation with COVID-19?

The changes have been under discussion for some time, so we expect that they will eventually be incorporated in the new version of 1200.07 (which will be a Directive rather than a Handbook, and is close to going into concurrence now). Accordingly, the best interpretation right now is that they are permanent.

17. If our local SOPs specify more stringent requirements than these changes allow, do we have to have the IACUC formally vote to approve the changes in each of the current SOPs?

Normally, if you have more stringent local policies, they take precedence over less stringent regulatory requirements. Under the current “extraordinary circumstances” though, all parties are trying to provide as much flexibility as possible, without jeopardizing animal welfare and personnel safety. We spoke with OLAW this week, and they agreed that it will suffice if your IACUC agrees generally to accept the changes allowed by VA, in place of your existing SOPs (this doesn’t have to be done separately for each SOP). They reminded us that there is actually no regulatory requirement for SOPs to be formally approved by a majority vote at a convened meeting of a quorum – it’s only necessary for someone on the IACUC to recommend them, all members to have the opportunity to register any concerns they may have, and all members to be informed of them. The same applies to changes in the SOPs.

18. If our PHS Assurance commits us to more stringent requirements than OLAW grants us a waiver for, do we have to formally process a modification of the Assurance with OLAW?

Again, normally, if your Assurance has more stringent requirements than PHS Policy, you are committed to complying with your Assurance. In this case, if you receive a waiver from OLAW, our understanding is that the waiver indicates OLAW’s approval for your station to treat the more flexible requirements as incorporated into your Assurance. As usual when you modify your Assurance, you should note this in your next annual report.

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19. How do we avoid problems if we get audited or site-visited sometime in the future, when all this is over, and our records show that we did not comply with the normal regulatory requirements?

To prevent confusion in the future, we recommend that you put a copy of whatever waivers or FAQs you are relying on, and some documentation that your IACUC accepted them, into the files of whatever matters are affected.

20. If an investigator wants to plan to perform animal research with COVID-19 virus, what containment practices will have to be followed?

All studies involving infectious COVID-19 must be conducted at Biosafety Level 3 (BSL-3), as defined in the CDC *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition.^a For the requirements specific to animal studies, see Section V, “Vertebrate Animal Biosafety Level Criteria for Vivarium Research Facilities.”

The World health organization has released specific guidance for COVID-19 studies, which requires includes a requirement for BSL-3 containment practices for bench and animal research.^b

There are two major issues to address when planning for or proposing animal studies with COVID-19:

- Facilities. Few VA facilities have onsite laboratory ABSL-3 containment facilities. The process of converting existing space to ABSL-3 space is lengthy and requires expert technical consultation on many issues. If your station does not have its own ABSL-3 facility, a far better option is to utilize another institution’s off-site facility.

There is a process developed by ORD^c for such off-site BSL-3/ABSL-3 facility use requests. Please contact Dr. Amanda Hunt (Amanda.hunt@va.gov) immediately if you anticipate the need for a waiver to utilize such an off-site facility.

- Training. Safely working with agents in ABSL-3 containment conditions requires extensive training, and possibly higher security clearances. Accordingly, it would be wise to consider partnering with a group that already has the necessary experience and clearances to reduce delays.

References for this item:

- <https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>
- https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2
- <https://www.research.va.gov/resources/policies/off-site.cfm>; see item 5.

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