**April 13, 2020**

**Frequently Asked Questions (FAQs)**

**COVID-19 and VA Animal Care and Use Programs**

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**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.

**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 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?**

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?**

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).

**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](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-052.html)).
* 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.

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.

**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 ORDc 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:

a. [https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF](https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF%20)

b. <https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2>

c. <https://www.research.va.gov/resources/policies/off-site.cfm>; see item 5.